

---

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

---

**Form S-4  
REGISTRATION STATEMENT  
UNDER  
THE SECURITIES ACT OF 1933**

---

**MEI Pharma, Inc.**

(Exact name of registrant as specified in its charter)

---

Delaware  
(State or other jurisdiction of  
incorporation or organization)

2834  
(Primary Standard Industrial  
Classification Code Number)

51-0407811  
(I.R.S. Employer  
Identification Number)

11455 El Camino Real, Suite 250  
San Diego, California 92130  
(858) 369-7100

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

---

Daniel P. Gold  
President and Chief Executive Officer  
MEI Pharma, Inc.  
11455 El Camino Real, Suite 250  
San Diego, California 92130  
(858) 369-7100

(Name, address, including zip code, and telephone number, including area code, of agent for service)

---

*Copies to:*

Steven Navarro  
Bryan Keighery  
Morgan, Lewis & Bockius LLP  
101 Park Avenue  
New York, NY 10178  
(212) 309-6000

Adelene Q. Perkins  
Chief Executive Officer  
Infinity Pharmaceuticals, Inc.  
1100 Massachusetts Ave  
Cambridge, MA 02138  
(617) 453-1000

Cynthia T. Mazareas, Esq.  
Hal J. Leibowitz, Esq.  
Wilmer Cutler Pickering Hale and Dorr LLP  
60 State Street  
Boston, MA 02109  
(617) 526-6000

---

**Approximate date of commencement of proposed sale to the public:** As soon as practicable after the effective date of this registration statement and the satisfaction or waiver of all other conditions under the Merger Agreement described herein.

If the securities being registered on this Form are being offered in connection with the formation of a holding company and there is compliance with General Instruction G, check the following box:

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act.

If applicable, place an X in the box to designate the appropriate rule provision relied upon in conducting this transaction:

Exchange Act Rule 13e-4(i) (Cross-Border Issuer Tender Offer)

Exchange Act Rule 14d-1(d) (Cross-Border Third-Party Tender Offer)

---

The Registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

DATED                      , 2023

---

## [Table of Contents](#)

The information in this joint proxy statement/prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This joint proxy statement/prospectus is not an offer to sell and it is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

**SUBJECT TO COMPLETION, DATED APRIL 27, 2023**

### **PROPOSED MERGER**

#### **YOUR VOTE IS VERY IMPORTANT**

To the stockholders of MEI Pharma, Inc. and Infinity Pharmaceuticals, Inc.:

The boards of directors of MEI Pharma, Inc., a Delaware corporation (“MEI”) and Infinity Pharmaceuticals Inc., a Delaware corporation (“Infinity”), have agreed upon a transaction in which Infinity will become a wholly-owned subsidiary of MEI. On February 22, 2023, MEI, Infinity, and Meadow Merger Sub, Inc. (“Merger Sub”), a Delaware corporation and a wholly-owned subsidiary of MEI, entered into an Agreement and Plan of Merger (the “Merger Agreement”), pursuant to which Merger Sub will merge with and into Infinity, with Infinity surviving as a wholly owned subsidiary of MEI, and the surviving company of the merger, which transaction is referred to herein as the “Merger.” MEI following the Merger is referred to herein as the combined company.

We are sending this joint proxy statement/prospectus to you to ask you to vote in favor of this transaction and other matters.

If the Merger is consummated, at the effective time of the Merger (the “Effective Time”) each share of Infinity’s common stock, par value \$0.001 per share, (the “Infinity Common Stock”), issued and outstanding immediately prior to the Effective Time (other than shares of Infinity Common Stock held in treasury, if any) will be automatically converted into the right to receive 0.052245 shares (the “Exchange Ratio”) of the common stock, par value \$0.00000002 per share, of MEI (the “MEI Common Stock”), subject to customary equitable adjustment in the event of any recapitalization, stock split, reverse stock split or similar change.

In addition, each outstanding option to purchase shares of Infinity Common Stock (each, an “Infinity Stock Option”) will become fully vested in accordance with the terms of the underlying stock option agreement. Each Infinity Stock Option will be assumed at the Effective Time by MEI and converted into a stock option to purchase shares of MEI Common Stock. The number of shares of MEI Common Stock underlying each such assumed Infinity Stock Option will be equal to the product of (i) the number of shares of Infinity Common Stock underlying the applicable Infinity Stock Option immediately prior to the Effective Time multiplied by (ii) the Exchange Ratio, with the resulting number of shares of MEI Common Stock rounded down to the nearest whole share, and the exercise price per share of each such assumed Infinity Stock Option will be equal to (a) the per share exercise price applicable to such Infinity Stock Option immediately prior to the Effective Time divided by (b) the Exchange Ratio, with the resulting exercise price per share rounded up to the nearest whole cent. Except as noted above, each assumed and converted Infinity Stock Option will continue to be governed by substantially the same terms and conditions (after giving effect to the full acceleration of vesting of such Infinity Stock Option in connection with the Merger) as were applicable to such Infinity Stock Option immediately prior to the Effective Time. Before the Effective Time, each outstanding Infinity restricted stock unit (each, an “Infinity RSU”) will become fully vested, and the shares of Infinity Common Stock subject to such Infinity RSU will be distributed in accordance with the terms of the applicable restricted stock unit agreement. The shares of Infinity Common Stock issued upon the vesting of Infinity RSUs will be treated as shares of Infinity Common Stock issued and outstanding immediately prior to the Effective Time in accordance with the terms and conditions of the Merger Agreement. No Infinity RSUs will be outstanding from and after the Effective Time.

Each share of MEI Common Stock and option to purchase MEI Common Stock that is issued and outstanding at the Effective Time will remain issued and outstanding, and such shares and options will be unaffected by the Merger. Immediately after the Merger, MEI stockholders as of immediately prior to the Merger are expected to own approximately 58% of the outstanding shares of the combined company, and Infinity stockholders are expected to own approximately 42% of the outstanding shares of the combined company.

Shares of MEI Common Stock are currently quoted on The Nasdaq Stock Market under the symbol “MEIP.” On \_\_\_\_\_, 2023, the last trading day before the date of the accompanying joint proxy statement/prospectus, the closing sale price of MEI Common Stock on The Nasdaq Stock Market was \$ \_\_\_\_\_ per share. Shares of Infinity Common Stock are currently quoted on The Nasdaq Global Select Market under the symbol “INFL.” On \_\_\_\_\_,

## Table of Contents

2023, the last trading day before the date of the accompanying joint proxy statement/prospectus, the closing sale price of Infinity Common Stock on The Nasdaq Global Select Market was \$ \_\_\_\_\_ per share. After completion of the Merger, it is expected that the common stock of the combined company will be quoted on the Nasdaq Stock Market under the symbol “KMBX” and the name of the combined company will be changed to “Kimbrx Therapeutics, Inc.”

**Your vote is very important.** We cannot complete the Merger unless the Infinity stockholders vote to adopt the Merger Agreement and the MEI stockholders vote to approve the issuance of MEI Common Stock. Abstentions or failures to properly cast an affirmative vote for the adoption of the Merger Agreement by any Infinity stockholder will have the same effect as a vote against the adoption of the Merger Agreement. This document is a prospectus relating to the shares of MEI Common Stock to be issued in the Merger and a joint proxy statement for Infinity and MEI to solicit proxies for their respective special meetings of stockholders. It contains answers to frequently asked questions and a summary of the important terms of the Merger, Merger Agreement, and related transactions, followed by a more detailed discussion.

More information about MEI, Infinity, the Merger Agreement and the transactions contemplated thereby (collectively the “Contemplated Transactions”), and the proposals is contained in the accompanying joint proxy statement/prospectus. MEI and Infinity urge you to read the accompanying joint proxy statement/prospectus carefully and in its entirety. IN PARTICULAR, YOU SHOULD CAREFULLY CONSIDER THE MATTERS DISCUSSED UNDER “[RISK FACTORS](#)” BEGINNING ON PAGE 26 OF THE ACCOMPANYING JOINT PROXY STATEMENT/PROSPECTUS.

MEI and Infinity are excited about the opportunities the Merger brings to MEI and Infinity stockholders. Thank you for your consideration and continued support.

Sincerely,

/s/ Charles V. Baltic III  
Charles V. Baltic III  
Chair of the Board  
MEI Pharma, Inc.  
, 2023

/s/ Adelene Q. Perkins  
Adelene Q. Perkins  
Chair of the Board  
Infinity Pharmaceuticals, Inc.  
, 2023

**Neither the U.S. Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of the accompanying joint proxy statement/prospectus. Any representation to the contrary is a criminal offense.**

The accompanying joint proxy statement/prospectus is dated \_\_\_\_\_, 2023, and is first being mailed to MEI stockholders and Infinity stockholders on or about \_\_\_\_\_, 2023.

**MEI PHARMA, INC.**  
**San Diego, California**

**NOTICE OF SPECIAL MEETING OF MEI STOCKHOLDERS**  
**TO BE HELD , 2023**

To the Stockholders of MEI Pharma, Inc.:

**NOTICE IS HEREBY GIVEN** that MEI Pharma, Inc. will hold a virtual special meeting of stockholders (the “MEI Special Meeting”), on \_\_\_\_\_, 2023, at \_\_\_\_\_ Eastern Pacific Time, unless postponed or adjourned to a later date. The MEI Special Meeting will be held entirely as a virtual meeting. You will be able to attend and participate in the MEI Special Meeting online by visiting \_\_\_\_\_, where you will be able to listen to the meeting live, submit questions and vote.

The MEI Special Meeting will be held for the following purposes:

1. To consider and vote upon the proposal to approve, for purposes of Nasdaq Listing Rule 5635(a), of the issuance of shares of MEI Common Stock, \$0.00000002 par value per share, to stockholders of Infinity pursuant to the terms of the Agreement and Plan of Merger, dated February 22, 2023, by and among MEI Pharma, Inc., a Delaware corporation (“MEI”), Infinity Pharmaceuticals Inc., a Delaware corporation (“Infinity”), and Meadow Merger Sub, Inc. (“Merger Sub”), a Delaware corporation and a wholly-owned subsidiary of MEI, as such agreement may be amended from time to time (the “MEI Nasdaq Proposal”); and
2. To consider and vote on a proposal to approve the adjournment of the MEI Special Meeting, from time to time, if necessary or appropriate, including to solicit additional proxies in the event that there are insufficient votes at the time of the MEI Special Meeting or any adjournment or postponement thereof to approve the MEI Nasdaq Proposal (the “MEI Adjournment Proposal”).

**Record Date:** MEI’s board of directors has fixed May 24, 2023 as the record date for the determination of stockholders entitled to notice of, and to vote at, the MEI Special Meeting and any adjournment or postponement thereof (the “MEI Record Date”). Only holders of record of shares of MEI Common Stock at the close of business on the MEI Record Date are entitled to notice of, and to vote at, the MEI Special Meeting. At the close of business on the MEI Record Date, MEI had \_\_\_\_\_ shares of common stock outstanding and entitled to vote.

Your vote is important. The majority of the votes cast by MEI stockholders entitled to vote on the proposal at the MEI Special Meeting is required for approval of the MEI Nasdaq Proposal and the MEI Adjournment Proposal. Approval of the MEI Nasdaq Proposal is a condition to the completion of the Merger. Therefore, the Merger cannot be consummated without the approval of the MEI Nasdaq Proposal. The MEI Nasdaq Proposal is described in more detail in the section titled “*Matters Being Submitted To A Vote Of MEI Stockholders*” in the accompanying joint proxy statement/prospectus, which you should read carefully in its entirety before you vote. A copy of the Merger Agreement is attached as Annex A to the accompanying joint proxy statement/prospectus.

Even if you plan to virtually attend the MEI Special Meeting, MEI requests that you sign and return the enclosed proxy card or voting instruction form or vote by Internet or phone to ensure that your shares will be represented at the MEI Special Meeting if you are unable to virtually attend. You may change or revoke your proxy at any time before it is voted at the MEI Special Meeting.

After careful consideration, the MEI board of directors (with Sujay R. Kango recusing himself from the vote) has approved the Merger Agreement and has determined that it is advisable to consummate the Merger. The MEI board of directors (with Sujay R. Kango recusing himself from the vote) has approved the MEI Nasdaq Proposal and the MEI Adjournment Proposal described in the accompanying joint proxy statement/prospectus and recommends that its stockholders vote “**FOR**” the proposals described in the accompanying joint proxy statement/prospectus.

---

[Table of Contents](#)

By Order of MEI's Board of Directors,

/s/ Brian G. Drazba

Brian G. Drazba  
Secretary and Chief Financial Officer  
MEI Pharma, Inc.  
, 2023



1100 Massachusetts Avenue  
Floor 4  
Cambridge, MA 02138  
Tel: (617) 453-1000  
Fax: (617) 453-1001  
[www.infi.com](http://www.infi.com)

NOTICE OF SPECIAL MEETING OF INFINITY STOCKHOLDERS  
TO BE HELD \_\_\_\_\_, 2023

To the Stockholders of Infinity Pharmaceuticals, Inc.:

**NOTICE IS HEREBY GIVEN** that Infinity Pharmaceuticals, Inc. will hold a virtual special meeting of stockholders (the “Infinity Special Meeting”), on \_\_\_\_\_, 2023, at \_\_\_\_\_ Eastern Time, unless postponed or adjourned to a later date. The Infinity Special Meeting will be held entirely as a virtual meeting. You will be able to attend and participate in the Infinity Special Meeting online by visiting [www.virtualshareholdermeeting.com/INFI2023SM](http://www.virtualshareholdermeeting.com/INFI2023SM), where you will be able to listen to the meeting live, submit questions and vote.

The Infinity Special Meeting will be held for the following purposes:

1. To approve the adoption of the Agreement and Plan of Merger, dated as of February 22, 2023, as it may be amended from time to time, by and between MEI Pharma, Inc., a Delaware corporation (“MEI”), Infinity Pharmaceuticals Inc., a Delaware corporation (“Infinity”), and Meadow Merger Sub, Inc. (“Merger Sub”), a Delaware corporation and a wholly-owned subsidiary of MEI (the “Merger Agreement”), pursuant to which Merger Sub will merge with and into Infinity, with Infinity surviving as a wholly owned subsidiary of MEI, and the surviving company of the merger (the “Merger”), which proposal is referred to as the “Infinity Merger Proposal”;
2. To approve, on a non-binding, advisory basis, the compensation that will or may be payable to Infinity’s named executive officers in connection with the Merger, which proposal is referred to as the “Infinity Compensation Proposal”; and
3. To consider and vote on a proposal to approve the adjournment of the Infinity Special Meeting, from time to time, if necessary or appropriate, including to solicit additional proxies in the event that there are insufficient votes at the time of the Infinity Special Meeting or any adjournment or postponement thereof to approve the Infinity Merger Proposal, which proposal is referred to as the “Infinity Adjournment Proposal”.

**Record Date:** Infinity’s board of directors has fixed \_\_\_\_\_, 2023 as the record date for the determination of stockholders entitled to notice of, and to vote at, the Infinity Special Meeting and any adjournment or postponement thereof (the “Infinity Record Date”). Only holders of record of shares of Infinity’s common stock (the “Infinity Common Stock”) on the Infinity Record Date are entitled to notice of, and to vote at, the Infinity Special Meeting. On the Infinity Record Date, there were \_\_\_\_\_ shares of Infinity Common Stock outstanding and entitled to vote.

Your vote is important. The affirmative vote of the holders of a majority of the outstanding shares of Infinity Common Stock entitled to vote thereon is required for approval of the Infinity Merger Proposal. **Any abstention or failure to properly cast an affirmative vote for the Infinity Merger Proposal will have the same effect as a vote against the Infinity Merger Proposal.** Assuming a quorum is present, the affirmative vote of a majority in voting power of the shares of Infinity Common Stock which are present virtually or by proxy and entitled to vote thereon is required for approval of the Infinity Compensation Proposal and the Infinity Adjournment Proposal. Approval of the Infinity Merger Proposal is a condition to the completion of the Merger. Therefore, the Merger cannot be completed without the approval of the Infinity Merger Proposal. The Infinity Merger Proposal is described in more detail in the section

---

## [Table of Contents](#)

titled “*Matters Being Submitted To A Vote Of Infinity Stockholders*” in the accompanying joint proxy statement/prospectus, which you should read carefully in its entirety before you vote. A copy of the Merger Agreement is attached as [Annex A](#) to the accompanying joint proxy statement/prospectus.

Even if you plan to virtually attend the Infinity Special Meeting, Infinity requests that you sign and return the enclosed proxy card or vote by Internet or phone to ensure that your shares will be represented at the Infinity Special Meeting if you are unable to virtually attend. You may change or revoke your proxy at any time before it is voted at the Infinity Special Meeting.

After careful consideration, the Infinity board of directors (with Sujay R. Kanjo recusing himself from the vote) has approved the Merger Agreement and has determined that it is advisable to consummate the Merger. The Infinity board of directors (with Sujay R. Kanjo recusing himself from the vote) has approved the Infinity Merger Proposal, the Infinity Compensation Proposal and the Infinity Adjournment Proposal described in the accompanying joint proxy statement/prospectus and recommends that its stockholders vote “**FOR**” the proposals described in the accompanying joint proxy statement/prospectus.

By Order of Infinity’s Board of Directors,

Seth A. Tasker  
Senior Vice President, Chief Business Officer, and Secretary  
Cambridge, Massachusetts  
, 2023

## ABOUT THIS JOINT PROXY STATEMENT/PROSPECTUS

This document, which forms part of a registration statement on Form S-4 filed with the SEC by MEI, constitutes a prospectus of MEI under the Securities Act of 1933, as amended (the “Securities Act”), with respect to the issuance of shares of MEI Common Stock to Infinity stockholders pursuant to the Merger Agreement. This document also constitutes a joint proxy statement of MEI and Infinity under Section 14(a) of the Securities Exchange Act of 1934 as amended (the “Exchange Act”). It also constitutes a notice of meeting with respect to the Infinity Special meeting, at which Infinity stockholders will be asked to consider and vote on the adoption of the Merger Agreement and certain related matters, and the MEI Special Meeting, at which MEI stockholders will be asked to consider and vote on the approval of the issuance of MEI Common Stock pursuant to the Merger Agreement.

Infinity has supplied all information contained in this joint proxy statement/prospectus relating to Infinity, and MEI has supplied all information contained in this joint proxy statement/prospectus relating to MEI.

You should rely only on the information contained in this joint proxy statement/prospectus. Infinity and MEI have not authorized anyone to provide you with information that is different from that contained in this joint proxy statement/prospectus. This joint proxy statement/prospectus is dated \_\_\_\_\_, 2023, and you should not assume that the information contained in this joint proxy statement/prospectus is accurate as of any date other than such date. Neither the mailing of this joint proxy statement/prospectus to MEI stockholders or Infinity stockholders nor the issuance by MEI of shares of MEI Common Stock pursuant to the Merger Agreement will create any implication to the contrary.



**TABLE OF CONTENTS**

<u>CAUTIONARY STATEMENT CONCERNING FORWARD-LOOKING STATEMENTS AND INDUSTRY AND MARKET DATA</u>	1
<u>QUESTIONS AND ANSWERS ABOUT THE MERGER</u>	3
<u>PROSPECTUS SUMMARY</u>	15
<u>Overview of the Companies</u>	15
<u>The Merger</u>	15
<u>Reasons for the Merger</u>	16
<u>Opinion of MEI’s Financial Advisor</u>	17
<u>Opinion of Infinity’s Financial Advisor</u>	17
<u>Interests of Certain Directors, Officers and Affiliates of MEI and Infinity</u>	18
<u>Management Following the Merger</u>	19
<u>The Merger Agreement</u>	19
<u>Voting by MEI’s and Infinity’s Directors and Executive Officers</u>	19
<u>Conditions to the Completion of the Merger</u>	20
<u>No Solicitation</u>	20
<u>Termination</u>	21
<u>Termination Fee</u>	21
<u>Material U.S. Federal Income Tax Consequences of the Merger</u>	22
<u>Anticipated Accounting Treatment</u>	22
<u>Appraisal Rights and Dissenters’ Rights</u>	22
<u>Comparison of Rights of Holders of Shares</u>	22
<u>Risk Factor Summary</u>	23
<u>RISK FACTORS</u>	26
<u>THE SPECIAL MEETING OF MEI STOCKHOLDERS</u>	108
<u>MATTERS BEING SUBMITTED TO A VOTE OF MEI STOCKHOLDERS</u>	113
<u>The MEI Nasdaq Proposal</u>	113
<u>The MEI Adjournment Proposal</u>	114
<u>THE SPECIAL MEETING OF INFINITY STOCKHOLDERS</u>	116
<u>MATTERS BEING SUBMITTED TO A VOTE OF INFINITY STOCKHOLDERS</u>	119
<u>The Infinity Merger Proposal</u>	119
<u>The Infinity Compensation Proposal</u>	120
<u>The Infinity Adjournment Proposal</u>	121
<u>THE MERGER</u>	122
<u>General Description of the Merger</u>	122
<u>Consideration to be Received by the Infinity Stockholders</u>	122
<u>Background of the Merger</u>	122
<u>MEI’s Reasons for the Merger; Recommendation of the MEI Board</u>	138
<u>Infinity’s Reasons for the Merger; Recommendation of the Infinity Board</u>	142
<u>Opinion of MEI Financial Advisor</u>	147
<u>Summary of Certain MEI Unaudited Prospective Financial Information</u>	155
<u>Opinion of Infinity Financial Advisor</u>	156
<u>Summary of Certain Infinity Unaudited Prospective Financial Information</u>	158
<u>Interests of MEI Directors and Executive Officers in the Merger</u>	167
<u>Interests of Infinity Directors and Executive Officers in the Merger</u>	167
<u>Delisting and Deregistration of Infinity Common Stock</u>	174
<u>Regulatory Approvals</u>	175
<u>Anticipated Accounting Treatment</u>	175
<u>Appraisal Rights and Dissenters’ Rights</u>	175
<u>MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES OF THE MERGER</u>	176

## Table of Contents

<u>THE MERGER AGREEMENT</u>	180
<u>General</u>	180
<u>Merger Consideration</u>	180
<u>Treatment of Infinity Stock Options</u>	182
<u>Treatment of Infinity RSUs</u>	182
<u>Directors and Officers of MEI Following the Merger</u>	183
<u>Conditions to the Completion of the Merger</u>	184
<u>Representations and Warranties</u>	186
<u>No Solicitation</u>	187
<u>Meetings of Stockholders</u>	190
<u>Covenants; Conduct of Business Pending the Merger</u>	191
<u>Regulatory Approvals and Related Matters</u>	193
<u>Indemnification; Directors' and Officers' Insurance</u>	193
<u>Other Agreements</u>	194
<u>Termination</u>	195
<u>Termination Fee</u>	195
<u>Specific Performance</u>	196
<u>Expenses</u>	197
<u>Amendment</u>	197
<u>Governing Law</u>	197
<u>MEI EXECUTIVE COMPENSATION</u>	198
<u>Executive Compensation</u>	198
<u>Employment Agreements with Named Executive Officers</u>	199
<u>Outstanding Equity Awards at 2022 Fiscal Year-End</u>	201
<u>INFINITY EXECUTIVE COMPENSATION</u>	204
<u>MEI DIRECTOR COMPENSATION</u>	210
<u>INFINITY DIRECTOR COMPENSATION</u>	212
<u>MEI'S BUSINESS</u>	214
<u>INFINITY'S BUSINESS</u>	231
<u>MEI MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	272
<u>INFINITY MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	285
<u>QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u>	298
<u>MANAGEMENT FOLLOWING THE MERGER</u>	299
<u>CERTAIN RELATIONSHIPS AND RELATED-PARTY TRANSACTIONS</u>	306
<u>Infinity Transactions</u>	306
<u>ANTICIPATED ACCOUNTING TREATMENT</u>	309
<u>UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL STATEMENTS</u>	310
<u>MARKET PRICE AND DIVIDEND INFORMATION</u>	321
<u>MEI Common Stock</u>	321
<u>MEI Dividends</u>	321
<u>Infinity Common Stock</u>	321
<u>Infinity Dividends</u>	321
<u>DESCRIPTION OF MEI COMMON STOCK</u>	322
<u>Authorized Common Stock</u>	322
<u>Common Stock</u>	322
<u>Preferred Stock</u>	322
<u>Anti-Takeover Effects of Amended and Restated Certificate of Incorporation and Fifth Amended and Restated Bylaws</u>	322
<u>Classified Board of Directors</u>	322
<u>Advance Notice Requirements for Shareholder Proposals and Nominations for Election as Directors</u>	322

## Table of Contents

<u>Special Meetings of Stockholders</u>	323
<u>COMPARISON OF RIGHTS OF HOLDERS OF MEI COMMON STOCK AND INFINITY COMMON STOCK</u>	324
<u>PRINCIPAL STOCKHOLDERS OF MEI</u>	331
<u>PRINCIPAL STOCKHOLDERS OF INFINITY</u>	332
<u>PRINCIPAL STOCKHOLDERS OF PROPOSED COMBINED COMPANY</u>	335
<u>LEGAL MATTERS</u>	337
<u>EXPERTS</u>	337
<u>WHERE YOU CAN FIND MORE INFORMATION</u>	338
<u>HOUSEHOLDING OF PROXY MATERIALS</u>	339
<u>COMMUNICATIONS FROM MEI STOCKHOLDERS</u>	339
<u>COMMUNICATIONS FROM INFINITY STOCKHOLDERS</u>	339
<u>INDEX TO FINANCIAL STATEMENTS</u>	F-1
<u>PART II – INFORMATION NOT REQUIRED IN PROXY STATEMENT/PROSPECTUS</u>	II-1
<u>EXHIBIT INDEX</u>	II-4
<u>SIGNATURES</u>	
<u>Annex A Agreement and Plan of Merger, dated February 22, 2023, by and among Infinity Pharmaceuticals, Inc., MEI Pharma, Inc., and Meadow Merger Sub, Inc.</u>	A-1
<u>Annex B Opinion of Torrey Partners</u>	B-1
<u>Annex C Opinion of Aquilo Partners</u>	C-1

## CAUTIONARY STATEMENT CONCERNING FORWARD-LOOKING STATEMENTS AND INDUSTRY AND MARKET DATA

This joint proxy statement/prospectus contains forward-looking statements that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this prospectus, including statements regarding future financial condition, business strategy and plans and objectives of management of either MEI and Infinity, or the combined company, as applicable for future operations, are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “anticipate,” “believe,” “continue,” “could,” “design,” “estimate,” “expect,” “intend,” “may,” “plan,” “potentially,” “predict,” “seek,” “should,” “will” or the negative of these terms or other similar expressions.

All statements other than statements of historical fact are statements that could be deemed forward-looking statements. These forward-looking statements include, but are not limited to, statements concerning the following:

- the plans, strategies and objectives of such management for future operations, including the execution of integration and restructuring plans and the anticipated timing of filings;
- plans to develop and commercialize products;
- the plans, strategies and objectives of such management with respect to the approval and consummation of the Merger;
- the expected benefits of and potential value created by the Merger for the stockholders of Infinity and MEI;
- the satisfaction of certain conditions to the completion of the Merger and whether and when the Merger will be consummated;
- MEI’s and Infinity’s ability to control and correctly estimate their operating expenses and their expenses associated with the Merger;
- the attraction and retention of highly qualified personnel;
- the ability to protect and enhance the combined organization’s products, product candidates and intellectual property;
- expectations concerning Infinity’s relationships and actions with third parties;
- future regulatory, judicial and legislative changes in the combined company’s industry.

You should not rely upon forward-looking statements as predictions of future events. Neither Infinity nor MEI can assure you that the events and circumstances reflected in the forward-looking statements will be achieved or occur. In addition, statements that “we believe” and similar statements reflect the beliefs and opinions on the relevant subject of Infinity, MEI or the combined company, as applicable. These statements are based upon information available as of the date of this prospectus, and while Infinity, MEI or the combined company, as applicable, believes such information forms a reasonable basis for such statements, such information may be limited or incomplete.

Actual results could differ materially from those contained in any forward-looking statement as a result of various factors, including, without limitation:

- the risk that the conditions to the consummation of the Merger (the “Closing”) are not satisfied, including the failure to timely, or at all, obtain stockholder approval for the Merger or the MEI Share Issuance;
- uncertainties as to the timing of the consummation of the Merger; risks related to MEI’s and Infinity’s ability to correctly estimate their operating expenses and their expenses associated with the Merger;

## Table of Contents

- the ability of Infinity, MEI or the combined company to protect its intellectual property rights;
- competitive responses to the Merger;
- unexpected costs, charges or expenses resulting from the Merger;
- potential adverse reactions or changes to business relationships resulting from the announcement or completion of the Merger;
- legislative, regulatory, political and economic developments; and
- the risks set forth in the section titled “Risk Factors” beginning on page 26 of this joint proxy statement/prospectus.

Additional factors that could cause actual results to differ materially from those expressed in the forward-looking statements are discussed in reports filed with the U.S. Securities and Exchange Commission (the “SEC”) by MEI and Infinity. Please see the section titled “Where You Can Find More Information” beginning on page 338 of this joint proxy statement/prospectus. There can be no assurance that the Merger will be completed, or if it is completed, that it will be completed within the anticipated time period or that the expected benefits of the Merger will be realized.

If any of these risks or uncertainties materializes or any of these assumptions proves incorrect, the results of Infinity, MEI or the combined company could differ materially from the forward-looking statements. All forward-looking statements in this joint proxy statement/prospectus are current only as of the date on which the statements were made. Infinity and MEI do not undertake any obligation to publicly update any forward-looking statement to reflect events or circumstances after the date on which any statement is made or to reflect the occurrence of unanticipated events, except as otherwise required by the federal securities laws.

In addition, this joint proxy statement/prospectus includes statistical and other industry and market data that was obtained from independent industry publications and research, surveys and studies conducted by independent third parties as well as MEI’s and Infinity’s estimates. The market data used in this prospectus involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such data. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. MEI’s and Infinity’s estimates include assumptions based on their respective industry knowledge, industry publications, third-party research and other surveys. While MEI and Infinity believe that their respective internal assumptions and estimates are reasonable, no independent source has verified such assumptions or estimates.

## QUESTIONS AND ANSWERS ABOUT THE MERGER

The following are answers to some questions that you, as a stockholder of MEI Pharma, Inc. (“MEI”) or a stockholder of Infinity Pharmaceuticals, Inc. (“Infinity”), may have regarding the proposed combination between MEI and Infinity and the proposals to be considered at the MEI Special Meeting and the Infinity Special Meeting. This section does not provide all the information that might be important to you with respect to the proposed combination between MEI and Infinity. MEI and Infinity urge you to carefully read the remainder of this joint proxy statement/prospectus, including the annexes.

### **Q: Why am I receiving this joint proxy statement/prospectus?**

**A:** MEI, Infinity and Meadow Merger Sub, Inc. (“Merger Sub”), a Delaware corporation and a wholly-owned subsidiary of MEI, have entered into an Agreement and Plan of Merger (as may be amended from time to time, the “Merger Agreement”). The Merger Agreement provides, among other things, that, upon the terms and subject to the conditions set forth in the Merger Agreement, Merger Sub will merge with and into Infinity, with Infinity surviving the Merger as a wholly-owned subsidiary of MEI. A copy of the Merger Agreement is included in this joint proxy statement/prospectus as [Annex A](#).

The Merger cannot be completed unless, among other things, Infinity stockholders adopt the Merger Agreement. The approval of the Merger Agreement by MEI stockholders is not required for the Merger to be completed; however, the Merger cannot be completed unless MEI stockholders have approved the issuance of shares to effect the Merger. MEI stockholders are asked to approve the issuance of shares of MEI’s common stock, \$0.00000002 par value per share (“MEI Common Stock”), to Infinity stockholders in exchange for their shares of Infinity’s common stock, par value \$0.001 per share (the “Infinity Common Stock”).

MEI and Infinity are using this document as a proxy statement to solicit proxies from MEI’s stockholders and Infinity’s stockholders in connection with proposals relating to the Merger at the MEI Special Meeting and Infinity Special Meeting, respectively. MEI is using this document as a prospectus by which MEI will offer and issue MEI Common Stock in connection with the Merger.

**This joint proxy statement/prospectus contains important information about the Merger and the proposals being voted on at the MEI Special Meeting and the Infinity Special Meeting. You should read it carefully and in its entirety. The enclosed materials allow MEI stockholders to have their shares voted by proxy without attending the MEI Special Meeting, which will be held virtually, and the Infinity stockholders to have their shares voted by proxy without attending the Infinity Special Meeting, which will be held virtually. Your vote is important. We encourage you to submit your proxy as soon as possible.**

### **Q: What am I being asked to vote on?**

**A:** At the MEI Special Meeting, MEI stockholders will be asked to consider and vote on the following proposals:

1. To consider and vote to approve, for purposes of Nasdaq Listing Rule 5635(a), the issuance of shares of MEI Common Stock to stockholders of Infinity pursuant to the terms of the Agreement and Plan of Merger, dated February 22, 2023, by and among MEI, Infinity, and Merger Sub as may be amended from time to time (the “MEI Nasdaq Proposal”); and
2. To consider and vote on a proposal to approve the adjournment of the MEI Special Meeting, from time to time, if necessary or appropriate, including to solicit additional proxies in the event that there are insufficient votes at the time of the MEI Special Meeting or any adjournment or postponement thereof to approve the MEI Nasdaq Proposal (the “MEI Adjournment Proposal”).

## [Table of Contents](#)

At the Infinity Special Meeting, Infinity stockholders will be asked to consider and vote on the following proposals:

1. To consider and vote upon a proposal to approve the adoption of the Agreement and Plan of Merger, dated as of February 22, 2023, by and between MEI, Infinity, and Merger Sub, pursuant to which Merger Sub will merge with and into Infinity, with Infinity surviving as a wholly owned subsidiary of MEI and the surviving company of the merger (the “Merger”), which proposal is referred to as the “Infinity Merger Proposal”;
2. To consider and vote upon a proposal to approve, on a non-binding, advisory basis, the compensation that will or may be payable to Infinity’s named executive officers in connection with the Merger, which proposal is referred to as the “Infinity Compensation Proposal”; and
3. To consider and vote on a proposal to approve the adjournment of the Infinity Special Meeting, from time to time, if necessary or appropriate, including to solicit additional proxies in the event that there are insufficient votes at the time of the Infinity Special Meeting or any adjournment or postponement thereof to approve the Infinity Merger Proposal, which proposal is referred to as the “Infinity Adjournment Proposal.”

### **Q: Why are MEI and Infinity proposing the Merger?**

**A:** The boards of directors of MEI and Infinity (with the exception of Sujay R. Kango who recused himself from the vote) each believe that the Merger will provide substantial strategic and financial benefits to their respective companies and stockholders. To review the reasons for the Merger, see “*The Merger—MEI’s Reasons for the Merger; Recommendation of the MEI Board*” and “*The Merger—Infinity’s Reasons for the Merger; Recommendation of the Infinity Board*” for more information.

### **Q: What will Infinity stockholders receive in the Merger?**

**A:** At the effective time of the Merger (the “Effective Time”), each share of Infinity Common Stock outstanding at that time (other than certain shares of Infinity Common Stock that may be cancelled pursuant to the terms and conditions of the Merger Agreement) will be converted into the right to receive a number of shares of MEI Common Stock equal to the Exchange Ratio (as defined below), subject to adjustment as described in this joint proxy statement/prospectus.

### **Q: What is the Exchange Ratio?**

**A:** Each share of Infinity Common Stock issued and outstanding immediately prior to the Merger (other than shares of Infinity Common Stock held in treasury, if any) shall be automatically converted into the right to receive 0.052245 shares of MEI Common Stock (the “Exchange Ratio”). The Exchange Ratio is subject to customary equitable adjustment in the event of any recapitalization, stock split, reverse stock split or similar change.

### **Q: Are Infinity stockholders guaranteed to receive exactly 0.052245 shares of MEI Common Stock for each share of Infinity Common Stock exchanged in the Merger?**

**A:** Yes, subject to equitable adjustments to the exchange ratio in the event of a stock split, recapitalization, or similar event involving one of the party’s stock. See “*Risk Factors*” and “*The Merger Agreement—Merger Consideration*.”

### **Q: What equity stake will Infinity stockholders hold in MEI immediately following the Merger?**

**A:** Upon the Closing of the Merger, based upon the number of shares of MEI Common Stock expected to be issued in the Merger and an unadjusted Exchange Ratio, pre-Merger MEI stockholders will own approximately 58% of the outstanding equity of the combined company and pre-Merger Infinity stockholders will own approximately 42% of the outstanding equity of the combined company.

## [Table of Contents](#)

### **Q: When and where is the MEI Special Meeting?**

**A:** The MEI Special Meeting will be held on \_\_\_\_\_, 2023, at \_\_\_\_\_ Pacific Time, unless postponed or adjourned to a later date. The MEI Special Meeting will be held entirely online. You will be able to attend and participate in the MEI Special Meeting online by visiting \_\_\_\_\_, where you will be able to listen to the meeting live, submit questions and vote.

### **Q: When and where is the Infinity Special Meeting?**

**A:** The Infinity Special Meeting will be held on \_\_\_\_\_, 2023, at \_\_\_\_\_ Eastern Time, unless postponed or adjourned to a later date. The Infinity Special Meeting will be held entirely online. You will be able to attend and participate in the Infinity Special Meeting online by visiting [www.virtualshareholdermeeting.com/INFI2023SM](http://www.virtualshareholdermeeting.com/INFI2023SM), where you will be able to listen to the meeting live, submit questions and vote.

### **Q: What do I need to do now?**

**A:** After you have carefully read this joint proxy statement/prospectus and have decided how you wish to vote your shares, please vote your shares promptly so that your shares are represented and voted at the MEI Special Meeting or the Infinity Special Meeting, respectively, even if you plan on attending. If you hold your shares in your name as a stockholder of record, you must complete, sign and mail your proxy card in the enclosed postage-paid return envelope as soon as possible or vote by Internet or phone, following the instructions on your proxy card. If you hold your shares in “street name” through a bank, broker or other nominee, you must direct that organization how to vote in accordance with the instructions you have received from it.

### **Q: What constitutes a quorum for the MEI Special Meeting?**

**A:** In order for business to be conducted at the MEI Special Meeting, a quorum must be present. A quorum of stockholders is necessary to hold a valid meeting. The presence, in person or by proxy, of the holders of one-third of the shares of the common stock issued and outstanding and entitled to vote at the MEI Special Meeting constitutes a quorum. In the absence of a quorum at any meeting or any adjournment thereof, the holders of record of a majority of the shares present in person or by proxy and entitled to vote at such meeting may adjourn such meeting from time to time. A quorum will be present at the MEI Special Meeting if the holders of one-third of the shares of the MEI Common Stock issued and outstanding and entitled to vote as of the close of business on May 24, 2023, which is the MEI Record Date of the MEI Special Meeting, are present virtually at the MEI Special Meeting or represented by proxy. As of the close of business on the MEI Record Date, there were \_\_\_\_\_ shares of MEI Common Stock issued and outstanding and entitled to vote. This means that at least 2,221,015 shares must be represented by stockholders present virtually at the MEI Special Meeting or represented by proxy to have a quorum. Your shares will be counted towards the quorum if you submit a valid proxy or attend the MEI Special Meeting. Abstentions and broker non-votes, if any, will be included in determining the number of shares present at the meeting for the purpose of determining the presence of a quorum.

### **Q: What constitutes a quorum for the Infinity Special Meeting?**

**A:** A quorum will be present at the Infinity Special Meeting if the holders of a majority of the Infinity Common Stock issued and outstanding and entitled to vote at the Infinity Special Meeting on \_\_\_\_\_, 2023 (the “Infinity Record Date”), is present virtually or represented by proxy. On the Infinity Record Date, there were \_\_\_\_\_ shares of Infinity Common Stock issued and outstanding and entitled to vote. This means that at least \_\_\_\_\_ shares must be represented virtually or by proxy at the Infinity Special Meeting to have a quorum. Your shares will be counted towards the quorum if you submit a valid proxy or attend the Infinity Special Meeting. Abstentions and broker non-votes, if any, will be included in determining the number of shares present at the meeting for the purpose of determining the presence of a quorum.



**Q: What is the vote required to approve each proposal?**

**A:** Approval of the MEI Nasdaq Proposal or the MEI Adjournment Proposal requires the majority of the votes cast by MEI stockholders entitled to vote on the proposal. **Assuming a quorum is present, if you mark “ABSTAIN” on your proxy card or when voting by Internet or phone, fail to submit a proxy, or fail to vote at the MEI Special Meeting with respect to the MEI Nasdaq Proposal or MEI Adjournment Proposal, it will have “NO EFFECT” on the proposal.**

Approval of the Infinity Merger Proposal requires the affirmative vote of the holders of a majority of the outstanding shares of Infinity Common Stock entitled to vote thereon. **Assuming a quorum is present, if you mark “ABSTAIN” on your proxy card or when voting by Internet or phone, or you attend the Infinity Special Meeting and either fail to submit a proxy or fail to vote at the Infinity Special Meeting with respect to the Infinity Merger Proposal, it will have the same effect as a vote “AGAINST” the proposal.** Approval of each of the Infinity Compensation Proposal and the Infinity Adjournment Proposal requires the affirmative vote of the holders of a majority in voting power of the shares of Infinity Common Stock which are present virtually or by proxy and entitled to vote on the proposal. **Assuming a quorum is present, if you mark “ABSTAIN” on your proxy card or when voting by Internet or phone, fail to submit a proxy, or fail to vote at the Infinity Special Meeting with respect to the Infinity Compensation Proposal or Infinity Adjournment Proposal, it will have the same effect as a vote “AGAINST” the proposal.**

**Q: How does the MEI board of directors recommend that I vote at the MEI Special Meeting?**

**A:** The MEI board of directors (with Sujay R. Kango recusing) recommends that MEI’s stockholders vote “**FOR**” the MEI Nasdaq Proposal and, “**FOR**” the MEI Adjournment Proposal.

**Q: How does the Infinity board of directors recommend that I vote at the Infinity Special Meeting?**

**A:** The Infinity board of directors (with Sujay R. Kango recusing) recommends that Infinity’s stockholders vote “**FOR**” each of the Infinity Merger Proposal, the Infinity Compensation Proposal and the Infinity Adjournment Proposal.

**Q: As an Infinity stockholder, why is my vote important?**

**A:** The Merger will not be completed unless Infinity stockholders vote to approve the Infinity Merger Proposal. Your vote is important no matter how many shares you own. Please take the time to vote. Take a moment to read the instructions below. Choose the way to vote that is easiest and most convenient for you and cast your vote as soon as possible. **Any abstention or failure to properly cast an affirmative vote if your shares of Infinity Common Stock for the Infinity Merger Proposal will have the same effect as a vote against the Infinity Merger Proposal.**

**Q: Who can vote at the MEI Special Meeting?**

**A:** Holders of outstanding shares of MEI Common Stock as of the close of business on the MEI Record Date are eligible to vote at the MEI Special Meeting.

**Q: Who can vote at the Infinity Special Meeting?**

**A:** Holders of outstanding shares of Infinity Common Stock on the Infinity Record Date are eligible to vote at the Infinity Special Meeting.

**Q: Am I a MEI stockholder of record or a beneficial owner? Why does this matter?**

**A:** If on the MEI Record Date your shares were registered directly in your name with MEI’s transfer agent, Computershare Trust Company, N.A., then you are a stockholder of record with respect to those shares.

## Table of Contents

If on the MEI Record Date your shares were held in an account at a broker, bank or other similar organization as your nominee, then you are the beneficial owner of shares held in “street name” and these proxy materials are being forwarded to you by that organization. The organization holding your account is considered the stockholder of record for purposes of voting at the MEI Special Meeting.

The form in which you own your shares affects how you vote your shares and how you can change your vote.

### **Q: Am I an Infinity stockholder of record or a beneficial owner? Why does this matter?**

**A:** If, on the Infinity Record Date, your shares were registered directly in your name with Infinity’s transfer agent, American Stock Transfer & Trust Company, LLC, then you are a stockholder of record with respect to those shares.

If, on the Infinity Record Date, your shares were held in an account at a broker, bank or other similar organization as your nominee, referred to as being held in “street name,” then you are the beneficial owner of such shares and these proxy materials are being forwarded to you by that organization. The organization holding your account is considered the stockholder of record for purposes of voting at the Infinity Special Meeting. The form in which you own your shares affects how you vote your shares and how you can change your vote.

### **Q: How do I attend the MEI Special Meeting or Infinity Special Meeting and how can I vote my shares?**

**A:** MEI and Infinity are conducting virtual special meetings so their stockholders can participate from any geographic location with internet connectivity. MEI and Infinity have designed the format of the virtual online special meetings to provide stockholders the same ability to participate that they would have at an in-person meeting.

To attend the MEI Special Meeting, you must go to the meeting website at [www.meetnow.global/M44PQGZ](http://www.meetnow.global/M44PQGZ) and enter the 16-digit control number found on your proxy card or voting instruction form sent to you by your bank, broker or other nominee. Once admitted, during the MEI Special Meeting, you may vote, submit questions and view the list of stockholders entitled to vote at the MEI Special Meeting by following the instructions available on the meeting website.

Access to the meeting platform will begin at \_\_\_\_\_ Pacific Time on \_\_\_\_\_, 2023. If you encounter any difficulties accessing the virtual meeting during check-in or during the meeting, please call the technical support number that will be posted on the meeting website login page at [www.meetnow.global/M44PQGZ](http://www.meetnow.global/M44PQGZ). Technical support will be available beginning at \_\_\_\_\_ Pacific Time on \_\_\_\_\_, 2023 and will remain available until the meeting has ended.

To attend the Infinity Special Meeting, you must go to the meeting website at [www.virtualshareholdermeeting.com/INFI2023SM](http://www.virtualshareholdermeeting.com/INFI2023SM) and enter the 16-digit control number found on your proxy card or voting instruction form sent to you by your bank, broker or other nominee. Once admitted, during the Infinity Special Meeting, you may vote, submit questions and view the list of stockholders entitled to vote at the Infinity Special Meeting by following the instructions available on the meeting website.

Access to the meeting platform will begin at \_\_\_\_\_ Eastern Time on \_\_\_\_\_, 2023. If you encounter any difficulties accessing the virtual meeting during check-in or during the meeting, please call the technical support number that will be posted on the meeting website login page at [www.virtualshareholdermeeting.com/INFI2023SM](http://www.virtualshareholdermeeting.com/INFI2023SM). Technical support will be available beginning at \_\_\_\_\_ Eastern Time on \_\_\_\_\_, 2023 and will remain available until the meeting has ended.

Rules for the conduct of the MEI Special Meeting and Infinity Special Meeting will be available on the applicable meeting website. To obtain a copy of the rules of conduct for the MEI Special Meeting in advance of the MEI Special Meeting, please submit an email to [legalproxy@computershare.com](mailto:legalproxy@computershare.com). To obtain a copy of the rules of conduct for the Infinity Special Meeting in advance of the Infinity Special Meeting, please submit an email to \_\_\_\_\_.

## Table of Contents

Regardless of whether you plan to participate in the MEI Special Meeting or Infinity Special Meeting, it is important that your shares be represented and voted at the MEI Special Meeting or Infinity Special Meeting, respectively. Accordingly, MEI and Infinity encourage you to vote in advance of the MEI Special Meeting and Infinity Special Meeting.

### **Q: How can I vote my shares of MEI Common Stock?**

**A:** For each proposal, you may vote “FOR” or “AGAINST” each proposal, or “ABSTAIN” from voting on such proposal.

If you are a stockholder of record, you may vote by proxy via telephone, over the Internet or by returning a proxy card, or you may vote online at the MEI Special Meeting. Regardless of whether you plan to participate in the MEI Special Meeting, we urge you to vote by proxy to ensure your vote is counted. You may still participate in the MEI Special Meeting and vote online during the MEI Special Meeting if you have already voted by proxy.

1. ***You may vote over the Internet.*** If you have Internet access, you may vote your shares at [www.proxyvote.com](http://www.proxyvote.com) by following the instructions on that site or on the “Vote by Internet” instructions on the enclosed proxy card.
2. ***You may vote by telephone.*** You may vote your shares by calling \_\_\_\_\_ and following the instructions provided or following the “Vote by Phone” instructions on the enclosed proxy card.
3. ***You may vote by mail.*** You may vote by completing and signing the proxy card enclosed with this joint proxy statement/prospectus and promptly mailing it in the enclosed postage-prepaid envelope. You do not need to put a stamp on the enclosed envelope if you mail it from the United States. The shares you own will be voted according to your completed proxy card. If you sign and return the proxy card, but do not give any instructions on a particular matter described in this joint proxy statement/prospectus, the MEI shares you own will be voted in accordance with the recommendations of the MEI board of directors.
4. ***You may vote online during the MEI Special Meeting.*** To attend the meeting virtually, you must go to the meeting website at \_\_\_\_\_. Once admitted, during the MEI Special Meeting, you may vote by following the instructions available on the meeting website.

The deadline for receipt of a completed proxy card returned by mail at the address stated on the proxy card for the MEI Special Meeting is \_\_\_\_\_ Pacific Time on \_\_\_\_\_. The deadline for voting via the Internet or by telephone is 11:59 p.m. Pacific Time on \_\_\_\_\_, 2023.

If you are a beneficial owner, you may vote your shares by directing the broker, bank or other similar organization that holds your shares as your nominee on how to vote the shares in your account. Please refer to the voting instructions provided by your broker, bank or other nominee. Many organizations allow beneficial owners to give voting instructions via telephone or the Internet, as well as in writing. If you are a beneficial owner and would like to vote your shares at the MEI Special Meeting, please contact your broker, bank or other nominee for instructions and documents that may be required in order to do so.

### **Q: How can I vote my shares of Infinity Common Stock?**

**A:** If you are the “record holder” of your shares, meaning that you own your shares in your own name and not through a bank or brokerage firm, you may vote in one of four ways:

1. ***You may vote over the Internet.*** If you have Internet access, you may vote your shares at [www.proxyvote.com](http://www.proxyvote.com) by following the instructions on that site or on the “Vote by Internet” instructions on the enclosed proxy card.
2. ***You may vote by telephone.*** You may vote your shares by calling 1-800-690-6903 and following the instructions provided or following the “Vote by Phone” instructions on the enclosed proxy card.

## Table of Contents

3. ***You may vote by mail.*** You may vote by completing and signing the proxy card enclosed with this joint proxy statement/prospectus and promptly mailing it in the enclosed postage-prepaid envelope. You do not need to put a stamp on the enclosed envelope if you mail it from the United States. The shares you own will be voted according to your completed proxy card. If you sign and return the proxy card, but do not give any instructions on a particular matter described in this joint proxy statement/prospectus, the Infinity shares you own will be voted in accordance with the recommendations of the Infinity board of directors.
4. ***You may vote online during the Infinity Special Meeting.*** To attend the meeting virtually, you must go to the meeting website at [www.virtualshareholdermeeting.com/INFI2023SM](http://www.virtualshareholdermeeting.com/INFI2023SM). Once admitted, during the Infinity Special Meeting, you may vote by following the instructions available on the meeting website.

The deadline for receipt of a completed proxy card returned by mail at the address stated on the proxy card for the Infinity Special Meeting is Eastern Time on . The deadline for voting via the Internet or by telephone is 11:59 p.m. Eastern Time on , 2023.

If you are a beneficial owner, you may vote your shares by directing the broker, bank or other similar organization that holds your shares as your nominee on how to vote the shares in your account. Please refer to the voting instructions provided by your broker, bank or other nominee. Many organizations allow beneficial owners to give voting instructions via telephone or the Internet, as well as in writing. If you are a beneficial owner and would like to vote your shares at the Infinity Special Meeting, please contact your broker, bank or other nominee for instructions and documents that may be required in order to do so.

### **Q: What if I return an MEI proxy card but do not make specific choices?**

**A:** You will only receive a proxy card if you are the record holder of your shares of MEI Common Stock. If you return a signed proxy card without marking any voting selections, your shares will be voted “**FOR**” the MEI Nasdaq Proposal and “**FOR**” the MEI Adjournment Proposal, in accordance with the recommendation of the MEI board of directors (with Sujay R. Kango recusing). If any other matter is properly presented at the meeting, your proxy (one of the individuals named on your proxy card) will vote your shares using his or her best judgment.

### **Q: What if I return an Infinity proxy card but do not make specific choices?**

**A:** You will only receive a proxy card if you are the record holder of your shares of Infinity Common Stock. If you return a signed proxy card without marking any voting selections, your shares will be voted “**FOR**” each of the Infinity Merger Proposal, the Infinity Compensation Proposal and the Infinity Adjournment Proposal in accordance with the recommendation of the Infinity board of directors (with Sujay R. Kango recusing). If any other matter is properly presented at the meeting, your proxy (one of the individuals named on your proxy card) will vote your shares using his or her best judgment.

### **Q: If my shares of MEI Common Stock or Infinity Common Stock are held in “street name” by my bank, broker or other nominee, will my bank, broker or other nominee automatically vote my shares for me?**

**A:** No. If the shares you own are held in the name of a bank, broker or other nominee, also known as “street name,” that organization, as the record holder of your shares, is required to vote your shares according to your instructions. In order to vote your shares held in “street name,” you will need to follow the directions your bank, broker or other nominee provides you. Many banks, brokers or nominees also offer the option of voting over the Internet or by telephone, instructions for which would be provided by your bank, broker or nominee on your voting instruction form.

Under applicable stock exchange rules, banks, brokers and other nominees may use their discretion to vote “uninstructed” shares (i.e., shares of record held by banks, brokers or other nominees, but with respect to which the beneficial owner of such shares has not provided instructions on how to vote on a particular proposal) with

## Table of Contents

respect to matters that are considered to be “discretionary.” Your bank, broker or other nominee will not be allowed to vote your shares with respect to certain “non-discretionary” items. A “broker non-vote” occurs when shares held by a bank, broker or other nominee in “street name” for a beneficial owner are voted on at least one proposal but not voted with respect to a particular proposal because that organization (i) has not received voting instructions from the beneficial owner for that proposal and (ii) lacks discretionary voting power to vote those shares for that proposal.

The Infinity Merger Proposal, the Infinity Compensation Proposal and the Infinity Adjournment Proposal are each expected to be treated as non-discretionary items. Accordingly, Infinity does not expect there to be broker non-votes at the Infinity Special Meeting.

The MEI Nasdaq Proposal and the MEI Adjournment Proposal are each expected to be treated as non-discretionary items. Therefore your bank, broker or other nominee cannot vote your shares of MEI Common Stock without your specific voting instructions. Because the only proposals for consideration at the MEI Special Meeting are non-routine proposals, it is not expected that there will be any broker non-votes at the MEI Special Meeting. However, if there are any broker non-votes, assuming a quorum is present they will have “**NO EFFECT**” on the outcome of the MEI Nasdaq Proposal and the MEI Adjournment Proposal.

If you are a beneficial owner and would like to vote your shares at the MEI Special Meeting or Infinity Special Meeting, please contact your broker, bank or other nominee for instructions and documents that may be required in order to do so.

### **Q: Can I change my vote?**

**A:** Yes. If you are a record holder of MEI Common Stock, you can revoke your proxy and change your vote at any time before the final vote at the meeting.

- You may return by mail another properly completed proxy card with a later date, which must be received at the address stated on the proxy card no later than \_\_\_\_\_, Pacific Time on \_\_\_\_\_, 2023.
- You may submit another properly completed proxy with a later date via the Internet or by telephone before the closing of those voting facilities at 11:59 p.m., Pacific Time on \_\_\_\_\_, 2023.
- You may participate in the virtual online MEI Special Meeting and vote at the meeting. Simply participating in the virtual online meeting will not, by itself, revoke your proxy.
- MEI stockholders may send a written notice that they are revoking their proxy to MEI’s Corporate Secretary at MEI Pharma, Inc., 11455 El Camino Real, Suite 250, San Diego, California 92130.

A revocation or later-dated proxy received by MEI after the vote will not affect the vote.

If you are a record holder of Infinity Common Stock, you can change your vote and revoke your proxy at any time before the polls close at the Infinity Special Meeting. To do so you must do one of the following:

1. Sign another proxy card with a later date;
2. Submit another properly completed proxy with a later date via the Internet or by telephone;
3. Give written notice before the Infinity Special Meeting that you want to revoke your proxy to Infinity’s corporate secretary at 1100 Massachusetts Avenue, Floor 4, Cambridge, MA 02138; or
4. Attend and vote at the virtual Infinity Special Meeting.

Your attendance at the Infinity Special Meeting alone will not change your vote or revoke your proxy.

Finally, if you are a beneficial holder (and hold your shares in “street name” through a bank, broker or other nominee), you should contact that organization to revoke your proxy or change your vote in accordance with its instructions.

**Q: How do I vote my Infinity 401(k) Plan shares?**

A: If you participate in the Infinity Pharmaceuticals Inc. Stock Fund through the Infinity Pharmaceuticals Inc. 401(k) Plan and Trust (the “Infinity 401(k) Plan”), your proxy will also serve as a voting instruction for Principal Trust Company (“Principal”), which serves as trustee of the Infinity 401(k) Plan, with respect to shares of Infinity Common Stock held in your Infinity 401(k) Plan account (the “Infinity 401(k) Plan Shares”), as of the Infinity Record Date. You should sign the proxy card and return it in the enclosed envelope to Broadridge Financial Solutions, Inc., or you may submit your proxy over the Internet or by telephone by following the instructions on the enclosed proxy card. Broadridge will notify Principal of the manner in which you have directed your Infinity 401(k) Plan Shares to be voted. Principal will vote your Infinity 401(k) Plan Shares as of the Infinity Record Date in the manner that you direct. If Broadridge does not receive your voting instructions from you by 11:59 p.m. Eastern Time on \_\_\_\_\_, 2023, Principal will vote your Infinity 401(k) Plan Shares in the same proportion as those Infinity 401(k) Plan Shares for which Principal has received proper direction for such matter.

**Q: What happens if I fail to submit a proxy or I abstain from voting?**

A: If you fail to submit a proxy or fail to instruct your bank, broker or other nominee to vote, assuming a quorum is present at the MEI Special Meeting, it will have no effect on the outcome of the MEI Nasdaq Proposal or the MEI Adjournment Proposal. An abstention occurs when an MEI stockholder returns a proxy with an “ABSTAIN” instruction or virtually attends the MEI Special Meeting and abstains from voting. Assuming a quorum is present, abstentions also will have “NO EFFECT” on such proposals.

If you fail to submit a proxy or fail to instruct your bank, broker or other nominee to vote, assuming a quorum is present at the Infinity Special Meeting (i) it will have no effect on the outcome of the Infinity Adjournment Proposal and Infinity Compensation Proposal, and (ii) it will have the effect of a vote “AGAINST” the Infinity Merger Proposal.

**Q: Will Infinity equity awards be affected by the Merger?**

A: At the Effective Time, each outstanding option to purchase shares of Infinity Common Stock (each, an “Infinity Stock Option”) will become fully vested in accordance with the terms of the underlying stock option agreement. Each Infinity Stock Option will be assumed at the Effective Time by MEI and converted into a stock option to purchase shares of MEI Common Stock. The number of shares of MEI Common Stock underlying each such assumed Infinity Stock Option will be equal to the product of (i) the number of shares of Infinity Common Stock underlying the applicable Infinity Stock Option immediately prior to the Effective Time multiplied by (ii) the Exchange Ratio, with the resulting number of shares of MEI Common Stock rounded down to the nearest whole share, and the exercise price per share of each such assumed Infinity Stock Option will be equal to (a) the per share exercise price applicable to such Infinity Stock Option immediately prior to the Effective Time divided by (b) the Exchange Ratio, with the resulting exercise price per share rounded up to the nearest whole cent. Except as noted above, each assumed and converted Infinity Stock Option will continue to be governed by substantially the same terms and conditions (after giving effect to the full acceleration of vesting of such Infinity Stock Option in connection with the Merger) as were applicable to such Infinity Stock Option immediately prior to the Effective Time.

Before the Effective Time, each outstanding Infinity restricted stock unit (each, an “Infinity RSU”) will become fully vested and the shares of Infinity Common Stock subject to such Infinity RSU will be distributed in accordance with the terms of the applicable restricted stock unit agreement. The shares of Infinity Common Stock issued upon the vesting of Infinity RSUs will be treated as shares of Infinity Common Stock issued and outstanding immediately prior to the Effective Time in accordance with the terms and conditions of the Merger Agreement. No Infinity RSUs will be outstanding from and after the Effective Time.

**Q: What will happen to the Infinity 2013 Employee Stock Purchase Plan, as amended?**

A: Prior to the Effective Time, the Infinity board of directors will take action to terminate the purchase periods and offering periods then in effect under the terms of the Infinity 2013 Employee Stock Purchase Plan, as amended (the “Infinity ESPP”), and to exercise all outstanding options under the Infinity ESPP to the extent of accumulated payroll deductions as of a date specified by the Infinity board of directors. No options under the Infinity ESPP will be outstanding from and after the Effective Time.

**Q: Who will solicit and pay the cost of soliciting proxies?**

A: MEI has engaged Alliance Advisors, LLC to assist in the solicitation of proxies for the MEI Special Meeting. MEI estimates that it will pay Alliance Advisors, LLC a fee of approximately \$35,000, plus reimbursement of reasonable expenses. MEI has agreed to indemnify Alliance Advisors, LLC against various liabilities and expenses that relate to or arise out of its solicitation of proxies (subject to certain exceptions).

Infinity has engaged Morrow Sodali LLC to assist in the solicitation of proxies for the Infinity Special Meeting and to provide related advice and informational support, for a services fee of \$35,000 plus the reimbursement of customary disbursements. Infinity has agreed to indemnify Morrow Sodali LLC against various liabilities and expenses that relate to or arise out of its solicitation of proxies (subject to certain exceptions).

MEI and Infinity also may be required to reimburse banks, brokers and other custodians, nominees and fiduciaries or their respective agents for their expenses in forwarding proxy materials to beneficial owners of MEI common stock and Infinity common stock, respectively. MEI’s directors, officers and employees and Infinity’s directors, officers and employees also may solicit proxies, by telephone, by mail, by electronic means or in person. They will not be paid any additional amounts for soliciting proxies.

**Q: What are the material U.S. federal income tax consequences of the Merger to Infinity stockholders?**

A: The Merger is intended to qualify as a “reorganization” within the meaning of Section 368(a) of the Internal Revenue Code of 1986 (as amended, the “Code”). The completion of the Merger is, however, not conditioned on the Merger qualifying as a “reorganization” within the meaning of Section 368(a) of the Code or upon the receipt of an opinion of counsel to that effect. No assurance can be given that the Merger will qualify as a “reorganization” within the meaning of Section 368(a) of the Code.

Neither Infinity nor MEI has sought or intends to seek a ruling from the Internal Revenue Service (the “IRS”) or an opinion of counsel as to the U.S. federal income tax consequences of the Merger. If the IRS were to successfully challenge the qualification of the Merger as a “reorganization,” the tax consequences would differ materially from those described in this joint proxy statement/prospectus as discussed below under “*Material U.S. Federal Income Tax Consequences of the Merger—Tax Consequences if the Merger Fails to Qualify as a Reorganization.*”

Assuming the Merger qualifies as a “reorganization” within the meaning of Section 368(a) of the Code, subject to the limitations and qualifications described below under “*Material U.S. Federal Income Tax Consequences of the Merger,*” a U.S. Holder (as defined in the section titled “*Material U.S. Federal Income Tax Consequences of the Merger*”) will generally (i) not recognize any gain or loss upon the exchange of Infinity Common Stock for MEI Common Stock in the Merger (other than with respect to cash received in lieu of a fractional share of Infinity Common Stock), (ii) have a tax basis in the MEI Common Stock received in the Merger (including any fractional share of Infinity Common Stock for which cash is received) equal to the tax basis of the Infinity Common Stock surrendered in exchange therefor, and (iii) have a holding period for the MEI Common Stock received in the Merger (including any fractional share of Infinity Common Stock for which cash is received) that includes its holding period for its Infinity Common Stock surrendered in exchange therefor.

For further information, see “*The Merger—Material U.S. Federal Income Tax Consequences of the Merger.*”



**Q: If I am not in favor of the Merger, what are my rights?**

**A:** Neither MEI stockholders nor Infinity stockholders are entitled to appraisal rights under the Delaware General Corporation Law (the “DGCL”). If they are not in favor of the Merger, MEI stockholders may vote against the MEI Nasdaq Proposal and Infinity stockholders may vote against the Infinity Merger Proposal. For more information, see the section entitled “*No Appraisal Rights*” beginning on page 175 of this joint proxy statement/prospectus. Information about how MEI stockholders may vote on the proposals being considered in connection with the Merger can be found under the section entitled “*The Special Meeting of the MEI Stockholders*” beginning on page 108 of this joint proxy statement/prospectus. Information about how Infinity stockholders may vote on the proposals being considered in connection with the Merger can be found under the section entitled “*The Special Meeting of the Infinity Stockholders*” beginning on page 116 of this joint proxy statement/prospectus.

**Q: Should I send in my Infinity stock certificates now?**

**A:** No. Please do not send in your Infinity stock certificates with your proxy. After the completion of the Merger, an exchange agent mutually acceptable to MEI and Infinity will send you instructions for exchanging Infinity stock certificates for the merger consideration.

**Q: Whom may I contact if I cannot locate my Infinity stock certificate(s)?**

**A:** If you are unable to locate your original Infinity stock certificate(s), you should contact Infinity’s transfer agent, American Stock Transfer & Trust Company, LLC, at 800-937-5449.

**Q: What should I do if I hold my shares of Infinity Common Stock in book-entry form directly with Infinity’s transfer agent, as opposed to a physical stock certificate?**

**A:** You are not required to take any special additional actions if your shares of Infinity Common Stock are not represented by a certificate and are instead held in book-entry form with Infinity’s transfer agent. After the completion of the Merger, an exchange agent mutually acceptable to Infinity and MEI will contact you to provide you with details regarding the merger consideration, including shares of MEI Common Stock in book-entry form and any cash to be paid instead of fractional shares in the Merger.

**Q: What should I do if I receive more than one set of voting materials?**

**A:** MEI stockholders or Infinity stockholders may receive more than one set of voting materials, including multiple copies of this joint proxy statement/prospectus and multiple proxy cards. For example, if you hold shares of MEI Common Stock or Infinity Common Stock in more than one brokerage account, you will receive a separate voting instruction card for each brokerage account in which you hold such shares. If you are a holder of record of MEI Common Stock or Infinity Common Stock and your shares are registered in more than one name, you will receive more than one proxy card. Please complete, sign, date and return each proxy card and voting instruction form that you receive or otherwise follow the voting instructions set forth in this joint proxy statement/prospectus to ensure that you vote every share of MEI Common Stock or Infinity Common Stock, as appropriate, that you own.

**Q: When do you expect to complete the Merger?**

**A:** MEI and Infinity expect to complete the Merger in mid-2023, subject to any potential regulatory review or approval. However, neither MEI nor Infinity can assure you of when or if the Merger will be completed. Infinity must obtain the approval of Infinity’s stockholders for the Infinity Merger Proposal and MEI must obtain the approval of MEI’s stockholders for the MEI Nasdaq Proposal, and both parties must satisfy certain closing conditions. If the Merger is not satisfied prior to the outside date of August 31, 2023, either party may elect to terminate the Merger Agreement, subject to certain caveats. See “*The Merger Agreement—Conditions to the Completion of the Merger*” for more information regarding conditions to the completion of the Merger.



**Q: What happens if the Merger is not completed?**

**A:** If the Merger is not completed, Infinity stockholders will not receive any consideration for their shares of Infinity Common Stock in connection with the Merger. Instead, MEI and Infinity will remain independent, public companies and, assuming that MEI and Infinity are able to comply with the required listing standards, MEI Common Stock will continue to be traded on The Nasdaq Capital Market and Infinity Common Stock will continue to be traded on The Nasdaq Global Select Market. In addition, if the Merger Agreement is terminated in certain circumstances, MEI and Infinity may be required to pay a termination fee. See “*The Merger Agreement—Termination*” for a complete discussion of the circumstances under which a termination fee will be required to be paid.

**Q: Where can I find the voting results of the MEI Special Meeting and the Infinity Special Meeting?**

**A:** The preliminary voting results will be announced at the MEI Special Meeting and Infinity Special Meeting, respectively. In addition, within four business days following the MEI Special Meeting and Infinity Special Meeting, MEI and Infinity will each disclose the preliminary or, if available, final voting results of the MEI Special Meeting and Infinity Special Meeting on a Current Report on Form 8-K filed with the SEC. If preliminary voting results are disclosed, MEI and Infinity will each file an amended Current Report on Form 8-K with the SEC to disclose final voting results within four business days following certification of the final voting results.

**Q: Is the completion of the Merger subject to a financing condition?**

**A:** No. The completion of the Merger is not subject to any financing condition.

**Q: How will I know when the other conditions to completion of the Merger have been satisfied?**

**A:** As of the date of this joint proxy statement/prospectus, the parties have not satisfied the closing conditions to the Merger. If the closing conditions are satisfied, MEI and Infinity will each announce the closing of the Merger via the filing of a Current Report on Form 8-K with the SEC. There is also a possibility that the closing conditions to the Merger will not be satisfied prior to the outside date of August 31, 2023, after which date either party may elect to terminate the Merger Agreement, subject to certain caveats. As a result, it is possible that factors outside the control of both companies could result in the Merger being completed at a different time or not at all.

Infinity stockholders will not know the actual Exchange Ratio or the value of the MEI Common Stock to be received as merger consideration until after the date of the MEI Special Meeting and the Infinity Special Meeting. See “*Risk Factors.*”

**Q: Are there any risks that I should consider in deciding whether to vote for the adoption of the Merger Agreement?**

**A:** Yes. You should read and carefully consider the risk factors set forth in the “*Risk Factors*” section.

**Q: Who can answer any questions I may have about the Merger or the transactions contemplated by the Merger Agreement?**

**A:** If you have any questions about the Merger or the transactions contemplated by the Merger Agreement, or if you need additional copies of this joint proxy statement/prospectus, you should contact:

For MEI stockholders: Alliance Advisors, LLC 200 Broadacres Drive, 3 <sup>rd</sup> Floor Bloomfield, NJ 07003 +1 (888) 511-2635 Email: MEIP@allianceadvisors.com	For Infinity stockholders: Morrow Sodali, LLC 509 Madison Avenue, Suite 1206 New York, NY 10022 Call (800) 662-5200 (Toll-free in North America) or + (212) 658-9400 Email: INFI@info.morrowsodali.com
---	--

## PROSPECTUS SUMMARY

*This summary highlights selected information from this joint proxy statement/prospectus and may not contain all of the information that is important to you. To better understand the Merger and the proposals being considered at the MEI Special Meeting and the Infinity Special Meeting, you should read this entire proxy statement/prospectus carefully, including the Merger Agreement and the other annexes to which you are referred in this joint proxy statement/prospectus. For more information, please see the section titled “Where You Can Find More Information” beginning on page 338 of this joint proxy statement/prospectus.*

### Overview of the Companies

#### ***Infinity Pharmaceuticals, Inc.***

1100 Massachusetts Avenue, Floor 4  
Cambridge, Massachusetts 02138  
Telephone: (617) 453-1000

Infinity Pharmaceuticals, Inc. is a clinical-stage innovative biopharmaceutical company dedicated to developing novel medicines for people with cancer. Infinity combines proven scientific expertise with a passion for developing novel small molecule drugs that target disease pathways for potential applications in oncology. Infinity is focused on advancing eganelisib, also known as IPI-549, an orally administered, clinical-stage, immuno-oncology product candidate that reprograms macrophages through selective inhibition of the enzyme phosphoinositide-3-kinase-gamma (“PI3K-gamma”). Infinity’s common stock is listed on the Nasdaq Global Select Market under the symbol “INFI.”

#### ***MEI Pharma, Inc.***

11455 El Camino Real, Suite 250  
San Diego, California 92130  
Telephone: (858) 369-7100

MEI Pharma, Inc. is a clinical stage pharmaceutical company focused on developing potential new therapies for cancer. MEI’s portfolio of drug candidates includes clinical-stage candidates with differentiated or novel mechanisms of action intended to address unmet medical needs and deliver improved benefit to patients, either as standalone treatments or in combination with other therapeutic options. MEI’s common stock is listed on the Nasdaq Capital Market under the symbol “MEIP.”

#### ***Meadow Merger Sub, Inc.***

11455 El Camino Real, Suite 250  
San Diego, California 92130  
Telephone: (858) 369-7100

Meadow Merger Sub, Inc. is a direct, wholly owned subsidiary of MEI. Merger Sub was incorporated in the State of Delaware on December 29, 2022, solely for the purpose of carrying out the Merger. Merger Sub has not carried on any activities to date, except for activities incidental to its formation and activities undertaken in connection with the Merger.

### **The Merger (see page 122)**

On February 22, 2023, MEI, Infinity and Merger Sub entered into the Merger Agreement. The Merger Agreement provides, among other things, that on the terms and subject to the conditions set forth therein: (i) Merger Sub will merge with and into Infinity, with Infinity being the surviving entity as a wholly-owned subsidiary of MEI (the “Merger” and, collectively with the other transactions contemplated by the Merger Agreement, the “Contemplated Transactions”), (ii) each share of Infinity Common Stock issued and outstanding

immediately prior to the Merger (other than shares of Infinity Common Stock held in treasury, if any) shall be automatically converted into the right to receive 0.052245 shares (the “Exchange Ratio”) of MEI Common Stock, subject to customary equitable adjustment in the event of any recapitalization, stock split, reverse stock split or similar change, (iii) each outstanding Infinity Stock Option will become fully vested in accordance with the terms of the underlying stock option agreement and will be assumed by MEI at the Effective Time and converted into a stock option to purchase shares of MEI Common Stock, and (iv) each Infinity RSU will become fully vested and the shares of Infinity Common Stock subject to such Infinity RSUs will be distributed before the Effective Time in accordance with the terms of the applicable restricted stock unit agreement, and any shares of Infinity Common Stock issued upon the vesting of Infinity RSUs will be treated in accordance with subpart (ii) hereof. Upon completion of the Merger, MEI’s stockholders will own approximately 58% of the combined company’s outstanding common stock and Infinity stockholders will own approximately 42%, subject to the terms of the Merger Agreement. The Merger is intended to qualify as a reorganization within the meaning of Section 368(a) of the Code.

For a more complete description of the Merger and the Exchange Ratio, please see the section titled “*The Merger Agreement*” in this joint proxy statement/prospectus.

The Merger will be completed as promptly as practicable, but in no event later than three business days following the day on which the last to be satisfied or waived of each of the conditions to consummation of the Merger set forth in the Merger Agreement (other than those conditions that by their nature are to be satisfied at the consummation of the Merger (the “Closing”), but subject to the satisfaction or waiver of those conditions) are satisfied or waived, including the adoption of the Merger Agreement by the Infinity stockholders and the approval by the MEI stockholders of the issuance of MEI Common Stock in the Merger. The Merger is anticipated to close promptly after the MEI Special Meeting and Infinity Special Meeting scheduled to be held on \_\_\_\_\_, 2023. However, MEI and Infinity cannot predict the exact timing of the completion of the Merger because it is subject to the satisfaction or waiver of various conditions.

### **Reasons for the Merger (see pages 138 and 142)**

#### *MEI’s Reasons for the Merger*

After consideration and consultation with its senior management and its financial and legal advisors, the MEI board of directors (with Sujay R. Kango recusing himself from the vote) determined that the Merger Agreement, the Merger and other transactions contemplated thereby are advisable, fair to and in the best interests of MEI and its stockholders. The MEI board of directors considered various reasons to reach its determination. For example:

- the MEI board’s consideration of Infinity’s strategic fit with the MEI business after giving effect to the Merger, including with respect to the development of MEI’s existing product candidates, voruciclib and ME-344, and Infinity’s product candidate, eganelisib;
- the prospects of and risks associated with the other strategic or licensing candidates that had made inquiries for a potential transaction with MEI based on the scientific, technical and other due diligence conducted by MEI management and its advisors;
- the MEI board’s view that, as a result of the significant, majority equity interest that the MEI stockholders would have in the post-Merger combined company, MEI stockholders have the opportunity to meaningfully participate in the growth and value creation of the combined company following the closing of the Merger by virtue of their continued ownership of MEI Common Stock; and
- the MEI board’s view of the combined clinical development and regulatory expertise of Infinity and MEI, which both possess relevant experience in the development of pharmaceutical products to treat cancer, particularly including kinase biology target cancer inhibition.

*Infinity's Reasons for the Merger*

After consideration, the Infinity board of directors (with Sujay R. Kango recusing himself from the vote), by a vote of directors at its meeting on February 22, 2023, approved and declared advisable the Merger Agreement and the Merger, and recommended that Infinity stockholders vote to approve the Merger Agreement.

In the course of evaluating the Merger Agreement and the Contemplated Transactions, the Infinity board of directors held numerous meetings and consulted with Infinity management and Infinity's legal and financial advisors and considered a number of factors in reaching its decision to approve the Merger Agreement, the Merger and the Contemplated Transactions, which included the following (not in order of relative importance):

- the Infinity board of directors' belief that eganelisib has significant commercial potential and the Merger would allow for eganelisib's continued development;
- the Infinity board of directors' belief that, as a result of arm's length negotiations with MEI, Infinity, through Infinity's management team and financial advisor, negotiated the most favorable equity split for its pre-closing stockholders to which MEI was willing to agree, and that the terms of the Merger Agreement include the most favorable terms to Infinity in the aggregate to which MEI was willing to agree;
- the Infinity board of directors' belief that, as a result of the significant equity interest that the Infinity stockholders would have in the post-merger combined company, the Infinity stockholders could meaningfully participate in potential value creation from successful development of eganelisib;
- the Infinity board of directors' belief, after a thorough review of strategic alternatives and discussions with Infinity's senior management, financial advisor and legal counsel, that the Merger Agreement was more favorable to Infinity's pre-closing stockholders than the potential value that might have resulted from other strategic and financing options available to Infinity, including a liquidation of Infinity and the distribution of any available cash; and
- the anticipated combined scientific, clinical development and regulatory expertise of Infinity and MEI, which both possess relevant experience in the development of pharmaceutical products to treat cancer.

For a more complete description of the reasons for the Merger, please see the sections titled "*The Merger—MEI's Reasons for the Merger; Recommendation of the MEI Board*" and "*The Merger—Infinity's Reasons for the Merger; Recommendation of the Infinity Board*" beginning on pages 138 and 142, respectively, of this joint proxy statement/prospectus.

**Opinion of MEI's Financial Advisor (see page 147)**

Torrey Capital, LLC ("Torrey") rendered the Torrey Opinion to the MEI board of directors that, as of February 22, 2022, based on and subject to the factors and assumptions set forth in the Torrey Opinion, the Exchange Ratio was fair, from a financial point of view to the holders of shares of MEI. For a more complete description of the Torrey Opinion, please see the section titled "The Merger—Opinion of MEI's Financial Advisor—Torrey Capital, LLC" beginning on page 147.

**Opinion of Infinity's Financial Advisor (see page 156)**

Aquilo Partners ("Aquilo") delivered its oral opinion to the Infinity board of directors, which was subsequently confirmed in writing, that, as of February 22, 2023, and based upon and subject to the qualifications, limitations and assumptions set forth therein, the Exchange Ratio is fair, from a financial point of view, to the holders of Infinity Common Stock. For a more complete description of Aquilo's opinion, please see the section titled "*The Merger—Opinion of Infinity's Financial Advisor*" beginning on page 156.

**Interests of Certain Directors, Officers and Affiliates of MEI and Infinity (see page 167)**

*Interests of MEI Directors and Executive Officers in the Merger*

In considering the recommendation of the board of directors of MEI with respect to issuing shares of MEI Common Stock pursuant to the Merger Agreement and the other matters to be acted upon by MEI stockholders at the Special Meeting, MEI stockholders should be aware that certain members of the MEI board of directors and executive officers of MEI have interests in the Merger that may be different from, or in addition to, interests they have as MEI stockholders.

- Daniel P. Gold, Ph.D., Charles V. Baltic III, Thomas C. Reynolds, and Sujay R. Kango, members of the MEI board of directors, will continue as directors after the Merger, and, following the closing of the Merger, Daniel P. Gold, Ph.D., Charles V. Baltic III, Thomas C. Reynolds, and Sujay R. Kango will be eligible to be compensated as directors of MEI pursuant to the MEI's compensation policy that is expected to remain in place following the Merger.
- Sujay R. Kango serves on the boards of directors of each of MEI and Infinity and holds stock options exercisable for shares of MEI Common Stock and Infinity Common Stock.

These interests and others are discussed in more detail in the section titled "*The Merger—Interests of MEI Directors and Executive Officers in the Merger*" beginning on page 167 of this joint proxy statement/prospectus. The members of MEI's board of directors were aware of and considered these interests, among other matters, in reaching their decisions to adopt the Merger Agreement, to approve the transactions contemplated by the Merger Agreement and to recommend the approval of the MEI Nasdaq Proposal to MEI's stockholders.

*Interests of Infinity Directors and Executive Officers in the Merger*

In considering the recommendations of the Infinity board of directors (with Sujay R. Kango recusing himself from the vote) with respect to the Infinity Merger Proposal, the Infinity Compensation Proposal and the Infinity Adjournment Proposal, Infinity's stockholders should be aware that certain of Infinity's directors and executive officers have interests in the Merger, including financial interests, that may be different from, or in addition to, the interests of the other Infinity stockholders generally. Interests of the directors and executive officers may be different from or in addition to the interests of the stockholders for the following reasons, among others:

- As of March 31, 2023, Infinity's directors and executive officers beneficially owned, in the aggregate, approximately 11% of the outstanding shares of Infinity Common Stock.
- Subject to the terms of the Merger Agreement, at the Effective Time, each outstanding Infinity Stock Option will become fully vested in accordance with the terms of the underlying stock option agreement and be assumed by MEI.
- Before the Effective Time, each outstanding Infinity RSU will become fully vested and the shares of Infinity Common Stock subject to such Infinity RSU will be distributed in accordance with the terms of the applicable restricted stock unit agreement. The shares of Infinity Common Stock issued upon the vesting of Infinity RSUs will be treated as shares of Infinity Common Stock issued and outstanding immediately prior to the Effective Time in accordance with the terms and conditions of the Merger Agreement. No Infinity RSUs will be outstanding from and after the Effective Time.
- Following a termination without cause (as defined in the Infinity Severance Plan) or a resignation for good reason (as defined in the Infinity Severance Plan), including in each case within one year following a change in control, certain executive officers of Infinity would be entitled to certain severance benefits, which include, among other things, an amount, payable in a single lump sum for each executive officer, equal to twelve months of the executive's monthly base salary, and

immediate vesting of the portion of any outstanding equity awards of the executive which would have vested within the one year-period following such change in control.

- Certain executive officers have entered into retention agreements, which among other things, would entitle these executive officers to a retention bonus.
- Norman Selby, Adelene Q. Perkins and Richard Gaynor, M.D., members of the Infinity board of directors, will be appointed as members of the combined company’s board of directors after the Merger, and, following the closing of the Merger, will be eligible to be compensated as directors of the combined company pursuant to MEI’s compensation policy that is expected to remain in place following the Merger.
- Sujay R. Kango serves on the boards of directors of each of MEI and Infinity and holds stock options exercisable for shares of MEI Common Stock and Infinity Common Stock (Sujay R. Kango recused from the merger discussions and vote).

These interests and others are discussed in more detail in the section titled “*The Merger—Interests of Infinity Directors and Executive Officers in the Merger*” beginning on page 167 of this joint proxy statement/prospectus. The members of Infinity’s board of directors were aware of and considered these interests, among other matters, in reaching their decisions to adopt the Merger Agreement, to approve the transactions contemplated by the Merger Agreement and to recommend the adoption of the Merger Agreement to Infinity’s stockholders.

**Management Following the Merger (see page 172)**

Effective as of the Closing, the combined company’s executive officers are expected to be:

<u>Name</u>	<u>Title</u>
David M. Urso	Chief Executive Officer
Robert Ilaria, Jr.	Chief Medical Officer
Stéphane Peluso	Chief Scientific Officer
Brian G. Drazba	Chief Financial Officer

Following the Closing, the board of directors of the combined company is expected to be composed of eight members, consisting of Norman C. Selby (currently Infinity’s Lead Independent Director), who is expected to chair the combined company board, Mr. Urso (currently MEI’s Chief Operating Officer and General Counsel), Daniel P. Gold, Ph.D. (currently MEI’s Chief Executive Officer), Adelene Q. Perkins (currently Infinity’s Chief Executive Officer and Chair of the board of directors of Infinity), Richard Gaynor, M.D. (currently a director of Infinity), Charles V. Baltic III (currently Chair of the board of directors of MEI), Thomas C. Reynolds, M.D., Ph.D. (currently a director of MEI) and Sujay R. Kango (currently a director of MEI and Infinity).

**The Merger Agreement and Agreements Related to the Merger Agreement (see page 180)**

The terms and conditions of the Merger Agreement are contained in the Merger Agreement, which is attached to this joint proxy statement/prospectus as [Annex A](#) and is incorporated by reference herein in its entirety. MEI and Infinity encourage you to read the Merger Agreement carefully, as it is the legal document that governs the business combination. For more information on the Merger Agreement, see the section entitled “*The Merger Agreement*.”

**Voting by MEI’s Directors and Executive Officers (see page 109)**

As of the MEI Record Date, directors and executive officers of MEI and their affiliates owned and were entitled to vote \_\_\_\_\_ shares of MEI Common Stock, representing approximately \_\_\_\_\_ % of the shares of MEI Common Stock outstanding on the MEI Record Date. MEI currently expects that its directors and executive officers will vote any shares of MEI Common Stock they hold in favor of the MEI Nasdaq Proposal, although none of them has entered into any agreement obligating him or her to do so.

**Voting by Infinity’s Directors and Executive Officers (see page 117)**

As of the Infinity Record Date, directors and executive officers of Infinity and their affiliates owned and were entitled to vote \_\_\_\_\_ shares of Infinity Common Stock, representing approximately \_\_\_\_\_ % of the shares of Infinity Common Stock outstanding on the Infinity Record Date. Infinity currently expects that its directors and executive officers will vote any shares of Infinity Common Stock they hold in favor of the Infinity Merger Proposal, the Infinity Compensation Proposal and the Infinity Adjournment Proposal, although none of them has entered into any agreement obligating him or her to do so.

**Conditions to the Completion of the Merger (see page 184)**

Under the Merger Agreement, the Closing is subject to, and will take place following the satisfaction or waiver by MEI or Infinity, as applicable, of certain customary closing conditions, including, without limitation: (i) the registration statement on Form S-4 of which this joint proxy statement/prospectus forms a part, which is being filed by MEI with the SEC to register the MEI Common Stock to be issued to the holders of the shares of Infinity Common Stock in connection with the Merger, must become effective and not subject to any stop order or proceeding seeking a stop order; (ii) Infinity must obtain the approval of its stockholders of the Merger and the Contemplated Transactions; (iii) MEI must obtain approval of its stockholders of the issuance of such shares of MEI Common Stock in connection with the Merger; (iv) the absence of any law or judgment of a governmental entity of competent jurisdiction that is in effect and restrains, enjoins, or otherwise prohibits consummation of the Merger; (v) the existing shares of MEI Common Stock must be continually listed on Nasdaq, and the shares of MEI Common Stock issuable pursuant to the Merger Agreement must be approved for listing on Nasdaq; (vi) the performance, in all material respects, by each of Infinity and MEI of such party’s respective obligations pursuant to the Merger Agreement; (vii) the absence of a continuing “material adverse effect”, as such term is defined in the Merger Agreement, on the business, financial condition or results of operations of, respectively, (a) Infinity and its subsidiaries, taken as a whole or (b) MEI and its subsidiaries, taken as a whole; (viii) the accuracy of MEI’s and Infinity’s representations and warranties, subject to specified materiality qualifications; (ix) delivery of customary closing documents, including a customary officer certificate from each of MEI and Infinity and (x) each of MEI and Infinity shall have, at the Closing, an amount of cash greater than or equal to such party’s “Minimum Net Cash” (as such term is defined in the Merger Agreement), in each case, on terms further described in the Merger Agreement.

**No Solicitation (see page 187)**

Each of MEI and Infinity agreed that, subject to limited exceptions, MEI and Infinity will not, and will cause their subsidiaries and their subsidiaries’ directors, officers and employees not to, and shall cause the investment bankers, attorneys, accountants and other advisors, agents or representatives of Infinity and MEI, and of any of the aforementioned entities and persons, not to, directly or indirectly:

- solicit, initiate, induce, encourage or facilitate any inquiries or the making of any proposal or offer that constitutes, or could reasonably be expected to lead to, an Infinity Acquisition Proposal (as defined in the Merger Agreement) or MEI Acquisition Proposal (as defined in the Merger Agreement);
- participate in any discussions or negotiations or cooperate in any way with any person regarding any Infinity Acquisition Proposal or MEI Acquisition Proposal or any inquiry, proposal or offer that could reasonably be expected to lead to an Infinity Acquisition Proposal or MEI Acquisition Proposal;
- provide any non-public information or data concerning MEI, Infinity or any of their subsidiaries to any person in connection with any Infinity Acquisition Proposal or MEI Acquisition Proposal or any inquiry, proposal or offer that could reasonably be expected to lead to an Infinity Acquisition Proposal or MEI Acquisition Proposal or for the purpose of soliciting, initiating, inducing, encouraging or facilitating an Infinity Acquisition Proposal or MEI Acquisition Proposal;



- enter into any binding or nonbinding letter of intent, term sheet, memorandum of understanding, merger agreement, acquisition agreement, agreement in principle, option agreement, joint venture agreement, partnership agreement, lease agreement or other similar agreement with respect to an Infinity Acquisition Proposal or MEI Acquisition Proposal;
- adopt, approve or recommend or make any public statement approving or recommending any inquiry, proposal or offer that constitutes, or could reasonably be expected to lead to, an Infinity Acquisition Proposal or MEI Acquisition Proposal (including by approving any transaction, or approving any person becoming an “interested stockholder,” for purposes of Section 203 of the DGCL);
- take any action or exempt any person (other than the other parties and their subsidiaries) from the restriction on “business combinations” or any similar provision contained in applicable takeover laws or its organizational or other governing documents; or
- publicly propose, resolve or agree to do any of the foregoing actions.

**Termination (see page 195)**

The Merger Agreement may be terminated under certain customary and limited circumstances at any time prior to the Closing, including without limitation: (i) by mutual written consent of MEI and Infinity; (ii) by either MEI or Infinity, if (a) a governmental authority shall have issued a final and non-appealable permanent restraining order, permanent injunction or other similar permanent order which has the effect of enjoining or otherwise prohibiting consummation of the Contemplated Transactions, (b) the Closing has not occurred on or before August 31, 2023, (c) the Infinity Stockholder Approval has not been obtained at the Infinity Special Meeting and (d) MEI Stockholder Approval has not been obtained at the MEI Special Meeting, in each of (a), (b), (c) and (d) where the terminating party’s material breach of the Merger Agreement is not the cause of, or has resulted in, the failure of such condition; (iii) by Infinity if (a) MEI breaches or fails to perform any of its representations, warranties or covenants contained in the Merger Agreement such that any of Infinity’s conditions to closing the Contemplated Transactions would not be satisfied, and such breach or failure, if curable, is not cured in accordance with the Merger Agreement, (b) MEI has materially breached or failed to perform its covenants to not solicit any alternative acquisition proposals, (c) MEI’s board has made a “Change of Recommendation” (as such term is defined in the Merger Agreement) or (d) MEI has failed to include the recommendation of its board to consummate MEI Share Issuance in its joint proxy statement/prospectus distributed to its stockholders; and (iv) by MEI if (a) Infinity breaches or fails to perform any of its representations, warranties or covenants contained in the Merger Agreement such that any of MEI’s conditions to closing the Contemplated Transactions would not be satisfied, and such breach or failure, if curable, is not cured in accordance with the Merger Agreement, (b) Infinity has materially breached or failed to perform its covenants to not solicit any alternative acquisition proposals, (c) Infinity’s board has made a “Change of Recommendation” (as such term is defined in the Merger Agreement) or (d) Infinity has failed to include the recommendation of its board to consummate the Merger in its joint proxy statement/prospectus distributed to its stockholders.

**Termination Fee (see page 195)**

The Merger Agreement provides that a termination fee in the amount of \$4,000,000, if payable by MEI, and in the amount of \$2,900,000, if payable by Infinity, will be payable if the Merger Agreement is terminated under certain circumstances. It also provides that each party will reimburse the other party for all reasonable out of pocket fees and expenses incurred by such party in connection with the Merger Agreement and the Contemplated Transactions, up to a maximum of \$1,000,000 if the Merger Agreement is terminated under certain circumstances.



**Material U.S. Federal Income Tax Consequences of the Merger (see page 176)**

It is intended that the Merger will qualify as a “reorganization” within the meaning of Section 368(a) of the Code and the Treasury regulations promulgated thereunder. The completion of the Merger is, however, not conditioned on the Merger qualifying as such a “reorganization” or upon the receipt of an opinion of counsel to that effect. No assurance can be given that the Merger will qualify as a “reorganization” within the meaning of Section 368(a) of the Code and the Treasury regulations promulgated thereunder. In general, and subject to the exceptions, qualifications and limitations set forth in the section titled “*Material U.S. Federal Income Tax Consequences of the Merger*,” assuming that the Merger qualifies as a “reorganization” within the meaning of Section 368(a) of the Code and the Treasury regulations promulgated thereunder, generally, a U.S. Holder (as defined in the section titled “*Material U.S. Federal Income Tax Consequences of the Merger*”) that exchanges Infinity Common Stock for MEI Common Stock in the Merger:

- will not recognize any gain or loss upon the exchange of Infinity Common Stock for MEI Common Stock in the Merger, except with respect to cash received in lieu of a fractional share of MEI Common Stock;
- will have a tax basis in the MEI Common Stock received in the Merger (including any fractional share of MEI Common Stock deemed received) equal to the tax basis of the Infinity Common Stock surrendered in exchange therefor; and
- will have a holding period for the MEI Common Stock received in the Merger (including any fractional share of MEI Common Stock deemed received) that includes its holding period for its Infinity Common Stock surrendered in exchange therefor.

All holders of Infinity Common Stock should consult their tax advisors as to the particular tax consequences to them of the Merger, including the applicability and effect of any U.S. federal, state, local, non-U.S., and other tax laws.

**Anticipated Accounting Treatment (see page 175)**

The Merger is expected to be accounted for as an asset acquisition as substantially all of the fair value of the gross assets acquired is concentrated in a group of similar identifiable assets, primarily in-process research and development. In accordance with ASC 805, asset acquisitions are accounted for by allocating the cost of the acquisition, including transaction costs, to the individual assets acquired and liabilities assumed on a fair value basis without the recognition of goodwill. MEI is considered to be the accounting acquirer based on the structure of the Merger, relative outstanding share ownership at closing and the composition of the combined company’s board of directors.

**No Appraisal Rights (see page 175)**

Neither MEI stockholders nor Infinity stockholders are entitled to appraisal rights under the DGCL.

**Comparison of Rights of Holders of Common Stock (see page 324)**

MEI and Infinity, respectively, are incorporated under the laws of the State of Delaware. If the Merger is completed, Infinity stockholders will become holders of MEI Common Stock and will have different rights as holders of MEI Common Stock than they had as holders of Infinity Common Stock. The differences between the rights of these respective holders result from the differences of the respective governing documents of MEI and Infinity, as the same may be amended in connection with the Merger. For additional information, see the section titled “*Comparison of Rights of Holders of MEI Common Stock and Infinity Common Stock*” beginning on page 324 of this joint proxy statement/prospectus.

**Risk Factor Summary (see page 26)**

Both MEI and Infinity are subject to various risks associated with their businesses and their industries. In addition, the Merger, including the possibility that the Merger may not be completed, poses a number of risks to each company and its respective securityholders, including, without limitation, the following risks:

***Risks Related to the Merger***

- The Exchange Ratio will not be adjusted based on the market price of MEI Common Stock or Infinity Common Stock, so the merger consideration at the closing may have a greater or lesser value than at the time the Merger Agreement was signed.
- If the conditions to the Merger are not satisfied or waived, the Merger may not occur.
- The Merger may be completed even though a material adverse effect may result from the announcement of the Merger, industry wide changes or certain other causes.
- If MEI and Infinity complete the Merger, the combined company will need to raise additional capital by issuing equity securities or additional debt or through licensing arrangements, which may cause significant dilution to the combined company's stockholders or restrict the combined company's operations.
- MEI and Infinity directors and executive officers have interests in the Merger that are different from yours and that may influence them to support or approve the Merger without regard to your interests.
- MEI and Infinity securityholders will have a reduced ownership and voting interest in, and will exercise less influence over the management of, the combined company following the completion of the Merger as compared to their current ownership and voting interests in the respective companies.
- If the Merger is not completed, MEI's and Infinity's stock prices may fluctuate significantly.
- During the pendency of the Merger, MEI and Infinity may not be able to enter into a business combination with another party on more favorable terms because of restrictions in the Merger Agreement, which could adversely affect their respective business prospects.
- The financial analyses, estimates and forecasts presented herein and considered by MEI and Infinity in connection with the Merger may not be realized.
- If the Merger is not consummated, each of MEI and Infinity would need to determine whether to continue its business, consummate another strategic transaction, or dissolve and liquidate its assets.
- Lawsuits could delay or prevent the Merger.

***Risks Related to MEI***

- MEI will need substantial additional funds to progress the clinical trial programs for its drug candidates, and to develop new compounds. The actual amount of funds MEI will need will be determined by a number of factors, some of which are beyond MEI's control.
- MEI is a clinical research and development stage company and is likely to incur operating losses for the foreseeable future.
- MEI is subject to significant obligations to Presage in connection with MEI's license of voruciclib, and MEI may become subject to significant obligations in connection with future

licenses it obtains, which could adversely affect the overall profitability of any products MEI may seek to commercialize, and such licenses of drug candidates, the development and commercialization for which MEI is solely responsible, may never become profitable.

- MEI's business strategy may include entry into additional collaborative or license agreements. MEI may not be able to enter into collaborative or license agreements or may not be able to negotiate commercially acceptable terms for these agreements.
- Changes in funding for the FDA and other government agencies or future government shutdowns could cause delays in the submission and regulatory review of marketing applications, which could negatively impact MEI's business or prospects.
- If any products MEI develops become subject to unfavorable pricing regulations, third party reimbursement practices or healthcare reform initiatives, MEI's ability to successfully commercialize its products will be impaired.
- MEI's product candidates may face competition sooner than anticipated.
- MEI's commercial success is dependent, in part, on obtaining and maintaining patent protection and preserving trade secrets, which cannot be guaranteed.
- MEI faces a risk of product liability claims and claims may exceed MEI's insurance limits.

***Risks Related to Infinity***

- If the Merger is not completed, substantial doubt exists as to Infinity's ability to continue as a going concern.
- Raising additional capital may cause dilution to Infinity's stockholders, restrict its operations or require Infinity to relinquish rights to its technologies or product candidates.
- Infinity has a history of operating losses, expects to incur significant and increasing operating losses in the future, and may never become profitable, or if Infinity becomes profitable, it may not remain profitable.
- If the Merger is not completed, Infinity will need substantial additional funding, and if Infinity is unable to raise capital when needed, it could be forced to delay, reduce or eliminate the development of eganelisib or future efforts to commercialize eganelisib.
- Infinity is dependent on the success of eganelisib, its only product candidate, which remains subject to clinical testing and regulatory approval. If Infinity is unable to initiate or complete clinical development of, obtain marketing approval for or successfully commercialize eganelisib, either alone or with a collaborator, or if Infinity experiences significant delays in doing so, its business could be substantially harmed.
- If a collaborator terminates or fails to perform its obligations under agreements with Infinity, the development and commercialization of eganelisib or any future product candidates Infinity may develop could be delayed or terminated.
- If Infinity fails to obtain or maintain necessary or useful intellectual property rights, Infinity could encounter substantial delays in the research, development and commercialization of eganelisib and any product candidates that it may develop in the future.
- Even if Infinity completes the necessary preclinical studies and clinical trials, the regulatory approval process is expensive, time-consuming and uncertain and may prevent Infinity from obtaining approvals for the commercialization of eganelisib. If Infinity or its collaborators are not

able to obtain, or if there are delays in obtaining, required regulatory approvals, or if they are not able to successfully commercialize eganelisib, then Infinity's ability to generate revenue will be materially impaired.

- If Infinity is not able to retain key personnel and advisors, it may not be able to operate its business successfully.
- Infinity's common stock may have a volatile trading price and low trading volume.
- Infinity does not currently meet the requirements for continued listing on the Nasdaq Global Select Market. If Infinity fails to regain compliance with such requirements, its common stock could be delisted from trading, which would decrease the liquidity of Infinity's common stock and Infinity's ability to raise additional capital.

***Risks Related to the Combined Company***

- The failure to successfully integrate the businesses and operations of Infinity and MEI in the expected time frame may adversely affect the combined company's future results.
- The market price of the combined company's common stock is expected to be volatile, and the market price of the common stock may drop following the Merger.
- MEI and Infinity will incur substantial direct and indirect costs in contemplation of and as a result of the Merger and the combined company will incur substantial direct and indirect costs in connection with combining the business of MEI and Infinity following the Merger.
- The actual financial position and results of operations of the combined company after the Merger may differ materially from the unaudited pro forma condensed combined financial information for the combined company included in this joint proxy statement/ prospectus.
- The combined company may be exposed to increased litigation, including stockholder litigation, which could have an adverse effect on the combined company's business and operations.

These risks and other risks are discussed in greater detail under the section titled "*Risk Factors*" beginning on page 26 of this joint proxy statement/prospectus. MEI and Infinity both encourage you to read and consider all of these risks carefully.

## RISK FACTORS

The combined company (for the purpose of this “Risk Factors” section, “we,” “us” and “our”) will be faced with a market environment that cannot be predicted and that involves significant risks and uncertainties, many of which will be beyond our control. You should carefully consider all of the information set forth in this joint proxy statement/prospectus. The combined company’s business, financial condition and results of operations could be materially and adversely affected by any of these risks. In that event, the trading price of our common stock would likely decline and you might lose all or part of your investment. You should also read and consider the risks associated with each of the businesses of MEI and Infinity because these risks will also affect the combined company. In addition to the other information contained in this joint proxy statement/prospectus, you should carefully consider the material risks described below before deciding how to vote your shares of Infinity Common Stock or MEI Common Stock. You should also read and consider the other information in this joint proxy statement/prospectus and additional information about Infinity set forth in its Annual Report on Form 10-K for the fiscal year ended December 31, 2022 and about MEI set forth in its Annual Report on Form 10-K for the fiscal year ended June 30, 2022, as updated by its Quarterly Reports on Form 10-Q, which are filed with the SEC. Please see the section titled “*Where You Can Find More Information*” beginning on page 338 of this joint proxy statement/prospectus for further information. This joint proxy statement/prospectus also contains forward-looking statements that involve risks and uncertainties. Our results could materially differ from those anticipated in these forward-looking statements, as a result of certain factors including the risks described below and elsewhere in this report and our other SEC filings. See also “*Cautionary Statement Concerning Forward-Looking Statements and Industry and Market Data*” on page 1 of this joint proxy statement/prospectus.

### Risks Related to MEI’s Business

#### Risks Related to MEI’s Development Stage

***MEI is not in compliance with the Nasdaq continued listing requirements. If MEI is unable to comply with the continued listing requirements of the Nasdaq Capital Market, its common stock could be delisted, which could affect MEI common stock’s market price and liquidity and reduce its ability to raise capital.***

On May 9, 2022, MEI received a letter from the Nasdaq Stock Market, or Nasdaq, indicating that it had failed to comply with the minimum bid price requirement, which requires that companies listed on The Nasdaq Capital Market maintain a minimum closing bid price of at least \$1.00 per share (“Bid Price Requirement”). The notification of noncompliance had no immediate effect on the listing or trading of MEI common stock.

In accordance with Nasdaq rules, MEI had a 180-calendar day grace period, or until November 7, 2022 (the “Compliance Date”), to regain compliance with the Bid Price Requirement. The continued listing standard would have been met if MEI common stock had a minimum closing bid price of at least \$1.00 per share for a minimum of ten consecutive business days during the 180-calendar day grace period. If MEI does not regain compliance with the Bid Price Requirement by the Compliance Date, Nasdaq may grant an additional 180 calendar day compliance period, if MEI meets the continued listing requirement for value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market and provides written notice of its intention to cure the deficiency during the second 180 calendar day compliance period by effecting a reverse stock split, if necessary.

On November 10, 2022, MEI received a letter from Nasdaq that it had been granted an additional 180 calendar day compliance period and that MEI’s compliance period now ends on May 8, 2023. The letter states that Nasdaq will provide written notification that MEI has achieved compliance with its rules if, at any time before May 8, 2023, the bid price of MEI’s Common Stock closes at \$1.00 per share or more for a minimum of ten consecutive business days. The Nasdaq letter had no immediate effect on the listing or trading of MEI’s Common Stock and its common stock continued to trade on the Nasdaq Capital Market.

At the annual meeting of MEI stockholders held on January 5, 2023, MEI’s stockholders approved an amendment to MEI’s Amended and Restated Certificate of Incorporation (the “MEI COI”) to effect a reverse stock split of MEI’s outstanding shares of common stock by a ratio of any whole number between 1-for-10 and 1-for-20, at any time prior to June 30, 2023, with the exact ratio to be set within that range at the discretion of MEI’s board of

## Table of Contents

directors, without further approval or authorization of MEI's stockholders. Following the meeting, MEI's board of directors determined the appropriate ratio for the reverse stock split to be 1-for-20. The amendment became effective at 4:30 p.m. Eastern Time upon filing with the Secretary of State of the State of Delaware on April 14, 2023. MEI's common stock opened for trading on the Nasdaq Capital Market on Monday, April 17, 2023 on a split-adjusted basis under the current trading symbol "MEIP."

There can be no assurance that the reverse stock split will enable MEI to regain compliance with the Bid Price Requirement or otherwise remain in compliance with other Nasdaq listing criteria. If MEI's securities are delisted, it could be more difficult to buy or sell its securities and to obtain accurate quotations, and the price of MEI's securities could suffer a material decline. Delisting could also impair the liquidity of MEI common stock and could harm MEI's ability to raise capital through alternative financing sources on terms acceptable to MEI, or at all, and may result in potential loss of confidence by investors, employees, and fewer business development opportunities.

### ***MEI is currently operating in a period of capital markets disruption and economic uncertainty.***

The U.S. capital markets are currently experiencing extreme volatility and disruption following the global outbreak of COVID-19, high inflation and the government response thereto, potential economic downturn, publicized failures in the regional banking sector, the war in Ukraine, and other global events. Disruptions in the capital markets in the past have resulted in illiquidity in parts of the capital markets. Future market disruptions and/or illiquidity would be expected to have an adverse effect on MEI's business, financial condition, results of operations and cash flows. Unfavorable economic conditions also would be expected to increase MEI's funding costs, limit its access to the capital markets or result in a decision by lenders not to extend credit to MEI. These events have limited and could continue to limit MEI's investment considerations, limit its ability to grow and have a material negative impact on MEI's operating results.

### ***MEI will need substantial additional funds to progress the clinical trial programs for its drug candidates, and to develop new compounds. The actual amount of funds MEI will need will be determined by a number of factors, some of which are beyond MEI's control.***

MEI will need substantial additional funds to progress the clinical trial programs for its drug candidates and to develop any additional compounds. The factors that will determine the actual amount of funds that MEI will need to progress the clinical trial programs may include, but are not limited to, the following:

- the therapeutic indications for use being developed;
- the clinical trial endpoints required to achieve regulatory approval;
- the number of clinical trials required to achieve regulatory approval;
- the number of sites included in the trials;
- the length of time required to enroll suitable patients;
- the number of patients who participate in the trials and the rate that they are recruited;
- the number of treatment cycles patients complete while they are enrolled in the trials;
- costs and potential difficulties encountered in manufacturing sufficient drug product for the trials; and
- the efficacy and safety profile of the product.

MEI has been opportunistic in its efforts to obtain funding, and MEI expects to continue to evaluate various funding alternatives from time to time. If MEI obtains additional funding, it may adversely affect the market price of their common stock and may be dilutive to existing stockholders. If MEI is unable to obtain additional funds on favorable terms or at all, MEI may be required to cease or reduce its operations. MEI may sell additional shares of common stock, and securities exercisable for or convertible into shares of its common stock, or MEI may seek to obtain debt financing, in each case, to satisfy its capital and operating needs; however, such transactions will be subject to market conditions and there can be no assurance any such transactions will be completed.

***MEI may be required to seek additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties at terms which may be unfavorable to MEI.***

If MEI raises additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, MEI may have to relinquish certain valuable rights to its product candidates, technologies, intellectual property, future revenue streams or research programs or grant licenses on terms that may not be favorable to MEI. MEI could also be required to seek collaborators for one or more of its current or future product candidates at an earlier stage than otherwise would be desirable or relinquish MEI's rights to product candidates or technologies that it otherwise would seek to develop or commercialize itself. If MEI is unable to raise additional capital in sufficient amounts or on terms acceptable to MEI, MEI may have to significantly delay, scale back or discontinue the development or commercialization of one or more of its research and development initiatives. Any of the above events could significantly harm MEI's business, prospects, financial condition and results of operations and cause the price of MEI's Common Stock to decline.

***MEI is a clinical research and development stage company and is likely to incur operating losses for the foreseeable future.***

You should consider MEI's prospects in light of the risks and difficulties frequently encountered by clinical research stage and developmental companies. MEI has incurred net losses of \$380.5 million from its inception through December 31, 2022, including a net loss of \$8.0 million for the six months ended December 31, 2022 (excluding \$1.6 million of non-cash gain resulting from a change in fair value of MEI's warrant liability), a net loss of \$75.2 million for the year ended June 30, 2022 (excluding \$20.8 million of non-cash gain resulting from a change in fair value of MEI's warrant liability) and a net loss of \$59.4 million for the year ended June 30, 2021 (excluding \$18.1 million of non-cash gain resulting from a change in fair value of MEI's warrant liability). MEI anticipates that it will incur operating losses and negative operating cash flow for the foreseeable future. MEI has not yet commercialized any drug candidates and cannot be sure that it will ever be able to do so, or that MEI may ever become profitable.

### **Risks Related to MEI Clinical Trials**

***The results of pre-clinical studies and completed clinical trials are not necessarily predictive of future results, and MEI's current drug candidates may not have favorable results in later studies or trials.***

Pre-clinical studies and Phase 1 and Phase 2 clinical trials are an expensive and uncertain process that may take years to complete. Pre-clinical studies and Phase 1 and Phase 2 clinical trials are usually not primarily designed to test the efficacy of a drug candidate, but rather to test safety, to study pharmacokinetics and pharmacodynamics, and to understand the drug candidate's side effects at various doses and schedules. Favorable results in early studies or trials, as well as small studies or trials, may not be repeated in later studies or trials, including ongoing pre-clinical studies, large-scale Phase 3 clinical trials, or other studies intended as registration trials, and MEI's drug candidates in later-stage trials may fail to show desired safety and efficacy despite having progressed through earlier-stage trials. Interim and top-line results, as well as any results from post-hoc data analyses, may also not be predictive of the final results of a clinical study and/or may not support product approval. The FDA also generally does not accept post-hoc data analyses as support for regulatory approval.

Comparisons of results across different studies should be viewed with caution as such comparisons are limited by a number of factors, including differences in study designs and populations. Such comparisons also will not provide a sufficient basis for any comparative claims following product approval. Unfavorable results from ongoing pre-clinical studies or clinical trials could result in delays, modifications or abandonment of ongoing or future clinical trials, or abandonment of a clinical program. Pre-clinical and clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals or commercialization. Negative or inconclusive results or adverse medical events during a clinical trial could cause a clinical trial to be delayed, repeated or terminated, or a clinical program to be abandoned.

## [Table of Contents](#)

### ***The outbreak of the novel coronavirus disease, COVID-19, or other pandemic, epidemic or outbreak of an infectious disease may materially and adversely impact MEI's business, including its preclinical studies and clinical trials.***

In December 2019, the novel coronavirus disease, COVID-19, was identified in Wuhan, China. This virus has been declared a pandemic and has spread to multiple global regions. The outbreak and government measures taken in response have also had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. In response to the COVID-19 pandemic, "shelter in place" orders and other public health guidance measures were implemented across much of the U.S., Europe and Asia, including in the locations of MEI's offices, clinical trial sites, key vendors and partners. Although some of such orders have been lifted in certain geographic locations, such measures may be, and, in some cases, have been re-implemented due an increase in the number of positive cases of COVID-19 or severity thereof, including cases attributable to new variants. These restrictions, as well as government restrictions on travel and a lack of public confidence in the safety of air travel and the use of public transportation have reduced and may continue to reduce the willingness of patients to participate in MEI's clinical trials and the ability of regulatory officials and clinical monitors to perform visits of MEI's clinical trial locations. As a result, MEI's clinical development program timelines have been and may continue to be negatively affected by COVID-19, which could materially and adversely affect MEI's business, financial condition and results of operations. Despite the vaccination of a large portion of the U.S. adult population, a significant portion of the global adult population remains unvaccinated. The ineffectiveness of vaccines or public perception thereof, including in combating new variants of the virus, could lead to increased governmental restrictions and changes in public behavior adversely affecting the economy.

As a result of the ongoing COVID-19 pandemic, or similar pandemics, and related "shelter in place" orders and other public health guidance measures, MEI has experienced disruptions that have materially and adversely impacted its clinical trials, including delays in patient enrollment. MEI may in the future experience disruptions that could materially and adversely impact its clinical trials, business, financial condition and results of operations, including:

- additional delays or difficulties in enrolling patients in MEI clinical trials, including the potential need to suspend or delay enrollment;
- delays or difficulties in initiating or expanding clinical trials, including delays or difficulties with clinical site initiation and recruiting clinical site investigators and clinical site staff;
- increased rates of patients withdrawing from MEI's clinical trials following enrollment as a result of contracting COVID-19 or other health conditions, due to social distancing measures or state law requirements, or being forced to quarantine;
- diversion of healthcare resources away from the conduct of clinical trials or the closure of clinical trial sites, including the diversion of hospitals serving as MEI's clinical trial sites and hospital staff supporting the conduct of MEI's clinical trials;
- the need to modify, suspend, postpone, or terminate clinical trials;
- the need to implement alternative study procedures, including alternative methods for drug candidate delivery and administration, alternative study sites, remote study procedures, and alternative methods to obtain subject informed consent;
- potential noncompliance or deviations from the protocol or regulatory requirements due to necessary safety or public health measures;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures, which may impact the integrity of subject data and clinical study endpoints;



## Table of Contents

- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines and may limit MEI's ability to interact with agency representatives or obtain inspections or assessments that are necessary for approval;
- delays or disruptions in preclinical experiments and investigational new drug application-enabling studies due to restrictions of on-site staff and unforeseen circumstances at contract research organizations and vendors;
- interruption of, or delays in receiving, supplies of MEI's product candidates from its contract manufacturing organizations and other clinical or pre-clinical study materials due to staffing shortages, production slowdowns or stoppages, disruptions in delivery systems, material shortages, and order prioritization of other companies' products, such as under the Defense Production Act;
- changes or deviations from manufacturing requirements, that may adversely affect MEI's product candidates or that may require FDA pre-approval or notification;
- limitations on MEI's ability to recruit and hire key personnel due to the inability to meet with candidates because of travel restrictions and "shelter in place" orders;
- limitations on employee resources that would otherwise be focused on the conduct of MEI's preclinical studies and clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people; and
- interruption or delays to MEI's sourced discovery and clinical activities.

The foregoing may require that MEI consult with relevant review and ethics committees, Institutional Review Boards ("IRBs"), and the FDA. The foregoing may also impact the integrity of MEI's study data. The effects of the ongoing COVID-19 pandemic may also increase the need for clinical trial patient monitoring and regulatory reporting of adverse effects.

The ongoing COVID-19 pandemic and the governmental response continues to rapidly evolve. In light of the ongoing COVID-19 pandemic, the FDA has issued a number of guidance documents, including guidance related to the potential effect of the ongoing COVID-19 pandemic on many clinical trial programs. The FDA also issued guidance on additional steps that are required to maintain GMPs during the pandemic, in addition to a number of other COVID-19 related guidance.

The extent to which the outbreak impacts MEI's business, preclinical studies and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence. If MEI or any of the third parties with whom MEI engages were to experience shutdowns or other business disruptions, MEI's ability to conduct its business in the manner and on the timelines presently planned could be materially and negatively impacted.

### ***Changes in drug candidate manufacturing or formulation may result in additional costs or delay.***

As drug candidates are developed through preclinical studies to late-stage clinical trials toward approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, manufacturing sites, formulation, and methods of delivery are altered along the way in an effort to optimize processes and results. Any of these changes could cause MEI drug candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. Such changes may also require additional studies to demonstrate the comparability of the product candidate using prior processes, formulation, or manufacturers, FDA notification, or FDA approval. Any of the foregoing could limit MEI's future revenues and growth.

## Risks Related to MEI's Licensing and Collaboration Agreements

*If third parties with whom MEI collaborates on the development and commercialization of MEI's drug candidates do not satisfy their obligations, do not otherwise pursue development or commercialization of MEI's drug candidates or if they terminate their agreements with MEI, MEI may not be able to develop or commercialize its drug candidates.*

MEI has in the past and may in the future enter into agreements to collaborate with third parties on the development, manufacturing or commercialization of its drug candidates in the future. In connection with these agreements, MEI may grant certain rights regarding the use of its patents and technology. The counterparties may be responsible for development, manufacturing or commercialization of MEI's drug candidates and the costs related thereto.

MEI's counterparties might not fulfill all of their obligations to MEI. In addition, the agreements with MEI's counterparties provide the counterparties with substantial control of the development and commercialization of MEI's drug candidates and discretion whether to devote resources to the full pursuit thereof or otherwise fail to fully pursue the development and commercialization of MEI's drug candidates. Even without breaching their obligations to MEI, MEI's counterparties may not devote adequate resources or otherwise pursue the development and commercialization of MEI's drug candidates, whether as a result of their assessment of the likelihood of success of such efforts, for financial reasons or otherwise. MEI's ability to receive revenue from its drug candidates may be dependent upon their efforts. If they fail to devote adequate resources or otherwise do not successfully develop, commercialize or manufacture MEI's drug candidates, MEI may not receive the future milestone payments or royalties provided for in the agreement. In addition, under certain circumstances, including MEI's failure to satisfy its obligations under the agreement, the counterparty may have the right to terminate the agreement.

MEI could also become involved in disputes with its counterparties, which could lead to delays in or termination of the agreement and time-consuming and expensive litigation or arbitration.

If MEI's counterparties are unwilling or unable to fulfill their obligations or otherwise fail to fully pursue the development and commercialization of MEI's drug candidates or if the agreement is terminated, MEI may lack sufficient resources to develop and commercialize its drug candidates on its own and may be unable to reach agreement with a suitable alternative collaborator. The failure to develop and commercialize MEI drug candidates would have a material adverse effect on MEI's business, operating results, prospects and financial condition.

*MEI is subject to significant obligations to Presage in connection with MEI's license of voruciclib, and MEI may become subject to significant obligations in connection with future licenses it obtains, which could adversely affect the overall profitability of any products MEI may seek to commercialize, and such licenses of drug candidates, the development and commercialization for which MEI is solely responsible, may never become profitable.*

In September 2017, MEI entered into a license agreement with Presage ("the Presage License Agreement"). Under the terms of the agreement, Presage granted MEI exclusive worldwide rights to develop, manufacture and commercialize voruciclib, a clinical-stage, oral and selective CDK inhibitor, and related compounds. In exchange, MEI paid Presage \$2.9 million and are obligated for additional potential payments of up to \$181 million upon the achievement of certain development, regulatory and commercial milestones. MEI will also pay mid-single-digit tiered royalties on the net sales of any product successfully developed pursuant to such agreement. MEI may enter into similar agreements in the future that require it to make significant payments upon obtainment of development, regulatory or commercial milestones. MEI may be obligated to make milestone or royalty payments when it does not have the cash on hand to make these payments or have available cash for MEI's other development efforts. These milestone and royalty payments could adversely affect the overall profitability for MEI of any products that it may seek to commercialize. In addition, if MEI fails to comply with its obligations under the license agreement, the counterparty may have the right to terminate the agreement. In

## [Table of Contents](#)

such a case, MEI would lose its rights to the intellectual property covered by the license agreement and MEI would not be able to develop, manufacture or commercialize its drug candidates.

The profitability of MEI's license agreement with Presage depends on the successful development, regulatory approval and commercialization of voruciclib. MEI is solely responsible for the development and commercialization of voruciclib, including the related costs. Drug development is a long, expensive and uncertain process and delay or failure can occur at any stage of MEI's clinical trials. MEI cannot be certain that it will ever receive regulatory approval for voruciclib or that it will be successfully commercialized, even if approved.

***MEI's business strategy may include entry into additional collaborative or license agreements. MEI may not be able to enter into collaborative or license agreements or may not be able to negotiate commercially acceptable terms for these agreements.***

MEI's current business strategy may include the entry into additional collaborative or license agreements for the development and commercialization of its drug and drug candidates. The negotiation and consummation of these types of agreements typically involve simultaneous discussions with multiple potential collaborators or licensees and require significant time and resources. In addition, in attracting the attention of pharmaceutical and biotechnology company collaborators or licensees, MEI competes with numerous other third parties with product opportunities as well as the collaborators' or licensees' own internal product opportunities. MEI may not be able to consummate collaborative or license agreements, or MEI may not be able to negotiate commercially acceptable terms for these agreements.

If MEI does enter into such arrangements, it could be dependent upon the subsequent success of these other parties in performing their respective responsibilities and the cooperation of MEI's partners. MEI's collaborators may not cooperate with MEI or perform their obligations under MEI's agreements with them. MEI cannot control the amount and timing of its collaborators' resources that will be devoted to researching MEI product candidates pursuant to MEI's collaborative agreements with them or whether MEI's collaborators will comply with the applicable regulatory requirements. MEI's collaborators may choose to pursue existing or alternative technologies in preference to those being developed in collaboration with MEI.

Under agreements with any collaborators or licensees MEI may work with in the future, MEI may rely significantly on them to, among other activities:

- fund research and development activities with MEI;
- pay MEI fees upon the achievement of milestones; and
- market for or with MEI any commercial products that result from the collaborations.

If MEI does not consummate collaborative or license agreements, MEI may use its financial resources more rapidly on its drug development efforts, continue to defer certain development activities or forego the exploitation of certain geographic territories, any of which could have a material adverse effect on MEI's business prospects. Further, MEI may not be successful in overseeing any such collaborative arrangements. If MEI fails to establish and maintain necessary collaborative or license relationships, MEI's business prospects could suffer.

Collaboration agreements may not lead to development or commercialization of drug candidates in the most efficient manner, or at all. If any collaborations MEI might enter into do not result in the successful development and commercialization of drug candidates or if one of MEI's collaborators subsequently terminates its agreement with MEI, MEI may not receive any future research funding or milestone or royalty payments under the collaboration. If MEI does not receive the funding it expects under the agreements, MEI's development of its drug candidates could be delayed, and MEI may need additional resources to develop its drug candidates and its product platform. All of the risks relating to product development, regulatory approval and commercialization described in MEI's Annual Report also apply to the activities of MEI's collaborators. Moreover, should MEI's collaborators not comply with the applicable regulatory or legal requirements, MEI and/or they, may be subject to regulatory enforcement action.

## **Risks Related to FDA and Non-U.S. Regulation**

*Final approval by regulatory authorities of MEI's drug candidates for commercial use may be delayed, limited or prevented, any of which would adversely affect MEI's ability to generate operating revenues.*

MEI will not generate any operating revenue until MEI, a licensee, or a potential collaborator successfully commercialize one of MEI's drug candidates. Currently, MEI has drug candidates at different stages of development, and each will need to successfully complete certain clinical studies and obtain regulatory approval before potential commercialization. MEI may experience unforeseen events during product development that may substantially delay or prevent product approval. For example, the FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements or if the trial poses an unexpected serious harm to clinical trial patients. The FDA or an IRB may also impose conditions on the conduct of a clinical trial. Clinical trial sponsors may also choose to discontinue clinical trials as a result of risks to clinical trial patients, a lack of favorable results, or changing business priorities.

The pre-clinical and clinical development, manufacturing, labeling, packaging, storage, recordkeeping, export, marketing and distribution, and other possible activities relating to MEI's drug candidates are subject to extensive regulation by the FDA and other regulatory agencies. Failure to comply with applicable regulatory requirements may, either before or after product approval, subject MEI to administrative or judicially imposed sanctions that may negatively impact the approval of one or more of MEI's drug candidates or otherwise negatively impact MEI's business.

Neither collaborators, licensees nor MEI are permitted to market a drug candidate in the U.S. until the particular drug candidate is approved for marketing by the FDA. Specific pre-clinical data, chemistry, manufacturing and controls data, a proposed clinical trial protocol and other information must be submitted to the FDA as part of an IND application, and clinical trials may commence only after the IND application becomes effective. To market a new drug in the U.S., MEI must submit to the FDA and obtain FDA approval of an NDA. An NDA must be supported by extensive clinical and pre-clinical data, as well as extensive information regarding chemistry, manufacturing and controls to demonstrate the safety and effectiveness of the drug candidate.

Obtaining approval of an NDA can be a lengthy, expensive and uncertain process. Regulatory approval of an NDA is not guaranteed. The number and types of pre-clinical studies and clinical trials that will be required for FDA approval varies depending on the drug candidate, the disease or condition that the drug candidate is designed to target and the regulations applicable to any particular drug candidate. The FDA may also require additional studies or data after a trial has begun or more studies or data than MEI otherwise has anticipated. Despite the time and expense exerted in pre-clinical and clinical studies, failure can occur at any stage, and MEI could encounter problems that delay its product candidate development, trigger additional requirements from the FDA, or that cause MEI to abandon clinical trials or to repeat or perform additional pre-clinical studies and clinical trials. The FDA can delay, limit or deny approval of a drug candidate for many reasons, and product candidate development programs may be delayed or may not be successful for many reasons including but not limited to, the following:

- the FDA or IRBs may not authorize MEI to commence, amend, or continue clinical studies;
- MEI may be required to amend its clinical studies in such a way that it compromises the study data or makes the ongoing conduct of the study impracticable;
- there may be deviations from the clinical study protocol that may result in the need to drop patients from the study, increase the study enrollment size or duration, or that may compromise the reliability of the study and the resulting data;

## [Table of Contents](#)

- MEI may not be able to enroll a sufficient number of qualified patients for clinical trials in a timely manner or at all, patients may drop out of MEI's clinical trials or be lost to follow-up at a higher rate than MEI anticipates, patients may not follow the clinical trial procedures, or the number of patients required for clinical trials may be larger than MEI anticipates;
- MEI may have delays in adding new investigators or clinical trial sites, or MEI may experience a withdrawal of clinical trial sites;
- the supply or quality of MEI's product candidates or other materials necessary to conduct clinical trials of MEI's product candidates may be insufficient or inadequate, including as a result of global trade policies;
- a drug candidate may not be deemed adequately safe or effective for an intended use;
- the FDA may not find the data from pre-clinical studies and clinical trials sufficient;
- MEI may not be able to demonstrate that a product candidate provides an advantage over current standards of care or current or future competitive therapies in development;
- the FDA or comparable foreign regulatory authorities may disagree with MEI's chosen endpoints;
- results from MEI's non-primary endpoints may contradict the results of MEI's primary endpoints, raising questions regarding product efficacy;
- the FDA or comparable foreign regulatory authorities may not find MEI's dose-finding clinical trials and data from other sources adequate and/or may disagree with MEI's proposed product dosages for administration.
- there may be changes to standard of care that impact the design and conduct of MEI's trial, may result in studies no longer being clinically significant, may require that MEI changes its studies once they have already commenced, or may result in other products being preferred over MEI's product candidates, if they are approved;
- to the extent that MEI is developing drug candidates for use in combination with other products, clinical trials may be more complex, resulting data may be more difficult to interpret, MEI may not be able to demonstrate that clinical trial results are attributable to its drug candidate, or developments with respect to the other product or standard of care may impact MEI's ability to obtain product approval for its drug candidate or to successfully market MEI's drug candidate;
- even if MEI's product candidates perform satisfactorily in clinical studies, regulatory authorities may still have remaining questions or concerns based on outcomes observed with respect to other products and product candidates in the same pharmacologic class;
- the FDA or comparable foreign regulatory authorities may not accept data from studies with clinical trial sites in foreign countries;
- the FDA may require that MEI conducts additional pre-clinical or clinical studies, change its manufacturing process, or gather additional manufacturing information above what MEI currently has planned for;
- the FDA's interpretation and MEI's interpretation of data from pre-clinical studies and clinical trials may differ significantly;
- the FDA may not agree with MEI's intended indications, the design of MEI's clinical or pre-clinical studies, or there may be a flaw in the design that does not become apparent until the studies are well advanced;
- MEI may not be able to establish agreements with contractors or collaborators, including clinical trial sites and CROs, or they or MEI may fail to comply with applicable FDA, protocol, and other regulatory requirements, including those identified in other risk factors;
- the FDA may not approve the manufacturing processes or facilities;

## Table of Contents

- the FDA may change its approval policies or adopt new laws, guidance, or regulations and MEI's development program may not meet newly imposed requirements;
- the cost of clinical trials of MEI's product candidates may be greater than anticipated or MEI may have insufficient funds for a clinical trial or to pay the substantial user fees required by the FDA upon the filing of a marketing application; or
- the FDA may not accept an NDA or other submission due to, among other reasons, the content or formatting of the submission.

MEI's pre-clinical and clinical data, other information and procedures relating to a drug candidate may not be sufficient to support approval by the FDA or any other U.S. or foreign regulatory authority, or regulatory interpretation of these data and procedures may be unfavorable. MEI may not be successful in any effort to take advantage of expedited regulatory pathways for serious or life-threatening illnesses or to secure marketing authorization from the FDA. MEI may not be able to demonstrate that its product candidates provide a benefit over existing therapies and, when used in combination with other therapies, MEI may not be able to demonstrate that its product candidates contributed to any observed effect. MEI cannot be certain that any NDA it submits will be approved by the FDA for full or accelerated approval on a timely basis, if at all. Securing accelerated approval requires demonstrating a meaningful therapeutic benefit over available existing treatments. Accelerated approvals are based upon a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. If approved, the FDA will require post-marketing studies to verify clinical benefit. Failure to conduct required post-approval studies, or confirm a clinical benefit, will allow the FDA to withdraw the drug from the market on an expedited basis. Indeed, companies have previously withdrawn approved indications following failure to confirm a clinical benefit for their products. Moreover, in recent years, the accelerated approval pathway has come under significant FDA and public scrutiny. Accordingly, the FDA may be more conservative in granting accelerated approval or, if granted, may be more apt to withdrawal approval if clinical benefit is not confirmed. There may also be legislative or regulatory changes to the accelerated approval pathway which may impact the ability to obtain or maintain any such approvals, if received.

Should MEI decide to seek accelerated approval, the FDA may not agree that the accelerated approval pathway is appropriate, may disagree with MEI's chosen surrogate endpoints, or may find that the accelerated approval criteria are not met. Should the FDA disagree with MEI's approach, MEI would be required to conduct additional clinical studies prior to submitting an NDA and prior to the FDA granting marketing approval. Moreover, should MEI receive accelerated approval for a product candidate, the FDA-approved label will indicate that the clinical benefit of the product has not been established and that continued approval is contingent upon verification of a clinical benefit in confirmatory trials.

MEI's business and reputation may be harmed by any failure or significant delay in receiving regulatory approval for the sale of any drugs resulting from its drug candidates. As a result, MEI cannot predict when or whether regulatory approval will be obtained for any drug MEI develops. Additionally, other factors may serve to delay, limit or prevent the final approval by regulatory authorities of MEI drug candidates for commercial use, including, but not limited to:

- voruciclib and ME-344 are in various stages of development, and MEI or its licensees will need to conduct significant clinical testing and development work to demonstrate the quality, safety, and efficacy of these drug candidates before applications for marketing can be filed with the FDA, or with the regulatory authorities of other countries;
- development and testing of product formulation, including identification of suitable excipients, or chemical additives intended to facilitate delivery of MEI's drug candidates;
- it may take MEI many years to complete the testing of its drug candidates, and failure can occur at any stage of this process; and

## Table of Contents

- negative or inconclusive results, statistically or clinically insignificant results, or adverse medical events during a clinical trial could cause MEI to delay or terminate its development efforts.

Significant delays relating to any preclinical or clinical trials also could shorten any periods during which MEI may have the exclusive right to commercialize its product candidates or allow its competitors to bring products to market before MEI does. This may prevent MEI from receiving marketing approvals and impair MEI's ability to successfully commercialize its product candidates and may harm its business and results of operations. If MEI experiences delays in obtaining approval, if MEI fails to obtain approval of a product candidate or if the label for a product candidate does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate, the commercial prospects for such product candidate may be harmed and MEI's ability to generate revenues from that product candidate will be materially impaired. Accordingly, the successful development of any of MEI's drug candidates is uncertain and, accordingly, MEI may never commercialize any of these drug candidates or generate significant revenue.

### ***The FDA may determine that MEI drug candidates have undesirable side effects that could delay or prevent regulatory approval or commercialization.***

Undesirable side effects caused by MEI drug candidates could cause MEI, IRBs, and other reviewing entities or regulatory authorities to interrupt, delay, or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. Undesirable side effects may also result in requirements for costly post-marketing testing and surveillance, or other requirements, including REMS, to monitor the safety or efficacy of the products. These could prevent MEI from commercializing and generating revenues from the sale of its drug candidates.

Many compounds that initially showed promise in clinical or earlier stage testing have later been found to cause side effects that prevented further development of the compound. In addition, adverse events which had initially been considered unrelated to the study treatment may later be found to be caused by the study treatment. Moreover, incorrect or improper use of MEI's drug candidates could cause unexpected side effects or adverse events. If any of MEI's drug candidates are associated with serious adverse events or undesirable side effects or have properties that are unexpected, MEI may need to abandon development or limit development of that drug candidate to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. The therapeutic-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may significantly harm MEI's business, financial condition, results of operations, and prospects.

### ***If MEI experiences delays or difficulties in the enrollment of patients in clinical trials, MEI's completion of clinical trials and receipt of necessary regulatory approvals could be delayed or prevented.***

MEI may not be able to initiate or continue conducting clinical trials for its drug candidates if MEI is unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the U.S. Competitors of MEI may also have ongoing clinical trials for drug candidates that are intended to treat the same indications as MEI's drug candidates, and patients who would otherwise be eligible for MEI clinical trials may instead enroll in clinical trials of MEI's competitors' drug candidates. Patient enrollment is affected by other factors including:

- the size and nature of the patient population;
- the severity of the disease under investigation;
- the existence of current treatments for the indications for which MEI is conducting clinical trials;
- the eligibility criteria for and design of the clinical trial in question, including factors such as frequency of required assessments, length of the study and ongoing monitoring requirements;
- the perceived risks and benefits of the drug candidate, including the potential advantages or disadvantages of the drug candidate being studied in relation to other available therapies;



## Table of Contents

- competition in recruiting and enrolling patients in clinical trials;
- efforts to facilitate timely enrolment in clinical trials;
- patient referral practices of physicians;
- effectiveness of publicity created by clinical trial sites regarding the trial;
- patients' ability to comply with the specific instructions related to the trial protocol, proper documentation, and use of the drug candidate;
- an inability to obtain or maintain patient informed consents;
- the risk that enrolled patients will drop out before completion or not return for post-treatment follow-up;
- the ability to monitor patients adequately during and after treatment;
- the ability to compensate patients for their time and effort; and
- the proximity and availability of clinical trial sites for prospective patients.

MEI's inability to enroll a sufficient number of patients for its clinical trials would result in significant delays and could require MEI to abandon one or more clinical trials altogether. In particular, there may be low or slow enrollment, and the studies may enroll subjects that do not meet the inclusion criteria, requiring the erroneously enrolled subjects to be excluded and the trial population to be increased. Moreover, patients in MEI's clinical trials may be at risk for dropping out of MEI studies if they are not experiencing relief of their disease. A significant number of withdrawn patients would compromise the quality of MEI's data.

Enrollment delays in MEI's clinical trials may result in increased development costs for MEI's drug candidates, or the inability to complete development of MEI's drug candidates, which would cause the value of MEI to decline, limit MEI's ability to obtain additional financing, and materially impair MEI's ability to generate revenues.

### ***Changes in funding for the FDA and other government agencies or future government shutdowns could cause delays in the submission and regulatory review of marketing applications, which could negatively impact MEI's business or prospects.***

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept submission, applications, and the payment of user fees, and statutory, regulatory, and policy changes, including the Congressional reauthorization of the FDA's user fee bills. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies, including as a result of pandemics like COVID-19 and legislative actions, may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect MEI's business. For example, Congress is currently negotiating reauthorization of the FDA user fee bills, which are critical to the FDA's operations. Moreover, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown occurs, if the FDA is required to furlough review staff or other necessary employees, or if agency operations are otherwise impacted, it could significantly affect the ability of the FDA to timely review and process MEI's regulatory submissions, which could have a material adverse effect on MEI's business or prospects.

### ***Failure to obtain regulatory approval in foreign jurisdictions would prevent MEI from marketing its products internationally.***

MEI may attempt to have its drug candidates marketed outside the U.S. In order to market MEI products in many non-U.S. jurisdictions, MEI must obtain separate international regulatory approvals and comply with numerous



and varying regulatory requirements. To date, MEI has not filed for marketing approval for any of its drug candidates and may not receive the approvals necessary to commercialize its drug candidates in any market.

The approval procedure varies among countries and may include all of the risks associated with obtaining FDA approval. Further, the time required to obtain foreign regulatory approval may differ from that required to obtain FDA approval, and additional pre-clinical studies, clinical trials, other testing and data review may be required. MEI may not obtain foreign regulatory approvals on a timely basis, if at all. Additionally, approval by the FDA does not ensure approval by regulatory agencies in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory agencies in other foreign countries or by the FDA. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in other jurisdictions, including approval by the FDA. The failure to obtain regulatory approval in foreign jurisdictions could limit commercialization of MEI's products, reduce MEI's ability to generate profits and harm its business.

***Any designation granted by the FDA for any of MEI's product candidates may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that MEI's product candidates will receive marketing approval. MEI may also not be able to obtain or maintain any such designation.***

There are a number of FDA programs that are intended to speed the development of drugs that are intended to treat serious diseases and conditions when there is an unmet need, including Fast Track and Break Through Therapy Designation. Receipt of such designations is within the discretion of the FDA. Accordingly, even if MEI believes one of its drug candidates meets the criteria for a designation, the FDA may disagree. If MEI receives any designation, the potential reduced timelines associated with designation may introduce significant chemistry, manufacturing and controls challenges for product development as manufacturing development may need to take place at a faster pace than would otherwise be required because the FDA will expect that properly qualified and manufactured product be available at the time of product approval. In any event, the receipt of a designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even after granting a designation, the FDA may later decide that such product candidates no longer meet the conditions for qualification and rescind such designations.

***Any orphan drug designations MEI receives may not confer marketing exclusivity or other benefits.***

In the U.S., under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition. Such diseases and conditions are those that affect fewer than 200,000 individuals in the U.S., or if they affect more than 200,000 individuals in the U.S., there is no reasonable expectation that the cost of developing and making a drug available in the U.S. for these types of diseases or conditions will be recovered from sales of the drug. Orphan drug designation must be requested before submitting an NDA. If the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by that agency. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process, but it can lead to financial incentives, such as opportunities for grant funding toward clinical trial costs, tax advantages and user-fee waivers. The EMA and the UK also have programs for orphan drugs.

There is no guarantee that a drug candidate will receive orphan drug designation. There is also no guarantee that MEI would be able to maintain any designations that it receives. For instance, orphan drug designation in the U.S., EU or UK may be revoked for a number of reasons. If a drug that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the drug is entitled to orphan drug marketing exclusivity for a period of seven years. Orphan drug marketing exclusivity generally prevents the FDA from approving another application, including a full NDA, to market the same drug or biological product for the same orphan use for seven years, except in limited circumstances, including if the FDA concludes that the later drug is safer, more effective or makes a major contribution to patient care. For purposes

of small molecule drugs, the FDA defines “same drug” as a drug that contains the same active moiety and is intended for the same use as the drug in question. MEI may not be able to obtain future orphan drug designations that it may apply for or maintain any orphan drug designations that MEI may receive. A designated orphan drug also may not receive orphan drug marketing exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation or if it is deemed to be the same drug as a previously approved drug and cannot demonstrate clinical superiority. Similarly, in the EMA (and the MHRA), orphan drugs can receive an exclusivity period of ten years, but can be reduced to six years if the drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

Orphan drug exclusivity may be lost if the FDA, EMA or MHRA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. Orphan drug exclusivity also may not protect a product from competition. For instance, the FDA may approve a drug that is the same drug with orphan exclusivity for a different indication or a different drug for the same indication as the orphan product. Even after an orphan product is approved, the FDA can also subsequently approve a product containing the same principal molecular features for the same condition if the FDA concludes that the latter product is clinically superior. The FDA may further grant orphan designation to multiple sponsors for the same compound or active molecule and for the same indication. If another sponsor receives FDA approval for such product before MEI does, MEI would be prevented from launching its product in the U.S. for the orphan indication for a period of at least seven years unless MEI can demonstrate clinical superiority.

### **Risks Related to the Commercialization of MEI Drug Candidates**

***Even if MEI or MEI’s licensees receive regulatory approval to commercialize its drug candidates, MEI’s ability to generate revenues from any resulting products will be subject to a variety of risks, many of which are out of MEI’s control.***

Even if MEI’s drug candidates obtain regulatory approval, resulting products may not gain market acceptance among physicians, patients, healthcare payers or the medical community. MEI believes that the degree of market acceptance and MEI’s ability to generate revenues from such products will depend on a number of factors, including, but not limited to, the following:

- timing of market introduction of MEI’s drugs and competitive drugs;
- actual and perceived efficacy and safety of MEI’s drug candidates;
- prevalence and severity of any side effects;
- potential or perceived advantages or disadvantages over alternative treatments;
- potential post-marketing commitments imposed by regulatory authorities, such as patient registries;
- strength of sales, marketing and distribution support;
- price of MEI’s future products, both in absolute terms and relative to alternative treatments;
- the effect of current and future healthcare laws on MEI’s drug candidates; and
- availability of coverage and reimbursement from government and other third party payers.

If any of MEI’s drugs are approved and fail to achieve market acceptance, MEI may not be able to generate significant revenue to achieve or sustain profitability.

***If any products MEI develops become subject to unfavorable pricing regulations, third party reimbursement practices or healthcare reform initiatives, MEI's ability to successfully commercialize its products will be impaired.***

MEI's future revenues, profitability and access to capital will be affected by the continuing efforts of governmental and private third party payers to manage, contain or reduce the costs of health care through various means, such as capping prices, limiting price increases, reducing reimbursement, and requiring rebates. MEI is also unsure of the impact of any future health care reform legislation or other changes in healthcare policy may have on MEI's business or what actions federal, state, foreign and private payers may take or reforms that may be implemented in the future. Therefore, it is difficult to predict the effect of any potential reform on MEI's business. MEI's ability to commercialize its drug candidates successfully will depend, in part, on the extent to which reimbursement for the cost of such drug candidates and related treatments will be available from government health administration authorities, such as Medicare and Medicaid in the U.S., private health insurers and other organizations. Significant uncertainty exists as to the reimbursement status of newly approved health care products, particularly for indications for which there is no current effective treatment or for which medical care typically is not sought. Adequate third party coverage may not be available to enable MEI to maintain price levels sufficient to realize an appropriate return on its investment in research and development. If adequate coverage and reimbursement levels are not provided by government and third party payers for use of MEI products, MEI's products may fail to achieve market acceptance without a substantial reduction in price or at all and MEI's results of operations will be harmed. In addition, government regulation may restrict MEI's business and financial relationships with health care providers and managed care intermediaries in ways that could impact MEI's ability to successfully market its products.

Further, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which have resulted in several recent Congressional inquiries and proposed and enacted bills by Congress and the states designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. Most recently, in August 2022, President Biden signed into the law the Inflation Reduction Act of 2022 (the "IRA") which among other things, contains multiple provisions that may impact the prices of drug products that are both sold into the Medicare program and throughout the United States.

In addition, the U.S. government, state legislatures, and foreign governments have shown significant interest in implementing cost containment programs, including price-controls, restrictions on reimbursement, requirements for substitution of generic products for branded prescription drugs, and permitting importation of drugs from outside the U.S. to limit the growth of government paid health care costs. For example, the U.S. government has passed legislation requiring pharmaceutical manufacturers that participate in federal healthcare programs to provide rebates and discounts to certain entities and governmental payors. Further, Congress and the current administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. Individual states in the U.S. have also been increasingly passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

***MEI's drug candidates are subject to ongoing government regulation both before and after regulatory approval.***

Both before and after regulatory approval, MEI's drug candidates are subject to strict and ongoing regulation. Compliance with such regulations may consume substantial financial and management resources and expose MEI and its collaborators to the potential for other adverse circumstances. For example, a regulatory authority can place restrictions on the sale or marketing of a drug in order to manage the risks identified during initial clinical trials or after the drug is on the market. A regulatory authority can condition the approval for a drug on costly post-marketing follow-up studies. Based on these studies, if a regulatory authority does not believe that the drug demonstrates a clinical benefit to patients or an acceptable safety profile, it could limit the indications for which a drug may be sold or revoke the drug's marketing approval. In addition, identification of certain side

## Table of Contents

effects either during clinical trials or after a drug is on the market may result in reformulation of a drug, additional pre-clinical and clinical trials, labeling changes, termination of ongoing clinical trials or withdrawal of approval. Any of these events could delay or prevent MEI from generating revenue from the commercialization of these drugs and cause MEI to incur significant additional costs.

Compliance with the applicable regulatory requirements may result in significant expenses and MEI and its third party contractors and collaborators may be subject to unannounced FDA and other regulatory authority inspections and assessments. Any failure to comply with the applicable regulatory requirements or problems with MEI's drug candidates may result in regulatory enforcement or other actions, including:

- restrictions on manufacturing or distribution, or marketing of any approved products;
- restrictions on the labeling, including restrictions on the indication or approved patient population, and required additional warnings, such as black box warnings, contraindications, and precautions;
- modifications to promotional pieces or issuance of corrective information;
- requirements to conduct post-marketing studies or other clinical trials;
- clinical holds or termination of clinical trials;
- requirements to establish or modify a REMS or a comparable foreign authority may require that MEI establish or modify a similar strategy;
- changes to the way the product is administered;
- liability for harm caused to patients or subjects;
- reputational harm;
- the product becoming less competitive;
- warning, untitled, or cyber letters;
- suspension of marketing or withdrawal of the products from the market;
- regulatory authority issuance of safety alerts, Dear Healthcare Provider letters, press releases, or other communications containing warnings or other safety information about the product;
- refusal to approve pending applications or supplements to approved applications that MEI submits;
- recalls of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of MEI's products;
- product seizure or detention;
- FDA debarment, suspension and debarment from government contracts, and refusal of orders under existing government contracts, exclusion from federal healthcare programs, consent decrees, or corporate integrity agreements; or
- injunctions or the imposition of civil or criminal penalties, including imprisonment.

Non-compliance with any foreign jurisdictions' requirements, including requirements regarding the protection of personal information, can also lead to significant penalties and sanctions.

Any of these events could prevent MEI from achieving or maintaining regulatory product approval and market acceptance of the particular drug candidate, if approved, or could substantially increase the costs and expenses of developing and commercializing such product, which in turn could delay or prevent MEI from generating significant revenues from its sale.

## Table of Contents

Other changes may also impact MEI's ability to conduct studies and the approvability or marketability of MEI's drug candidates, including changes in law, government regulation, or FDA policy, including review policies, which may be due to changes in the U.S. government and U.S. administration, or changes in medical practice or standard of care.

If MEI is slow or unable to adapt to changes in existing requirements, standards of care, or the adoption of new requirements or policies, or if MEI is not able to maintain regulatory compliance, MEI may lose any marketing approval that it may have obtained and be subject to regulatory enforcement action. Should any of the above actions take place, they could adversely affect MEI's ability to achieve or sustain profitability.

### ***MEI may not be able to establish the contractual arrangements necessary to develop, market and distribute its drug candidates.***

A key part of MEI's strategy is to establish contractual relationships with third parties to package, market and distribute its drug candidates. There is no assurance that MEI will be able to negotiate commercially acceptable licensing or other agreements for the future exploitation of its drug candidates, including continued clinical development, manufacture or marketing. If MEI is unable to successfully contract for these services, or if arrangements for these services are terminated, MEI may have to delay its commercialization program which will adversely affect its ability to generate operating revenues.

### ***MEI's commercial opportunity will be reduced or eliminated if competitors develop and market products that are more effective, have fewer side effects or are less expensive than MEI's drug candidates.***

The development of drug candidates is highly competitive. A number of other companies have products or drug candidates that have either been approved or are in various stages of pre-clinical or clinical development that are intended for the same therapeutic indications for which MEI's drug candidates are being developed. Some of these potential competing drug candidates are further advanced in development than MEI's drug candidates and may be commercialized sooner. Even if MEI is successful in developing effective drugs, its compounds may not compete successfully with products produced by MEI's competitors.

MEI's competitors include pharmaceutical companies and biotechnology companies, as well as universities and public and private research institutions. In addition, companies active in different but related fields represent substantial competition for MEI. Many of MEI's competitors developing oncology drugs have significantly greater capital resources, larger research and development staffs and facilities and greater experience in drug development, regulation, manufacturing and marketing than MEI does. These organizations also compete with MEI and its service providers, to recruit qualified personnel, and with MEI to attract partners for joint ventures and to license technologies that are competitive with MEI. As a result, MEI's competitors may be able to more easily develop technologies and products that would render MEI's technologies or its drug candidates obsolete or non-competitive.

### ***MEI's product candidates may face competition sooner than anticipated.***

MEI's product candidates, if approved, may face competition from other products that are the same as or similar to MEI's product candidates. If the FDA or comparable foreign regulatory authorities approve generic or similar versions of any of MEI's product candidates that receive marketing approval, or such authorities do not grant MEI's products appropriate periods of regulatory exclusivity before approving generic or similar versions of MEI's products, the sales of MEI's products could be adversely affected.

Once an NDA is approved, the product will become a "reference listed drug" in the FDA's Orange Book. Other applicants may then seek approval of generic versions of MEI's products through submission of Abbreviated New Drug Applications ("ANDA") in the U.S. Generic products may be significantly less costly to bring to market than the reference listed drug and companies that produce generic products are generally able to offer them at lower prices, and are generally preferred by third party payors. As a result, the FDA, the administration

## [Table of Contents](#)

and Congress have recently taken steps to encourage increased generic drug competition in the market in an effort to bring down drug costs. Following the introduction of a generic drug, a significant percentage of the sales of any branded product or reference listed drug is typically lost to the generic product. Moreover, in addition to generic competition, MEI could face competition from other companies seeking approval of drug products that are similar to MEI's using the 505(b)(2) regulatory pathway. Such applicants may be able to rely on MEI's product candidates, if approved, or other approved drug products or published literature to develop drug products that are similar to MEI's. The introduction of a drug product similar to MEI's product candidates could expose MEI to increased competition.

Any ANDA or 505(b)(2) applicants seeking to rely upon any of MEI's product candidates, if such product candidates are approved, would need to submit patent certification statements with their applications for any of MEI's patents that are listed in the FDA's Orange Book. There are detailed rules and requirements regarding the patents that may be submitted to the FDA for listing in the Orange Book. MEI may be unable to obtain patents covering its product candidates that contain one or more claims that satisfy the requirements for listing in the Orange Book. If one of MEI's product candidates is approved and a patent covering that product candidate is not listed in the Orange Book, an ANDA or 505(b)(2) applicant would not have to submit a patent certification with regard to such patent to the FDA, in which case, MEI would not receive the protections provided by the Hatch Waxman Act.

Moreover, if an ANDA or 505(b)(2) applicant files a paragraph IV challenge to any patents that MEI may list in the FDA's Orange Book and if MEI does not file a timely patent infringement lawsuit, the ANDA or 505(b)(2) applicant would not be subject to a 30-month stay. If MEI did file such an action, the litigation or other proceedings to enforce or defend its intellectual property rights would likely be complex in nature, may be expensive and time consuming, may divert MEI's management's attention from its core business, and may result in unfavorable results that could adversely impact MEI's ability to prevent third parties from competing with its products. Accordingly, upon approval of MEI's product candidates MEI may be subject to generic competition or competition from similar products, or may need to commence patent infringement proceedings, which would divert its resources.

MEI currently anticipates that it may be eligible for five years of non-patent marketing exclusivity in the U.S. This exclusivity, however, would not prevent other companies from submitting full NDAs. To the extent MEI does not receive any anticipated periods of regulatory exclusivity or to the extent the FDA or foreign regulatory authorities approve any generic, similar, or other competing products, MEI's business would be adversely impacted. Competition that MEI's products may face from generic, similar, or other competing products could materially and adversely impact its future revenue, profitability, and cash flows and substantially limit MEI's ability to obtain a return on the investments it has made in those product candidates.

### **Risks Related to MEI's Reliance on Third Parties**

***MEI relies on third parties to conduct its clinical trials and pre-clinical studies. If those parties do not successfully carry out their contractual duties or meet expected deadlines, MEI's drug candidates may not advance in a timely manner or at all.***

In the course of MEI's pre-clinical testing and clinical trials, MEI relies on third parties, including laboratories, investigators, CROs, manufacturers, and distributors to perform critical services. For example, MEI relies on third parties to conduct its clinical trials and many of its pre-clinical studies, which are required to be conducted consistent with regulations on GLPs and GCPs. CROs and study sites are responsible for many aspects of the trials, including finding and enrolling subjects for testing and administering the trials. Although MEI relies on these third parties to conduct its pre-clinical and clinical trials, MEI is responsible for ensuring that each of its trials are conducted in accordance with its investigational plan and protocol and that the integrity of the studies and resulting data is protected. While MEI has agreements governing the activities of such third parties, MEI has limited influence and control over their actual performance and activities. Moreover, the FDA and foreign

## Table of Contents

regulatory authorities require MEI to comply with regulations and standards, commonly referred to as GCPs, for conducting, monitoring, recording, and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that the trial subjects are adequately informed of the potential risks of participating in clinical trials. MEI's reliance on third parties does not relieve it of these responsibilities and requirements. These third parties may not be available when MEI needs them or, if they are available, may not devote sufficient time or resources to MEI's studies, may not comply with all regulatory and contractual requirements, or may not otherwise perform their services in a timely or acceptable manner, and MEI may need to enter into new arrangements with alternative third parties and MEI's clinical trials may be extended, delayed or terminated. These independent third parties may also have relationships with other commercial entities, some of which may compete with MEI. In addition, if such third parties fail to perform their obligations in compliance with MEI's protocols or the applicable regulatory requirements, MEI's trials may not meet regulatory requirements or may need to be repeated, MEI may not receive marketing approvals, or MEI or such third parties may face regulatory enforcement.

Agreements with third parties conducting or otherwise assisting with MEI's clinical or preclinical studies might terminate for a variety of reasons, including a failure to perform by the third parties. If any of MEI's relationships with these third parties terminate, MEI may not be able to enter into arrangements with alternative providers or to do so on commercially reasonable terms. Switching or adding additional third parties involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, if MEI needs to enter into alternative arrangements, it could delay MEI's product development activities and adversely affect its business. Though MEI carefully manages its relationships with third parties, there can be no assurance that MEI will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on MEI's business, financial condition and prospects, and results of operations.

Accordingly, as a result of MEI's dependence on third parties, MEI may face delays, failures or cost increases outside of its direct control. These risks also apply to the development activities of collaborators, and MEI does not control their research and development, clinical trial or regulatory activities.

In addition, MEI will be required to report certain financial interests of its third party investigators if these relationships exceed certain financial thresholds or meet other criteria. The FDA or comparable foreign regulatory authorities may question the integrity of the data from those clinical trials conducted by investigators who may have conflicts of interest.

MEI also cannot assure you that upon inspection or review by a given regulatory authority, such regulatory authority will determine that any of MEI's trials complies with the applicable regulatory requirements. In addition, MEI's clinical trials must be conducted with drug candidates that were produced under cGMP conditions. Failure to comply with these regulations may require MEI to repeat clinical trials, which would delay the regulatory approval process. MEI is also required to register certain clinical trials and post the results of certain completed clinical trials on a government-sponsored database, [ClinicalTrials.gov](http://ClinicalTrials.gov), within specified timeframes. Failure to do so can result in enforcement actions and adverse publicity.

***MEI will depend on third party suppliers and contract manufacturers for the manufacturing of its drug candidates and have no direct control over the cost and timing of manufacturing these drug candidates. Increases in the cost of manufacturing MEI's drug candidates or delays in manufacturing would increase its costs of conducting clinical trials and could adversely affect MEI's future profitability.***

MEI does not intend to manufacture its drug candidates themselves, and will rely on third parties for its drug supplies both for clinical trials and for commercial quantities in the future. MEI has taken the strategic decision not to manufacture active pharmaceutical ingredients ("API"), nor finished product, for its drug candidates, as these can be more economically supplied by third parties with particular expertise in this area. MEI has identified contract facilities that are registered with the FDA, have a track record of large- scale API and drug product



## Table of Contents

manufacturing, and have already invested in capital and equipment. MEI has no direct control over the manufacturing of its drug candidates, or the cost thereof. If the contract manufacturers are unable to produce sufficient quantities of MEI's drug candidates, as a result of a lack of available materials or otherwise, MEI's ability to complete product candidate development and MEI's future profitability would be adversely affected. If the cost of manufacturing increases, or if the cost of the materials used increases, these costs will be passed on to MEI, making the cost of conducting clinical trials more expensive. Increases in manufacturing costs could adversely affect MEI's future profitability if MEI is unable to pass all of the increased costs along to its customers.

If these third party suppliers and contract manufacturers do not successfully carry out their contractual duties, meet expected deadlines or manufacture MEI's drug candidates in accordance with regulatory requirements, if there are disagreements between MEI and such parties, or if such parties are unable to expand capacities to support commercialization of any of MEI's drug candidates for which MEI obtains marketing approval, MEI may not be able to produce, or may be delayed in producing sufficient drug candidates to meet its supply requirements. Any delays in obtaining adequate supplies with respect to MEI's drug candidates and components may delay the development or commercialization of its drug candidates.

Further, MEI, along with its contract manufacturers, are required to comply with FDA requirements for cGMPs, related to product testing, quality assurance, manufacturing and documentation. MEI's contract manufacturers may not be able to comply with the applicable FDA regulatory requirements, which could result in delays to MEI's product development programs, could result in adverse regulatory actions against MEI or its contract manufacturers, and could prevent MEI from ultimately receiving product marketing approval. They also generally must pass an FDA preapproval inspection or assessment for conformity with cGMPs before MEI can obtain approval to manufacture its drug candidates and will be subject to ongoing, periodic, unannounced inspection or assessment by the FDA and corresponding state agencies to ensure strict compliance with cGMP, and other applicable government regulations and corresponding foreign standards. If MEI and its contract manufacturers fail to achieve and maintain high manufacturing standards in compliance with cGMP, MEI may experience manufacturing errors resulting in defective products that could be harmful to patients, product recalls or withdrawals, delays or interruptions of production or failures in product testing or delivery, clinical trial or other development program delays, delay or prevention of filing or approval of marketing applications for MEI's products, cost overruns or other problems that could seriously harm MEI's business. Not complying with FDA requirements could result in a product recall, costly and time-consuming corrective or preventative actions, or prevent commercialization of MEI's drug candidates and delay MEI's business development activities. In addition, such failure could be the basis for the FDA to issue a warning or untitled letter or take other regulatory or legal enforcement action, including recall or seizure, total or partial suspension of production, suspension of ongoing clinical trials, refusal to approve pending applications or supplemental applications, and potentially civil and/or criminal penalties depending on the matter.

If MEI needs to replace any of its manufacturers or establish additional manufacturing arrangements, MEI may not succeed in its efforts. MEI's drug candidates may compete with other products and drug candidates for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that are both capable of manufacturing for MEI and willing to do so. If MEI's existing third party manufacturers, or the third parties that MEI engages in the future to manufacture a product or component for commercial sale or for MEI's clinical trials should cease to continue to do so for any reason, MEI would likely experience delays in obtaining sufficient quantities of its drug candidates for MEI to meet commercial demand or to advance its clinical trials while MEI identifies and qualifies replacement suppliers. These third party facilities may also be affected by natural disasters, such as floods or fire, or such facilities could face manufacturing issues, such as contamination or regulatory findings following a regulatory inspection or assessment of such facility. In such instances, MEI may need to locate an appropriate replacement third party relationship, which may not be readily available or on acceptable terms, which would cause additional delay and increased expense. The addition of a new or alternative manufacturer may also require FDA approvals and may have a material adverse effect on MEI's business.



MEI or its third party manufacturers may also encounter shortages in the raw materials, therapeutic substances, or active pharmaceutical ingredients necessary to produce MEI's drug candidates in the quantities needed for its clinical trials or, if MEI's drug candidates are approved, in sufficient quantities for commercialization or to meet an increase in demand. Such shortages may occur for a variety of reasons, including capacity constraints, delays or disruptions in the market, and shortages caused by the purchase of such materials by MEI's competitors or others. MEI or its third party manufacturers' failure to obtain the raw materials, therapeutic substances, or active pharmaceutical ingredients necessary to manufacture sufficient quantities of MEI's drug candidates may have a material adverse effect on MEI's business. If for any reason MEI is unable to obtain adequate supplies of its drug candidates or the components used to manufacture them, it will be more difficult for MEI to develop its drug candidates and compete effectively.

***MEI relies on acquisitions or licenses from third parties to expand its pipeline of drug candidates.***

MEI is not presently engaged in drug discovery activities. In order to expand MEI's pipeline of drug candidates for future development, MEI may need to purchase or in-license any such drug candidates. The success of this strategy depends in large part on the combination of MEI's regulatory and development capabilities and expertise and its ability to identify, select and acquire or in-license clinically-enabled product candidates on terms that are acceptable to MEI. Identifying, selecting and acquiring or in-licensing promising product candidates requires substantial technical expertise, and MEI has limited experience in identifying and integrating any acquired product candidates into its current infrastructure. Efforts to do so may not result in the actual acquisition or in-license of a particular drug candidate, potentially resulting in a diversion of MEI's management's time and the expenditure of its resources with no resulting benefit. If MEI is unable to identify, select and acquire or license suitable product candidates from third parties on terms acceptable to MEI, MEI's business and prospects may be limited.

**Risks Related to MEI's Intellectual Property**

***MEI's commercial success is dependent, in part, on obtaining and maintaining patent protection and preserving trade secrets, which cannot be guaranteed.***

Patent protection and trade secret protection are important to MEI's business and its future will depend, in part on MEI's ability to maintain trade secret protection, obtain patents and operate without infringing the proprietary rights of others both in the U.S. and abroad. Litigation or other legal proceedings may be necessary to defend against claims of infringement, to enforce MEI's patents or to protect its trade secrets. Such litigation could result in substantial costs and diversion of MEI's management's attention.

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions. MEI acquired patents and patent applications related to voruciclib from Presage in 2017, and acquired both issued patents and pending patent applications related to ME-344 from Novogen in relation to its Isoflavone-based compounds, which MEI previously licensed from Novogen, in 2011. Additionally, Novogen had previously applied for patents in a number of countries with respect to the use of their isoflavone compounds, including ME-344. Finally, in September 2013, MEI acquired patents and patent applications related to zandelisib from Pathway Therapeutics, Inc.

The patent applications may not proceed to grant or may be amended to reduce the scope of protection of any patent granted. The applications and patents may also be opposed or challenged by third parties. MEI's commercial success will depend, in part, on its ability to obtain and maintain effective patent protection for its compounds and their use in treating, preventing, or curing cancer, and to successfully defend patent rights in those technologies against third party challenges. As patent applications in the U.S. are maintained in secrecy until published or issued and as publication of discoveries in the scientific or patent literature often lag behind the actual discoveries, MEI cannot be certain that MEI or Presage were the first to make the inventions covered by the pending patent applications or issued patents referred to above or that MEI or Presage were the first to file patent applications for such inventions. Additionally, the breadth of claims allowed in biotechnology and pharmaceutical patents or their enforceability cannot be predicted. MEI cannot be sure that, should any patents

## Table of Contents

issue, MEI will be provided with adequate protection against potentially competitive products. Furthermore, MEI cannot be sure that should patents issue, they will be of commercial value to MEI, or that private parties, including competitors, will not successfully challenge its patents or circumvent MEI's patent position in the U.S. or abroad.

### ***Claims by other companies that MEI infringes on their proprietary technology may result in liability for damages or stop MEI's development and commercialization efforts.***

The pharmaceutical industry is highly competitive, and patents have been applied for by, and issued to, other parties relating to products competitive with the compounds that MEI has acquired. Therefore, voruciclib, ME-344, and zandelisib, and any other drug candidates, may give rise to claims that they infringe the patents or proprietary rights of other parties existing now and in the future.

Furthermore, to the extent that MEI or its consultants or research collaborators use intellectual property owned by others in work performed for MEI, disputes may also arise as to the rights in such intellectual property or in resulting know-how and inventions. An adverse claim could subject MEI to significant liabilities to such other parties and/or require disputed rights to be licensed from such other parties.

MEI has contracted formulation development and manufacturing process development work for its product candidates. This process has identified a number of excipients, or additives to improve drug delivery, which may be used in the formulations. Excipients, among other things, perform the function of a carrier of the active drug ingredient. Some of these identified excipients or carriers may be included in third party patents in some countries. MEI intends to seek a license if it decides to use a patented excipient in the marketed product or MEI may choose one of those excipients that does not have a license requirement.

MEI cannot be sure that any license required under any such patents or proprietary rights would be made available on terms acceptable to MEI, if at all. If MEI does not obtain such licenses, it may encounter delays in product market introductions, or may find that the development, manufacture or sale of products requiring such licenses may be precluded.

### ***MEI may be subject to claims by third parties asserting that MEI or its employees have misappropriated their intellectual property, or claiming ownership of what MEI regards as its own intellectual property.***

Many MEI employees and the employees of Kyowa Kirin and third parties upon which MEI relies to conduct its clinical trials were previously employed at universities or at other biotechnology or pharmaceutical companies, some of which may be competitors or potential competitors. Some of these employees executed proprietary rights, non-disclosure and non-competition agreements, or similar agreements, in connection with such previous employment. Although MEI tries to ensure that its employees do not use the proprietary information or know-how of others in their work for MEI, MEI may be subject to claims that MEI or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such third party. Litigation may be necessary to defend against such claims. If MEI fails in defending any such claims, in addition to paying monetary damages, MEI may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and MEI could be required to obtain a license from such third party to commercialize MEI's technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if MEI is successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while MEI typically requires its employees, consultants, advisors and collaborators who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to MEI, MEI may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that MEI regards as its own, which may result in claims by or against MEI related to the ownership of such intellectual property. If MEI fails in prosecuting or defending any such claims, in addition to paying monetary damages, MEI may lose valuable intellectual property rights. Even if MEI is successful in prosecuting

or defending against such claims, litigation could result in substantial costs and be a distraction to MEI's senior management and scientific personnel.

***MEI may be subject to substantial costs stemming from its defense against third party intellectual property infringement claims.***

Third parties may assert that MEI is using their proprietary information without authorization. Third parties may also have or obtain patents and may claim that technologies licensed to or used by MEI infringe their patents. If MEI is required to defend patent infringement actions brought by third parties, or if MEI sues to protect its own patent rights, MEI may be required to pay substantial litigation costs and managerial attention may be diverted from business operations even if the outcome is not adverse to MEI. In addition, any legal action that seeks damages or an injunction to stop MEI from carrying on its commercial activities relating to the affected technologies could subject MEI to monetary liability and require MEI or any third party licensors to obtain a license to continue to use the affected technologies. MEI cannot predict whether it would prevail in any of these types of actions or that any required license would be made available on commercially acceptable terms or at all.

#### **General Business Risks**

***MEI faces a risk of product liability claims and claims may exceed MEI's insurance limits.***

MEI's business exposes MEI to the risk of product liability claims. This risk is inherent in the manufacturing, testing and marketing of human therapeutic products. Moreover, regardless of merit or eventual outcome, liability claims can have other adverse consequences, including:

- loss of revenue from decreased demand for MEI's products and/or drug candidates;
- impairment of MEI's business reputation or financial stability;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;
- diversion of management attention;
- withdrawal of clinical trial participants and potential termination of clinical trial sites or entire clinical programs;
- the inability to commercialize MEI's drug candidates;
- significant negative media attention;
- decrease in MEI's stock price; or
- initiation of investigations, and enforcement actions by regulators; and product recalls, withdrawals, revocation of approvals, or labeling, marketing or promotional restrictions.

MEI's product liability insurance coverage is subject to deductibles and coverage limitations. MEI may not be able to obtain or maintain adequate protection against potential liabilities, or claims may exceed MEI's insurance limits. If MEI cannot or does not sufficiently insure against potential product liability claims, MEI may be exposed to significant liabilities, which may materially and adversely affect its business development and commercialization efforts.

***MEI employees, independent contractors, consultants, commercial partners, principal investigators, or CROs may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on MEI's business.***

MEI is exposed to the risk of employee fraud or other misconduct. Misconduct by employees, independent contractors, consultants, commercial partners, manufacturers, investigators, or CROs could include intentional, reckless, negligent, or unintentional failures to comply with FDA regulations, comply with applicable fraud and abuse laws, provide accurate information to the FDA, properly calculate pricing information required by federal

## [Table of Contents](#)

programs, comply with federal procurement rules or contract terms, report financial information or data accurately or disclose unauthorized activities to MEI. This misconduct could also involve the improper use or misrepresentation of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to MEI's reputation. It is not always possible to identify and deter this type of misconduct, and the precautions MEI takes to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting MEI from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Moreover, it is possible for a whistleblower to pursue a False Claims Act, ("FCA"), case against MEI even if the government considers the claim unmeritorious and declines to intervene, which could require MEI to incur costs defending against such a claim. Further, due to the risk that a judgment in an FCA case could result in exclusion from federal health programs or debarment from government contracts, whistleblower cases often result in large settlements. If any such actions are instituted against MEI, and MEI is not successful in defending itself or asserting its rights, those actions could have a significant impact on MEI's business, financial condition, and results of operations, including the imposition of significant fines or other sanctions.

### ***MEI's business and operations would suffer in the event of system failures.***

MEI's internal computer systems and those of its CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war, and telecommunication and electrical failures. If such an event were to occur and cause interruptions in MEI's operations, it could result in a material disruption of MEI's drug candidate development and, if such drug candidates are approved commercialization programs. For example, the loss of clinical trial data from completed, ongoing or planned clinical trials could result in delays in MEI's regulatory approval efforts and significantly increase MEI's costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to MEI's data or applications, or inappropriate disclosure of personal, confidential or proprietary information, MEI could incur liability and regulatory enforcement actions, and the further development of any of MEI's drug candidates could be delayed.

### ***MEI's efforts will be seriously jeopardized if MEI is unable to retain and attract key employees.***

MEI's success depends on the continued contributions of its principal management, development and scientific personnel. MEI faces competition for such personnel, and MEI believe that risks and uncertainties related to its business, including the timing and risk associated with research and development, MEI's available and anticipated cash resources, and the volatility of MEI's stock price, may impact its ability to hire and retain key and other personnel. The loss of services of MEI's Chief Executive Officer or other key employees could adversely impact MEI's operations and ability to generate or raise additional capital.

### ***Negative U.S. and global economic conditions may pose challenges to MEI's business strategy, which relies on funding from the financial markets or collaborators.***

Negative conditions in the U.S. or global economy, including financial markets, may adversely affect MEI's business and the business of current and prospective vendors, licensees and collaborators, and others with whom MEI does or may conduct business. The duration and severity of these conditions is uncertain. If negative economic conditions occur, MEI may be unable to secure funding on terms satisfactory to MEI to sustain its operations or to find suitable collaborators to advance MEI's internal programs, even if MEI achieves positive results from its drug development programs.

### ***Laws, rules and regulations relating to public companies may be costly and impact MEI's ability to attract and retain directors and executive officers.***

Laws and regulations affecting public companies, including rules adopted by the SEC and by Nasdaq, may result in increased costs to MEI. These laws, rules and regulations could make it more difficult or costly for MEI to obtain certain types of insurance, including director and officer liability insurance, and MEI may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar

## [Table of Contents](#)

coverage. The impact of these events could also make it more difficult for MEI to attract and retain qualified persons to serve on its board of directors, on its board committees or as executive officers. MEI cannot estimate accurately the amount or timing of additional costs it may incur to respond to these laws, rules and regulations.

***MEI identified a material weakness in its internal control over financial reporting and determined that its disclosure controls and procedures were ineffective as of June 30, 2021. As a result, MEI restated its financial statements as of and for the years ended June 30, 2021 and 2020. Relevant unaudited interim financial information for each of the quarterly periods ended September 30, 2020 through December 31, 2021 were also restated. As of December 31, 2022, MEI is in the process of remediating this material weakness. In the future, MEI may identify additional material weaknesses or otherwise fail to maintain an effective system of internal control over financial reporting or adequate disclosure controls and procedures, which may result in material errors in its financial statements or cause MEI to fail to meet its period reporting obligations.***

Under the supervision and with the participation of MEI's management, including its Chief Executive Officer and Chief Financial Officer, MEI conducted an assessment of the effectiveness of its internal control over financial reporting as of June 30, 2021. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of MEI's annual or interim financial statements will not be prevented or detected on a timely basis. In Management's Report on Internal Control over Financial Reporting included in MEI's original Form 10-K for the year ended June 30, 2021, filed on September 2, 2021, (the "Original Form 10-K") MEI's management previously concluded that it maintained effective internal control over financial reporting as of June 30, 2021. MEI's management subsequently concluded that a material weakness existed and its internal control over financial reporting was not effective as of June 30, 2021.

In May 2022, MEI determined that it had made certain errors in the manner in which MEI recognized revenue from its License, Development and Commercialization Agreement with Kyowa Kirin Co., Ltd (the "Kyowa Kirin Commercialization Agreement") with the result that revenue was overstated in some quarters and understated in other quarters in MEI's financial statements during 2020 and 2021. The errors relate to the appropriate timing and amounts of revenue recognized over time under the cost-to-cost method associated with the Kyowa Kirin Commercialization Agreement.

As a result, MEI determined that there were material errors in the financial statements that required a restatement of the June 30, 2021 and 2020 financial statements included in the Original Form 10-K for the year ended June 30, 2021 and MEI's Forms 10-Q for the quarterly periods ended September 30, 2020 through December 31, 2021. This was due to the inadequate design and implementation of controls to evaluate and monitor the accounting for revenue recognition related to license agreements.

MEI's management is implementing enhanced internal controls to remediate the material weakness. The remediation plan includes enhancement of MEI's contract review of license agreements to confirm appropriate understanding of the terms, as well as implementation of a control designed to evaluate and monitor, at inception and on a quarterly basis, the estimated consideration to be received under license agreements for purposes of revenue recognition, analysis of deferred revenue balances, and enhanced detailed review of MEI's revenue recognition models. As of December 31, 2022, MEI is in the process of remediating this material weakness.

If MEI is not able to comply with the requirements of the Sarbanes-Oxley Act or if MEI is unable to maintain effective internal control over financial reporting, MEI may not be able to produce timely and accurate financial statements or guarantee that information required to be disclosed by MEI in the reports that it files with the SEC, is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms. Any failure of MEI's internal control over financial reporting or disclosure controls and procedures could cause MEI's investors to lose confidence in its publicly reported information, cause the market price of MEI's stock to decline, expose MEI to sanctions or investigations by the SEC or other regulatory authorities, or impact MEI's results of operations.

***Security breaches and privacy issues could compromise MEI's information and expose it to liability, which would cause MEI's business and reputation to suffer.***

In the ordinary course of MEI's business, MEI collects and stores sensitive data, including intellectual property, MEI's proprietary business information and that of its suppliers, as well as personally identifiable information of clinical trial participants and employees. Similarly, MEI's third party providers possess certain of MEI's sensitive protected health data. The secure maintenance of this information is critical to MEI's operations and business strategy. Despite MEI's reasonable security measures, MEI's information technology and infrastructure may be vulnerable to cyberattacks or breached due to employee error, malfeasance or other disruptions. Cyberattacks and other security incidents are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. Although MEI develops and maintains systems and controls designed to prevent these events from occurring, and MEI has a process to identify and mitigate threats, the development and maintenance of these systems, controls and processes is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become more sophisticated, and such systems, controls and processes may not be successful in preventing a breach or other incident. Any such security incident could compromise MEI's networks and the information stored there could be accessed, publicly disclosed, encrypted, lost or stolen. MEI could be required to expend significant amounts of money and other resources to repair or replace information systems or networks. In addition, MEI's liability insurance may not be sufficient in type or amount to cover MEI against claims related to security breaches, cyberattacks and other related security incidents.

The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing amount of focus on privacy and data protection issues with the potential to affect MEI's business, including compliance with the Health Insurance Portability and Accountability Act of 1996 and state laws requiring security breach notification. The collection and use of personal health data of individuals in the European Union is also governed by strict data protection laws. In addition to existing laws, since May 25, 2018, the General Data Protection Regulation ("GDPR") has imposed obligations with respect to European Union data and substantial fines for breaches of the data protection rules. The GDPR increased MEI's responsibility and potential liability in relation to personal data that it processes, and MEI was required to implement additional mechanisms to comply with the GDPR and related European Union data protection rules. Enforcement uncertainty and the costs associated with ensuring GDPR compliance may be onerous and adversely affect MEI's business, operating results, prospects and financial condition.

MEI continues to evaluate the legal issues that arise concerning transfer of personal data of residents of the European Economic Area ("EEA") member states or the U.K. to the U.S. or other jurisdictions that are not deemed adequate by the European Commission. Among other steps, MEI is implementing the new standard contractual clauses issued on June 4, 2021 by the European Commission. It remains uncertain how these standard contractual clauses will be implemented by the data exporters and data importers and whether they will ultimately be deemed sufficient by European courts. MEI Pharma observes the developments and will agree to the appropriate data transfer mechanism. In addition to standard contractual clauses, MEI may rely on individual contents of the patients where appropriate and necessary to safeguard the data flow from the EU to the U.S. Present solutions to legitimize transfers of personal data from the EEA may be challenged or deemed insufficient. MEI may, in addition to other impacts, experience additional costs associated with increased compliance burdens, and MEI and its customers face the potential for regulators in the EEA or U.K. to apply different standards to the transfer of personal data from the EEA/ U.K. to the U.S., and to block, or require ad hoc verification of measures taken with respect to, certain data flows from the EEA or U.K. to the U.S. MEI may also be required to engage in new contract negotiations with third parties that aid in processing data on MEI's behalf. MEI may experience reluctance or refusal by current or prospective European clinical trial sites and CROs to use its products, and MEI may find it necessary or desirable to make further changes to its processing of personal data of EEA or U.K. data subjects.

## [Table of Contents](#)

Additionally, California has the California Consumer Privacy Act (“CCPA”), which creates individual privacy rights for consumers (as that word is broadly defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA may significantly impact MEI’s business activities and require substantial compliance costs that adversely affect business, operating results, prospects and financial condition. Amendments to the CCPA mandated by the California Privacy Rights Act (“CPRA”) will impose additional privacy requirements, effective on January 1, 2023. Similarly comprehensive state consumer privacy laws in other states, such as Virginia, Utah, Connecticut and Colorado will also become effective in 2023. These new state privacy measures may reflect the start of a movement in other state legislatures to enact more comprehensive privacy laws, which would create a more complex privacy regulatory landscape for MEI’s business in the U.S. In addition, there is privacy legislation and rulemaking efforts at the federal level which may increase MEI’s privacy obligations in the U.S.

Thus, any access, disclosure or other loss of information, including MEI’s data being breached at its partners or third party providers, along with violations of privacy laws that exist and are increasing around the world, could result in legal claims or proceedings and liability under laws that protect the privacy of personal information, disrupt MEI’s operations and damage its reputation, which could adversely affect MEI’s business.

***If MEI fails to comply with environmental, health and safety laws and regulations, MEI could become subject to fines or penalties or incur costs that could harm its business.***

MEI is subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. From time to time and in the future, MEI’s operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste. Even if MEI contracts with third parties for the disposal of these materials and waste, MEI cannot completely eliminate the risk of contamination or injury resulting from these materials. In the event of contamination or injury resulting from the use or disposal of MEI’s hazardous materials, MEI could be held liable for any resulting damages, and any liability could exceed MEI’s resources. MEI also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

MEI maintains workers’ compensation insurance to cover it for costs and expenses MEI may incur due to injuries to its employees resulting from the use of hazardous materials, but this insurance may not provide adequate coverage against potential liabilities. However, MEI does not maintain insurance for environmental liability or toxic tort claims that may be asserted against MEI.

In addition, MEI may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations may impair MEI’s research, development or production efforts. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions.

***MEI or the third parties upon whom MEI depends may be adversely affected by natural disasters and MEI’s business continuity and disaster recovery plans may not adequately protect it from a serious disaster.***

Events outside of MEI’s control, including natural disasters and public health emergencies, could severely disrupt its operations and have a material adverse effect on MEI’s business, operating results, prospects or financial condition. If a natural disaster, or public health emergency such as COVID-19, power outage or other event occurred that prevented MEI from conducting its clinical trials, including by damaging its critical infrastructure, such as third party facilities, or that otherwise disrupted operations and travel, it may be difficult or, in certain cases, impossible for MEI to continue its business for a substantial period of time. The disaster recovery and business continuity plans MEI has in place may prove inadequate in the event of a serious disaster or similar event. MEI may incur substantial expenses as a result of the limited nature of its disaster recovery and business continuity plans, which could have a material adverse effect on MEI’s business, operating results, prospects or financial condition.



***Limitations on the deductibility of net operating losses could adversely affect MEI's business and financial condition.***

MEI has a history of net operating losses. In December 2017, the U.S government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act (the "Tax Act"). The Tax Act limits the deduction of net operating losses to 80% of current year taxable income. The limitations on the net operating loss deduction, as well other changes in tax policy, may subject MEI to additional taxation, adversely affecting MEI's results of operations and financial condition.

**Risks Related to Securities Markets and Investment in MEI Stock**

***The trading price of the shares of MEI common stock has been and may continue to be highly volatile and could decline in value and MEI may incur significant costs from class action litigation.***

The trading price of MEI common stock could be highly volatile in response to various factors, many of which are beyond MEI's control, including, but not limited to, the following:

- failure to successfully develop MEI's drug candidates;
- design, results and timing of clinical trials and pre-clinical studies;
- announcements of technological innovations by MEI or its competitors;
- new products introduced or announced by MEI or its competitors;
- changes in financial estimates by securities analysts;
- actual or anticipated variations in operating results;
- expiration or termination of licenses, research contracts or other collaboration agreements;
- conditions or trends in the regulatory climate and the biotechnology, pharmaceutical and genomics industries;
- instability in the stock market as a result of current or future domestic and global events;
- changes in the market valuations of similar companies;
- the liquidity of any market for MEI's securities; and
- threatened or actual delisting of MEI common stock from a national stock exchange.

Equity markets in general, and the market for biotechnology and life sciences companies in particular, have experienced substantial price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of companies traded in those markets. In addition, changes in economic conditions in the U.S., the Europe or globally, particularly in the context of current global events, could impact upon MEI's ability to grow profitably. Adverse economic changes are outside of MEI's control and may result in material adverse impacts on MEI's business or its results of operations. These broad market and industry factors may materially affect the market price of shares of its common stock, regardless of MEI's development and operating performance. In the past, following periods of volatility in the market price of a company's securities, securities class-action litigation has often been instituted against that company. Such litigation, if instituted against MEI, could cause MEI to incur substantial costs and divert management's attention and resources.

***Future sales of MEI common stock, including common stock issued upon exercise of outstanding warrants or options, may depress the market price of MEI's common stock and cause stockholders to experience dilution.***

The market price of MEI common stock could decline as a result of sales of substantial amounts of MEI common stock in the public market, including upon exercise of outstanding warrants or stock options, and any subsequent sales of such shares. As of December 31, 2022, MEI had outstanding warrants exercisable to purchase 802,949 shares of common stock at an exercise price of \$50.80 per share, which expire in May 2023. In October 2022, MEI engaged Torrey Partners as a financial adviser and agreed to issue warrants to acquire shares of MEI



## [Table of Contents](#)

Common Stock having a value equal to \$0.5 million. MEI issued 102,513 warrants at an exercise price of \$6.80 per share to Torrey in February 2023. MEI also had outstanding options to purchase 1,270,243 shares of common stock. MEI may seek additional capital through one or more additional equity transactions in the future; however, such transactions will be subject to market conditions and there can be no assurance any such transactions will be completed. If MEI sells shares in the future, the prices at which MEI sells these future shares will vary, and these variations may be significant. Stockholders will experience significant dilution if MEI sells these future shares at prices significantly below the price at which such previous stockholders invested.

***Because MEI does not intend to pay, and has not paid, any cash dividends on its shares of common stock, MEI stockholders will not be able to receive a return on their shares unless the value of MEI common stock appreciates and they sell their shares.***

MEI has never paid or declared any cash dividends on its common stock, and MEI intends to retain any future earnings to finance the development and expansion of its business. MEI does not anticipate paying any cash dividends on its common stock in the foreseeable future. Therefore, MEI stockholders will not be able to receive a return on their investment unless the value of MEI common stock appreciates and they sell their shares.

***MEI will have broad discretion over the use of the net proceeds from any exercise of outstanding warrants and options.***

MEI will have broad discretion to use the net proceeds to MEI upon any exercise of outstanding warrants and options, and investors in MEI stock will be relying on the judgment of MEI's board of directors and management regarding the application of these proceeds. Although MEI expects to use a substantial portion of the net proceeds from any exercise of the warrants and options for general corporate purposes and progression of its clinical trial programs, MEI has not allocated these net proceeds for specific purposes.

***MEI is authorized to issue blank check preferred stock, which could adversely affect the holders of MEI common stock.***

The MEI COI allows it to issue blank check preferred stock with rights potentially senior to those of MEI common stock without any further vote or action by the holders of MEI common stock. The issuance of a class of preferred stock could decrease the amount of earnings and assets available for distribution to the holders of MEI common stock or could adversely affect the rights and powers, including voting rights, of such holders. In certain circumstances, such issuance could have the effect of decreasing the market price of MEI shares, or making a change in control of the Company more difficult.

***Anti-takeover provisions contained in the MEI COI and fifth amended and restated bylaws ("MEI Bylaws"), as well as provisions of Delaware law, could impair a takeover attempt.***

The MEI COI and MEI Bylaws contain provisions that may discourage unsolicited takeover proposals that stockholders may consider to be in their best interests. MEI is also subject to anti-takeover provisions under Delaware law, which could delay or prevent a change of control. Together, these provisions may make more difficult the removal of management and may discourage transactions that otherwise could involve payment of a premium over prevailing market prices for MEI securities. These provisions include:

- a staggered board providing for three classes of directors, which limits the ability of a stockholder or group to gain control of MEI's board;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the right of MEI's board to elect a director to fill a vacancy created by the expansion of MEI's board or the resignation, death or removal of a director in certain circumstances, which prevents stockholders from being able to fill vacancies on MEI's board; and

## Table of Contents

- advance notice procedures that stockholders must comply with in order to nominate candidates to MEI's board or to propose matters to be acted upon at a meeting of stockholders, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of MEI.

***The MEI Bylaws require, to the fullest extent permitted by law, that derivative actions brought in MEI's name, actions against its directors, officers other employees for breach of fiduciary duty and other similar actions may be brought only in the Court of Chancery in the State of Delaware and, if brought outside of Delaware, the stockholder bringing the suit will be deemed to have consented to service of process on such stockholder's counsel, which may have the effect of discouraging lawsuits against MEI's directors, officers, other employees or stockholders.***

The MEI Bylaws provide that, unless MEI consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will, to the fullest extent permitted by law, be the sole and exclusive forum for any stockholder to bring (i) any derivative action or proceeding brought on behalf of MEI, (ii) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of MEI to MEI or MEI's stockholders, (iii) any action asserting a claim pursuant to any provision of the Delaware General Corporation Law, or (iv) any action asserting a claim governed by the internal affairs doctrine, and, if brought outside of Delaware, the stockholder bringing the suit will be deemed to have consented to service of process on such stockholder's counsel, provided, however, that, in each case, if the Court of Chancery does not have jurisdiction, the forum for such action shall be another state court located within the State of Delaware or, if no state court located within the State of Delaware has jurisdiction, the federal district court for the District of Delaware, in all cases subject to the court having personal jurisdiction over the indispensable parties named as defendants therein.

Any person or entity purchasing or otherwise acquiring or holding any interest in shares of capital stock of MEI shall be deemed to have notice of and consented to such provisions.

Notwithstanding the foregoing, the forum selection provision of MEI's fifth amended and restated bylaws will not apply to suits brought to enforce any liability or duty created by the federal securities laws or any other claim for which the federal district courts of the U.S. of America shall be the sole and exclusive forum.

This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with MEI or any of its directors, officers, other employees or stockholders, which may discourage lawsuits with respect to such claims. Alternatively, if a court were to find the choice of forum provision contained in the MEI Bylaws to be inapplicable or unenforceable in an action, MEI may incur additional costs associated with resolving such action in other jurisdictions, which could harm MEI's business, operating results and financial condition.

***MEI's executive officers and directors may sell shares of their stock, and these sales could adversely affect MEI's stock price.***

Sales of MEI stock by its executive officers and directors, or the perception that such sales may occur, could cause the market price of MEI common stock to decline or could make it more difficult for MEI to raise funds through the sale of equity in the future, either as part, or outside, of trading plans under Rule 10b5-1 under the Securities Exchange Act of 1934, as amended (the "Exchange Act").

## **RISKS RELATED TO INFINITY**

### **Risks Related to Infinity's Financial Position and Need for Additional Capital**

***If the Merger is not completed, substantial doubt exists as to Infinity's ability to continue as a going concern.***

As of December 31, 2022 and 2021, Infinity had cash and cash equivalents of \$38.3 million and \$80.7 million, respectively. As of December 31, 2022, Infinity had an accumulated deficit of \$856.0 million and during the year

## [Table of Contents](#)

ended December 31, 2022 used \$42.4 million in cash and cash equivalents to fund operating activities. Infinity expects to continue to incur substantial operating losses and negative cash flows from operations for the foreseeable future. These conditions raise substantial doubt about Infinity's ability to continue as a going concern for at least twelve months from the date Infinity's consolidated financial statements were issued on March 28, 2023. Moreover, Infinity has not established a source of revenue and it expects to continue to incur losses for the foreseeable future as it continues its development of, and seek marketing approvals for, its product candidates. These factors individually and collectively raise substantial doubt about Infinity's ability to continue as a going concern and therefore it may be more difficult for it to attract investors. Unless Infinity is able to raise additional capital to finance its operations, its long-term business plan may not be accomplished, and it may be forced to cease, reduce, or delay operations.

***Raising additional capital may cause dilution to Infinity's stockholders, restrict its operations or require Infinity to relinquish rights to its technologies or product candidates.***

If the Merger is not completed, Infinity may seek additional funding through public or private financings of equity or debt securities, but such financing may not be available on acceptable terms, if at all. If Infinity raises additional funds through the issuance of additional debt or equity securities, it may not be able to raise capital at the price it desires, as underscored by its current noncompliance with the Minimum Bid Requirement (as defined below). Any public offering could result in dilution to Infinity's existing stockholders, increased fixed payment obligations and the existence of securities with rights that may adversely affect the rights of Infinity's existing stockholders including liquidation or other preferences and anti-dilution protections.

In addition, securing financing could require a substantial amount of time and attention from Infinity's management and may divert a disproportionate amount of its attention away from day-to-day activities, which may adversely affect Infinity's management's ability to oversee the development of its product candidates.

Infinity may also seek additional funds through arrangements with collaborators or other third parties, or through project financing. These arrangements would generally require it to relinquish or encumber valuable rights to its technologies, future revenue streams, or product candidates, and Infinity may not be able to enter into such agreements on acceptable terms, if at all.

If Infinity is unable to obtain additional funding on a timely basis, Infinity's board of directors may conclude that it is in the best interest of stockholders to cease normal operations and wind down the company through bankruptcy or dissolution proceedings. In such case, there would be no assurances as to the amount or timing of available cash remaining, if any, to distribute to stockholders after paying Infinity's obligations and setting aside funds for reserves.

***Infinity has a history of operating losses, expects to incur significant and increasing operating losses in the future, and may never become profitable, or if Infinity becomes profitable, it may not remain profitable.***

Infinity has no approved products, has not generated product revenue from sales, and have primarily incurred operating losses. As of December 31, 2022, Infinity had an accumulated deficit of \$856.0 million. Infinity expects to continue to spend significant resources to fund eganelisib, its selective inhibitor of PI3K-gamma. While Infinity may have net income in some periods as the result of non-recurring collaboration revenue, it expects to incur substantial operating losses over the next several years as its clinical trial and drug manufacturing activities continue. In addition, if Infinity proceeds to seek and possibly obtain regulatory approval of eganelisib, Infinity would expect to incur significant commercialization expenses for product sales, marketing, manufacturing and distribution, to the extent such sales, marketing, manufacturing and distribution are not the responsibility of a future collaborator. As a result, Infinity expects that its accumulated deficit would also increase significantly.

Eganelisib is under clinical development and may never be approved for sale or generate any revenue. Infinity will not be able to generate product revenue unless and until eganelisib successfully completes clinical trials and receives regulatory approval. Infinity does not expect to generate revenue from product sales for the foreseeable future. Even if Infinity eventually generate revenues, it may never be profitable, and if Infinity does achieve

## Table of Contents

profitability, it may not be able to sustain or increase profitability on a quarterly or annual basis. Infinity's failure to become and remain profitable would decrease the value of Infinity and could impair its ability to raise capital, expand its business, and maintain its research and development efforts, and cause a decline in the value of its common stock.

***If the Merger is not completed, Infinity will need substantial additional funding, and if Infinity is unable to raise capital when needed, it could be forced to delay, reduce or eliminate the development of eganelisib or future efforts to commercialize eganelisib.***

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a time consuming, expensive and uncertain process that takes years to complete. Infinity will need substantial additional funds to support its planned operations, but substantial doubt exists about its ability to continue as a going concern for at least twelve months from the date Infinity's consolidated financial statements were issued on March 28, 2023. See the risk factor "If the Merger is not completed, substantial doubt exists as to Infinity's ability to continue as a going concern" for more information.

Infinity's estimate as to how long it expects its existing cash and cash equivalents to be able to continue to fund its operations will depend on many factors, which assumptions may prove to be wrong, and Infinity could use its available capital resources sooner than it currently expects. Further, changing circumstances, some of which may be beyond Infinity's control, could cause it to consume capital significantly faster than it currently anticipates, and it may need to seek additional funds sooner than planned. Infinity's future funding requirements, both short-term and long-term, will depend on many factors, including, but not limited to, the scope, progress, results and costs of developing and marketing eganelisib, including costs of acquiring raw materials and manufacturing, as well as the impact of delays as a result of the COVID-19 pandemic. Infinity's funding requirements will further depend on the timing and amount of additional revenues, if any, received from commercial sales of eganelisib and from collaboration agreements and funding arrangements, regulatory and commercial-based milestone payments from Sol-Gel related to patidegib, and additional royalty and milestone payments owed to Takeda Pharmaceutical Company Limited ("Takeda").

***Infinity has broad discretion in the use of its available cash and other sources of funding and may not use them effectively.***

Infinity's management has broad discretion in the use of its available cash and other sources of funding and could spend those resources in ways that do not improve its results of operations or enhance the value of its common stock. The failure by Infinity's management to apply these funds effectively could result in financial losses that could cause the price of its common stock to decline and delay the development of eganelisib or any future product candidate. Infinity may invest its available cash pending its use in a manner that does not produce income or that loses value.

### **Risks Related to the Development and Commercialization of Eganelisib and Any Future Product Candidate**

***Infinity is dependent on the success of eganelisib, its only product candidate, which remains subject to clinical testing and regulatory approval. If Infinity is unable to initiate or complete clinical development of, obtain marketing approval for or successfully commercialize eganelisib, either alone or with a collaborator, or if Infinity experiences significant delays in doing so, its business could be substantially harmed.***

Infinity currently has no products approved for sale and are investing substantially all of its efforts and financial resources in the development of eganelisib. The success of eganelisib will depend on Infinity's ability to generate product revenue, which will heavily depend on the successful completion of the Merger and the successful clinical development and eventual commercialization of eganelisib. Infinity also expects that the success of eganelisib will depend primarily on its therapeutic potential in combination with other therapeutics, such as checkpoint inhibitor therapies, and not as a monotherapy.

## [Table of Contents](#)

To date, Infinity has not obtained approval from the Food and Drug Administration (“FDA”) or any comparable foreign regulatory authority to market or sell eganelisib or any other product candidates. Rigorous preclinical testing, testing in clinical trials, and an extensive regulatory approval process are required in the United States and in many foreign jurisdictions prior to the commercial sale of medicinal products. If Infinity’s current clinical trials for eganelisib are successful, it will need to conduct further clinical trials and will need to apply for regulatory approval before it may market or sell any products based on eganelisib. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. It is possible that eganelisib will not obtain marketing approval. Even if eganelisib has a beneficial effect, that effect may not be detected during clinical evaluation as a result of one or more of a variety of factors, including the size, duration, design, measurements, conduct or analysis of Infinity’s clinical trials. Conversely, as a result of the same factors, Infinity’s clinical trials may indicate an apparent positive effect of eganelisib that is greater than the actual positive effect, if any. Similarly, in clinical trials Infinity may fail to detect toxicity of or intolerability caused by eganelisib or mistakenly believe that eganelisib is toxic or not well tolerated when that is not in fact the case.

Infinity cannot predict whether it will encounter problems with any of its ongoing or planned clinical trials that will cause it or regulatory authorities to delay, suspend, or discontinue clinical trials or to delay the analysis of data from ongoing clinical trials. Moreover, Infinity, or any collaborators, may experience any of a number of possible unforeseen adverse events in connection with clinical trials, many of which are beyond Infinity’s control, including:

- insufficient or inadequate supply, delays in distribution or deficient quality of, or inability to purchase or manufacture drug product, combination drugs, comparator drugs or other materials necessary to conduct Infinity’s or any collaborators’ clinical trials. For example, in 2021 Bristol Myers Squibb Company (“BMS”) experienced a temporary global manufacturing-related supply shortage of nab-paclitaxel, or Abraxane<sup>®</sup>, a drug used in the MARIO-3 combination study of patients with unresectable locally advanced or metastatic front-line TNBC;
- unfavorable results of discussions with the FDA or comparable foreign authorities regarding the scope or design of Infinity’s, or any collaborators’, clinical trials or Infinity’s or their interpretation of data from preclinical studies and clinical trials;
- delays in receiving, or the inability to obtain, required approvals from institutional review boards or other reviewing entities at clinical sites selected for participation in Infinity’s clinical trials;
- delays in enrolling patients into clinical trials;
- a lower than anticipated retention rate of patients in clinical trials due to, among other reasons, patients that enroll in a clinical trial misrepresenting their eligibility to do so or otherwise not complying with the clinical trial protocol, resulting in the need to drop the patients from the clinical trial, increase the needed enrollment size for the clinical trial or extend the clinical trial’s duration and cost;
- the number of patients required for clinical trials of eganelisib, the speed of patient enrollment and the rate of participant drop outs may differ from the expectations of Infinity or its collaborators;
- the cost of planned clinical trials of eganelisib may be greater than Infinity anticipates;
- comparator or combination drugs, or components or ingredients thereof or conducting clinical trials on Infinity’s behalf or on behalf of any collaborators, to comply with regulatory requirements or meet their contractual obligations to Infinity or any collaborators in a timely manner or at all;
- the requirement by regulators or institutional review boards that Infinity, or any collaborators, or Infinity’s or their investigators, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or their standards of conduct, a finding that the participants are being exposed to unacceptable health risks, undesirable side effects or other unexpected characteristics of eganelisib, or findings of undesirable effects caused by a chemically or mechanistically similar product or product candidate;

## Table of Contents

- the need to repeat or discontinue clinical trials as a result of inconclusive or negative results or unforeseen complications in testing, or because the results of later trials may not confirm positive results from earlier preclinical studies or clinical trials;
- unfavorable FDA or other foreign regulatory inspection and review of a clinical trial site, us, or a vendor of Infinity, or records of any clinical or preclinical investigation;
- delays or failures by Infinity or any collaborators in reaching agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- failures by the FDA or comparable foreign regulatory authorities to approve the manufacturing processes or facilities of third-party manufacturers with which Infinity, or any collaborators, enter into agreements for clinical and commercial supplies, or subsequent findings of fault with such processes or facilities;
- insufficient or inadequate supply or quality of raw materials, manufactured product candidates, combination or comparator drugs or other materials necessary to conduct clinical trials of eganalisib, or the inability to acquire such materials at acceptable cost, which may result in interruptions in supply;
- significant changes in the approval policies or regulations of the FDA or comparable foreign regulatory authorities, which may rendering Infinity's clinical data insufficient to obtain marketing approval;
- serious and unexpected drug-related side effects experienced by participants in Infinity or any collaborators' clinical trials, which may occur even if they were not observed in earlier trials or only observed in a limited number of participants;
- a finding that the trial participants are being exposed to unacceptable health risks, undesirable side effects or other unexpected characteristics of eganalisib;
- the placement by the FDA or a foreign regulatory authority of a clinical hold on a trial;
- outcomes of third party trials of drugs and drug candidates that Infinity also uses in its combination trials, such as F. Hoffmann-La Roche Ltd. ("Roche")'s decision to voluntarily withdraw its accelerated approval in the United States for atezolizumab in combination with nab-paclitaxel for patients with PD-L1(+) metastatic TNBC after IMpassion131, Roche's post marketing study evaluating atezolizumab and paclitaxel in TNBC patients, did not meet its primary endpoint; and
- any restrictions on, or post-approval commitments with regard to, any regulatory approval Infinity ultimately obtains that render the product candidate not commercially viable.

The delay, suspension or discontinuation of any of Infinity's or any collaborators' clinical trials, or a delay in the analysis of clinical data for eganalisib, for any of the foregoing reasons, could adversely affect Infinity's ability to obtain regulatory approval for and to commercialize eganalisib, increase Infinity's operating expenses and have a material adverse effect on its financial results.

Product development costs for Infinity, or any collaborators, will increase if Infinity, or they, experience delays in testing or pursuing marketing approvals and Infinity, or they, may be required to obtain additional funds to complete clinical trials and prepare for possible commercialization of eganalisib. Infinity does not know whether its clinical trials will begin as planned, will need to be restructured, or will be completed on schedule or at all. Significant preclinical study or clinical trial delays also could shorten any periods during which Infinity, or any collaborators, may have the exclusive right to commercialize eganalisib or allow its competitors, or the competitors of any current or future collaborators, to bring products to market before Infinity, or any collaborators, do and impair its ability, or the ability of any collaborators, to successfully commercialize eganalisib and may harm Infinity's business and results of operations. In addition, many of the factors that lead to clinical trial delays may ultimately lead to the denial of marketing approval of eganalisib, or, in the event that Infinity's clinical trials remain unable to demonstrate meaningful clinical benefit, its failure to reach the marketing approval stage at all.

***Adverse events or undesirable side effects caused by, or other unexpected properties of, eganelisib, alone or in combination with other agents, may be identified during clinical development and could delay or prevent eganelisib marketing approval or limit its use.***

Adverse events or undesirable side effects caused by, or other unexpected properties of, eganelisib, alone or in combination with other agents, could cause Infinity, any collaborators, an institutional review board or regulatory authorities to interrupt, delay or halt clinical trials of eganelisib and could result in a more restrictive label or the delay or denial of marketing approval by the FDA or comparable foreign regulatory authorities. If eganelisib is associated with adverse events or undesirable side effects or has properties that are unexpected, Infinity, or any collaborators, may need to abandon or delay development of eganelisib, or limit its development to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Even though eganelisib has initially shown promise in earlier stage testing, it may later be found to cause undesirable or unexpected side effects that prevent its further development. Combining two or more agents may increase the instances of or severity of adverse events or undesirable effects.

***Interim top-line and preliminary results from Infinity's clinical trials that it announces or publishes from time to time may change as more patient data become available and are subject to audit and verification procedures, which could result in material changes in the final data.***

From time to time, Infinity may publish interim top-line or preliminary results from its clinical trials. Interim results from clinical trials that Infinity may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or top-line results also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data Infinity previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Differences between preliminary or interim data and final data could significantly harm Infinity's business prospects and may cause the trading price of Infinity's common stock to fluctuate significantly.

***Even assuming approval of a drug candidate, Infinity's business may suffer if the market opportunities for eganelisib or product candidates it may develop in the future are smaller than Infinity believes them to be.***

Infinity's projections of both the number of people who are affected by disease within Infinity's target indications, as well as the subset of these people who have the potential to benefit from treatment with eganelisib or product candidates Infinity may develop in the future, are based on Infinity's beliefs and estimates. These estimates have been derived from a variety of sources, including the scientific literature, healthcare utilization databases and market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The potentially addressable patient population for eganelisib may be limited or may not be amenable to treatment with eganelisib, and new patients may become increasingly difficult to identify or gain access to, which would adversely affect Infinity's results of operations and its business.

***Infinity is conducting clinical trials for eganelisib, and may conduct additional clinical trials in the future, at sites outside the United States. The FDA may not accept data from trials conducted in such locations and the conduct of trials outside the United States could subject Infinity to additional delays and expense.***

MARIO-275, Infinity's Phase 2 global study, is being conducted, and Infinity may choose to conduct future clinical trials, at trial sites located in the United States and Europe. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of these data is subject to certain conditions imposed by the FDA, such as the clinical trial must be well designed and conducted and performed by qualified investigators in accordance with good clinical practices; the FDA must be able to validate the data from the trial through an onsite inspection if necessary; the trial population must also have a similar profile to the U.S. population; and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful, except to the extent the disease being studied does not typically



## [Table of Contents](#)

occur in the United States. In addition, while these clinical trials are subject to the applicable local laws, FDA acceptance of the data will be dependent upon its determination that the trials also complied with all applicable U.S. laws and regulations. There can be no assurance that the FDA will accept data from trials conducted outside of the United States. If the FDA does not accept the data from any trial that Infinity conducts outside the United States, it would likely result in the need for additional trials, which would be costly and time-consuming and delay or permanently halt Infinity's development of eganelisib or any future product candidates.

In addition, the conduct of clinical trials outside the United States could have a significant adverse impact on Infinity. Risks inherent in conducting international clinical trials include:

- clinical practice patterns and standards of care that vary widely among countries;
- non-U.S. regulatory authority requirements that could restrict or limit Infinity's ability to conduct its clinical trials;
- administrative burdens of conducting clinical trials under multiple non-U.S. regulatory authority schema;
- foreign exchange fluctuations;
- diminished protection of intellectual property in some countries; and
- geopolitical actions, including war and terrorism, disease outbreak, such as the COVID-19 pandemic, or natural disasters including earthquakes, typhoons, floods and fires.

***If Infinity is slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, its development plans may be impacted.***

In addition, the FDA's and other regulatory authorities' policies with respect to clinical trials may change and additional government regulations may be enacted.

For example, in December 2022, with the passage of Food and Drug Omnibus Reform Act ("FDORA"), Congress required sponsors to develop and submit a diversity action plan for each phase 3 clinical trial or any other "pivotal study" of a new drug or biological product. These plans are meant to encourage the enrollment of more diverse patient populations in late-stage clinical trials of FDA-regulated products. Specifically, actions plans must include the sponsor's goals for enrollment, the underlying rationale for those goals, and an explanation of how the sponsor intends to meet them. In addition to these requirements, the legislation directs the FDA to issue new guidance on diversity action plans. Similarly, the regulatory landscape related to clinical trials in the EU recently evolved. The EU Clinical Trials Regulation ("CTR"), which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. While the Clinical Trials Directive required a separate clinical trial application ("CTA") to be submitted in each member state, to both the competent national health authority and an independent ethics committee, the CTR introduces a centralized process and only requires the submission of a single application to all member states concerned. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state's decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed.

***Results of preclinical studies and early clinical trials may not be predictive of results of future late-stage clinical trials.***

The outcome of preclinical studies and early clinical trials may not be predictive of the success of later clinical trials, and interim results of clinical trials do not necessarily predict success in future clinical trials. Many



## Table of Contents

companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in earlier development, and Infinity could face similar setbacks. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the dosing regimen and other clinical trial protocols and the rate of dropout among clinical trial participants. If Infinity fails to receive positive results in clinical trials of eganelisib, the development timeline and regulatory approval and commercialization prospects for eganelisib and, correspondingly, its business and financial prospects, would be negatively impacted.

***Infinity's inability to enroll sufficient numbers of patients in its clinical trials, or any delays in patient enrollment, could result in increased costs and longer development periods for Infinity's product candidates.***

Clinical trials require sufficient patient enrollment. Infinity's failure to enroll patients in a clinical trial could delay the initiation or completion of the clinical trial beyond current expectations. In addition, the FDA or other comparable foreign regulatory authorities could require Infinity to conduct clinical trials with a larger number of patients than has been projected for eganelisib or any product candidates Infinity may develop in the future. As a result of these factors, Infinity may not be able to enroll a sufficient number of patients in a timely or cost-effective manner. Furthermore, enrolled patients may drop out of a clinical trial for reasons such as being included in a placebo or comparator arm in a trial, the occurrence of adverse side effects, whether or not related to Infinity's product candidate, or low or no activity of its product candidate at one or more dose levels being tested, which could impair the validity or statistical significance of the clinical trial. Please refer to "Risks Related to COVID-19 Pandemic" for a further discussion of the impact of COVID-19 on enrollment in Infinity's clinical trials. A delay in Infinity's clinical trial activities could adversely affect its ability to obtain regulatory approval for and to commercialize its product candidates, increase its operating expenses, and have a material adverse effect on its financial results.

***Even if a product candidate receives marketing approval in the future, Infinity or others may later discover that the product is less effective than previously believed or causes undesirable side effects that were not previously identified, which could compromise Infinity's ability, or that of any future collaborator, to market such product candidate.***

Even if Infinity receives regulatory approval for a product candidate, it will have tested it in only a small number of patients in carefully defined subsets and over a limited period of time during its clinical trials, such as is the case for eganelisib. If any future applications for marketing are approved and more patients begin to use Infinity's products, or patients use such products for a longer period of time, such products might be less effective than indicated by Infinity's clinical trials. Furthermore, new risks and side effects associated with such products may be discovered or previously observed risks and side effects may become more prevalent and/or clinically significant.

In addition, supplemental clinical trials that may be conducted on a drug following its initial approval may produce findings that are inconsistent with the trial results previously submitted to regulatory authorities. As a result, regulatory authorities may revoke their approvals, or Infinity may be required to conduct additional clinical trials, make changes in labeling of a product (including a "black box" warning or a contraindication) or the manner in which it is administered, reformulate such product or make changes to and obtain new approvals for Infinity and its suppliers' manufacturing facilities. Infinity also might have to withdraw or recall such product from the marketplace, and regulators might seize such product. Infinity might be subject to fines, injunctions, or the imposition of civil or criminal penalties. Any of these results could decrease or prevent any sales of Infinity's approved product or substantially increase the costs and expenses of commercializing and marketing its product, harm its reputation, business and operations, result in Infinity and its collaborators' becoming subject to lawsuits, including class actions and could negatively impact Infinity's stock price.

## Table of Contents

***Even if a product candidate receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success, in which case Infinity may not be able to generate significant revenues from product sales to become profitable.***

Even if a product candidate obtains regulatory approval, it may not gain market acceptance among physicians, patients, managed care organizations, third-party payors, and the medical community for a variety of reasons including:

- timing of Infinity's receipt of any marketing approvals, the terms of any such approvals and the countries in which any such approvals are obtained;
- timing of market introduction of competitive products;
- lower demonstrated clinical safety or efficacy, or less convenient or more difficult route of administration, compared to competitive products;
- lack of cost-effectiveness;
- lack of reimbursement from government payors, managed care plans and other third-party payors;
- prevalence and severity of side effects;
- potential advantages of alternative treatment methods;
- whether it is designated under physician treatment guidelines as a first, second or third line therapy;
- changes in the standard of care for targeted indications;
- limitations or warnings, including distribution or use restrictions, contained in the product's approved labeling;
- safety concerns with similar products marketed by others;
- the reluctance of the target population to try new therapies and of physicians to prescribe those therapies;
- the lack of success of Infinity's physician education programs; and
- ineffective sales, marketing and distribution support.

If any product candidate Infinity develops, such as eganelisib, received marketing approval but fails to achieve market acceptance, Infinity would not be able to generate significant revenue, which may adversely impact its ability to become profitable.

***If Infinity obtains approval to commercialize a product candidate outside of the United States, a variety of risks associated with international operations could materially adversely affect Infinity's business.***

Infinity expects that it will be subject to additional risks in commercializing any product candidate outside the United States, including:

- different regulatory requirements for approval of drugs and biologics in foreign countries;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;

## Table of Contents

- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, disease outbreak, or natural disasters including earthquakes, typhoons, floods and fires.

***Even if Infinity receives regulatory approvals for marketing any product candidates it may develop, it could lose its regulatory approvals and its business would be adversely affected if Infinity, its collaborators, or its contract manufacturers fail to comply with continuing regulatory requirements.***

The FDA and other regulatory agencies continue to review products even after they receive initial approval. If Infinity receives approval to commercialize any product candidates, the manufacturing, marketing and sale of these drugs will be subject to continuing regulation, including compliance with quality systems regulations, the FDA's current good manufacturing practices ("cGMPs"), adverse event requirements and prohibitions on promoting a product for unapproved uses. Enforcement actions resulting from Infinity's failure to comply with government and regulatory requirements could result in fines, suspension of approvals, withdrawal of approvals, product recalls, product seizures, mandatory operating restrictions, criminal prosecution, civil penalties and other actions that could impair the manufacturing, marketing and sale of any product candidates and Infinity's ability to conduct its business.

***If Infinity is unable to establish sales, marketing and distribution capabilities or enter into sales, marketing and distribution arrangements with third parties, it may not be successful in commercializing any product candidates if approved.***

Infinity has no experience in the sale, marketing or distribution of pharmaceutical products and does not currently have the necessary infrastructure to do so. To achieve commercial success for any approved product, Infinity must either develop a sales and marketing organization or outsource these functions to third parties. The development of sales, marketing and distribution capabilities would require substantial resources, would be time consuming and could delay any product launch. If the commercial launch of a product candidate for which Infinity recruits a sales force and establish marketing and distribution capabilities is delayed or does not occur for any reason, Infinity could have prematurely or unnecessarily incurred these commercialization costs, and Infinity's investment could be lost if it cannot retain or reposition its sales and marketing personnel. In addition, Infinity may not be able to hire or retain a sales force that is sufficient in size or has adequate expertise in the medical markets that it chooses to target. If Infinity is unable to establish or retain a sales force and marketing and distribution capabilities, its operating results may be adversely affected. Infinity may seek to collaborate with potential partners if it believes they have development or commercialization expertise relevant to one or more of its products, even if it believes it could otherwise develop and commercialize the product independently. As a result of entering into these arrangements, Infinity's product revenues or the profitability of these product revenues may be lower, perhaps substantially lower, than if it were to directly market and sell its products in those markets. Furthermore, Infinity may be unsuccessful in entering into the necessary arrangements with third parties or may be unable to do so on terms that are favorable to Infinity. In addition, Infinity may have little or no control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market its products effectively.

***Infinity's competitors and potential competitors may develop products that make eganelisib less attractive or obsolete.***

Immuno-oncology ("IO") is a highly competitive and rapidly changing segment of the pharmaceutical industry. Many large pharmaceutical and biotechnology companies, academic institutions, governmental agencies and other public and private research organizations are pursuing the development of novel drugs that target various oncology diseases. Infinity currently faces, and expects to continue to face, intense and increasing competition as new products enter the market and advanced technologies become available. Infinity believes that there are competitors in clinical and pre-clinical development of their PI3K-gamma selective inhibitors and that other competitors are developing or commercializing therapies targeting macrophage reprogramming biology. For

more information on Infinity's competitors, please see the section titled "Infinity's Business" in this joint proxy statement/prospectus.

Infinity's competitors may commence and complete clinical testing of their product candidates, obtain regulatory approvals and begin commercialization of their products sooner than Infinity and/or its collaborators may for eganelisib. These competitive products may have superior safety or efficacy, have more attractive pharmacologic properties, or be manufactured less expensively than eganelisib. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of Infinity's competitors. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with Infinity in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, the development of eganelisib or future product candidates Infinity may develop. If Infinity is unable to compete effectively against these companies on the basis of safety, efficacy or cost, then it may not be able to commercialize eganelisib or achieve a competitive position in the market. This would adversely affect Infinity's ability to generate revenues.

***Even if Infinity, or any future collaborators, are able to commercialize eganelisib, the product may become subject to unfavorable pricing regulations, third-party payor reimbursement practices or healthcare reform initiatives, any of which could harm its business.***

The commercial success of eganelisib will depend substantially, both domestically and abroad, on the extent to which the costs of eganelisib will be paid by third-party payors, including government healthcare programs and private health insurers. If coverage is not available, or reimbursement is limited, Infinity, or any future collaborators, may not be able to successfully commercialize eganelisib. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow Infinity, or any future collaborators, to establish or maintain pricing sufficient to realize a sufficient return on its or their investments. In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors and coverage and reimbursement levels for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time consuming and costly process that may require Infinity to provide scientific and clinical support for the use of its products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

The extent to which patients have third-party payor coverage that could in principle cover treatment with eganelisib may be affected by legislative and regulatory changes relating to the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, the "ACA"). For instance, the so-called "individual mandate" provisions of the ACA require most individuals to carry acceptable insurance for themselves and their family, whether through the government or a private insurer, or else incur a penalty. However, the tax reform legislation signed into law on December 22, 2017, eliminated the penalty for failure to comply with the individual mandate, effective for periods beginning after December 31, 2018. This change and other legislative or regulatory actions in relation to the ACA may increase the pool of patients lacking third-party payor coverage. There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved drugs. Marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, Infinity, or any future collaborators, might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay commercial launch of the product, possibly for lengthy time periods, or prevent it altogether, which may negatively impact the revenues Infinity is able to generate from the sale of the product in that country. Adverse pricing limitations may hinder Infinity's ability or the ability of any future collaborators to recoup Infinity's or their investment in eganelisib, even if eganelisib obtains marketing approval.

## Table of Contents

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Therefore, Infinity's ability, and the ability of any future collaborators, to successfully commercialize eganelisib will depend in part on the extent to which coverage and adequate reimbursement for eganelisib and related treatments will be available from third-party payors. Third-party payors decide which medications they will cover and establish reimbursement levels. The healthcare industry is acutely focused on cost containment, both in the United States and elsewhere. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications, which could affect Infinity's ability or that of any future collaborators to sell eganelisib profitably. These payors may not view eganelisib as cost-effective, and coverage and reimbursement may not be available to Infinity's customers, or those of any future collaborators, or may not be sufficient to allow eganelisib to be marketed on a competitive basis. Cost-control initiatives could cause Infinity, or any future collaborators, to decrease the price Infinity, or they, might establish for eganelisib, which could result in lower than anticipated product revenues. If the prices for eganelisib decrease or if governmental and other third-party payors do not provide coverage or adequate reimbursement, Infinity's prospects for revenue and profitability will suffer.

There may also be delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the indications for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers Infinity's costs, including research, development, manufacture, sale and distribution. Reimbursement rates may vary, by way of example, according to the use of the product and the clinical setting in which it is used. Reimbursement rates may also be based on reimbursement levels already set for lower cost drugs or may be incorporated into existing payments for other services.

In addition, third-party payors are requiring higher levels of evidence of the benefits and clinical outcomes of new technologies and are challenging the prices charged. Further, the net reimbursement for drug products may be subject to additional reductions if there are changes to laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. An inability to promptly obtain coverage and adequate payment rates from both government-funded and private payors for eganelisib could significantly harm Infinity's operating results, its ability to raise capital needed to commercialize eganelisib and its overall financial condition.

***If the FDA or comparable foreign regulatory authorities grant marketing approval for generic versions of eganelisib, or such authorities do not grant eganelisib appropriate periods of data exclusivity before approving generic versions of eganelisib, sales of eganelisib could be adversely affected.***

Once an NDA is approved, the product covered thereby becomes a "reference-listed drug" in the FDA's publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," or the Orange Book. Manufacturers may seek approval of generic versions of reference-listed drugs through submission of abbreviated new drug applications ("ANDAs") in the United States. In support of an ANDA, a generic manufacturer need not conduct clinical trials. Rather, the applicant generally must show that its product has the same active ingredient(s), dosage form, strength, route of administration and conditions of use or labeling as the reference-listed drug and that the generic version is bioequivalent to the reference-listed drug, meaning it is absorbed in the body at the same rate and to the same extent. Generic products may be significantly less costly to bring to market than the reference-listed drug and companies that produce generic products are generally able to offer them at lower prices. Thus, following the introduction of a generic drug, a significant percentage of the sales of any branded product or reference-listed drug may be lost to the generic product.

The FDA may not approve an ANDA for a generic product until any applicable period of non-patent exclusivity for the reference-listed drug has expired. The FDCA provides a period of five years of non-patent exclusivity for a new drug containing a new chemical entity ("NCE"). Specifically, in cases where such exclusivity has been granted, an ANDA may not be filed with the FDA until the expiration of five years unless the submission is

accompanied by a Paragraph IV certification that a patent covering the reference-listed drug is either invalid or will not be infringed by the generic product, in which case the applicant may submit its application four years following approval of the reference-listed drug. When the composition of matter patents underlying Infinity's product candidates expire, it is possible that another applicant could obtain approval to produce generic versions of Infinity's product candidates. If any product Infinity develops does not receive five years of NCE exclusivity, the FDA may approve generic versions of such product three years after its date of approval, subject to the requirement that the ANDA applicant certifies to any patents listed for Infinity's products in the Orange Book. Manufacturers may seek to launch these generic products following the expiration of the applicable marketing exclusivity period, even if Infinity still has patent protection for its product.

***Product liability lawsuits against Infinity or any licensees could cause Infinity or its licensees to incur substantial liabilities and could limit commercialization of any products that Infinity or they may develop.***

Infinity faces an inherent risk of product liability exposure related to the testing of eganelisib or any future product candidates in human clinical trials, and Infinity and any licensees will face an even greater risk as Infinity or they commercially sell any products that Infinity or they may develop, such as duvelisib. If Infinity or its licensees cannot successfully defend itself or themselves against claims that Infinity's product candidates or products caused injuries, Infinity could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in, among other consequences, decreased demand for any product candidates or medicines that Infinity may develop, injury to its reputation and significant negative media attention, withdrawal of clinical trial participants, significant costs to defend the related litigation, substantial monetary awards to trial participants or patients, loss of revenue, reduced resources of Infinity's management to pursue its business strategy, and the inability to commercialize any medicines that Infinity may develop. Although Infinity maintains product liability insurance coverage, it may not be adequate to cover all liabilities that it may incur. Infinity anticipates that it will need to increase its insurance coverage as it advances or expands its clinical trials and if it successfully commercializes any products. Insurance coverage is increasingly expensive. Infinity may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. In addition, if one of Infinity's licensees were to become subject to product liability claims or were unable to successfully defend themselves against such claims, any such licensee could be more likely to terminate such relationship with Infinity and therefore substantially limit the commercial potential of its products.

***Unfavorable global economic conditions could adversely affect Infinity's business, financial condition or results of operations.***

Infinity's results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. The 2008 global financial crisis caused extreme volatility and disruptions in the capital and credit markets. More recently, the COVID-19 pandemic has also adversely impacted the global economy. A severe or prolonged economic downturn, such as that in 2008, could result in a variety of risks to Infinity's business, including weakened demand for eganelisib or any future product candidates Infinity may develop and its ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could strain Infinity's suppliers, possibly resulting in supply disruption, or cause delays in payments for its services by third-party payors or its collaborators. Any of the foregoing could harm Infinity's business and it cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact its business.

**Risks Related to the COVID-19 Pandemic**

***Public health epidemics or outbreaks, including the COVID-19 pandemic, have had, and may continue to have, an adverse impact on Infinity's business.***

In December 2019, a novel strain of coronavirus emerged in China causing the disease COVID-19. This disease has spread worldwide and was deemed a "pandemic" by the World Health Organization on March 11, 2020. As of March 2023, case rates for COVID-19 have dropped considerably, and most government-mandated

## Table of Contents

COVID-19 precautions were lifted in 2022. However, given the volatile nature of COVID-19 to date, such restrictions could return in part or in whole during a future spike in case rates. Infinity has highlighted the key risks associated with the COVID-19 pandemic on its operations throughout these risk factors, including without limitation the following:

- ***The COVID-19 pandemic may materially and adversely affect Infinity’s clinical trial operations and its financial results.*** Infinity is conducting its clinical trials at sites in geographies that were seriously impacted by the COVID-19 pandemic and could be in the event of a future spike. Infinity is continuing to evaluate enrollment trends in its studies as well as the impact of COVID-19 on its clinical programs. Patients currently enrolled on MARIO-275, MARIO-3 and MARIO-1 have continued treatment and study visits with limited disruption, and Infinity is working closely with trial sites to support the continued treatment of patients in compliance with study protocols. At this time, there are no anticipated disruptions to drug supply.
- ***The COVID-19 pandemic could impact Infinity’s future supply chain.*** Infinity currently relies on third-party manufacturers to produce its preclinical and clinical drug supplies, and it may also rely upon third-party manufacturers to produce commercial supplies of eganelisib, also known as IPI-549. Infinity believes it has already manufactured all drug product necessary to conduct its current clinical trials. Further, Infinity believes that a sufficient supply of drug substance and drug product intermediates is available in the United States for additional drug product manufacturing if required to support its clinical development program and potential preclinical studies. However, a future spike of the COVID-19 pandemic or any future pandemic could impact its future supply chain. Refer to the risk factor entitled “Infinity currently relies on third-party manufacturers to produce its preclinical and clinical drug supplies, and it may also rely upon third-party manufacturers to produce commercial supplies of eganelisib” for more information related to the risks related to Infinity’s dependence on third-party manufacturers to produce preclinical, clinical, and commercial supplies of eganelisib.
- ***COVID safety protocols, quarantine requirements, and social distancing measures adopted by or imposed upon Infinity and its vendors may impact Infinity’s business operations.*** Governments and employers have combated the COVID-19 pandemic through implementation of safety protocols and quarantine requirements that may require prolonged absences from work and social distancing measures intended to keep individuals physically distant from one another. Such measures, which have been lifted at the present time, may be re-instated during periods of increased COVID case rates and have had or may have an adverse impact on Infinity’s business operations.

On January 30, 2023, the Biden Administration announced that it will end the public health emergency declarations related to COVID-19 on May 11, 2023. On January 31, 2023, the FDA indicated that it would soon issue a Federal Register notice describing how the termination of the public health emergency will impact the agency’s COVID-19 related guidance’s, including the clinical trial guidance and updates thereto.

### **Risks Related to Infinity’s Dependence on Third Parties**

***If a collaborator terminates or fails to perform its obligations under agreements with Infinity, the development and commercialization of eganelisib or any future product candidates Infinity may develop could be delayed or terminated.***

Infinity currently has worldwide development and commercialization rights to eganelisib, subject to certain success-based milestone payment obligations to its licensor, Takeda, as described in more detail under “Infinity’s Business” in this joint proxy statement/prospectus. Infinity licenses certain patent and other intellectual property rights under that certain Amended and Restated Development and License Agreement, dated as of December 2012, by and between Infinity and Intellikine, Inc. (as amended, the “Takeda Agreement”) and that certain License Agreement, dated as of November 1, 2016, by and between Infinity and Verastem Inc. (the “Secura Bio Agreement”). Infinity may in the future seek other third-party collaborators. The success of a strategic alliance



## Table of Contents

with any partner is largely dependent on the resources, efforts, technology and skills brought to such alliance by such partner. The benefits of such alliances will be reduced or eliminated if any such partner:

- does not or cannot devote the necessary resources to the development, marketing and distribution of such product or products;
- decides not to pursue development and commercialization of the program or to continue or renew development or commercialization programs, based on clinical trial results, changes in the collaborators' strategic focus or available funding, the belief that other product candidates may have a higher likelihood of obtaining regulatory approval or potential to generate a greater return on investment, or external factors, such as an acquisition, that divert resources or create competing priorities;
- does not perform its obligations as expected;
- does not have sufficient resources necessary or is otherwise unable to carry the program through clinical development, regulatory approval and commercialization;
- cannot obtain the necessary regulatory approvals;
- delays clinical trials, provides insufficient funding for a clinical trial program, stops a clinical trial or abandons the program, repeats or conducts new clinical trials or requires a new formulation of the program for clinical testing;
- independently develops, or develops with third parties, products that compete directly or indirectly with the program;
- does not properly maintain or defend Infinity's intellectual property rights or uses Infinity's proprietary information in such a way as to invite litigation that could jeopardize or invalidate Infinity's intellectual property or proprietary information or expose Infinity to potential litigation;
- infringes the intellectual property rights of third parties, which may expose Infinity to litigation and potential liability; or
- terminates the collaboration prior to its completion.

If such partner were to terminate its arrangements with Infinity, or breach such arrangements, or fail to maintain the financial resources necessary to continue financing its portion of development, manufacturing, and commercialization costs, as applicable, Infinity may not have the financial resources or capabilities necessary to continue development and commercialization of the product candidate on its own. Consequently, the development and commercialization of the affected product candidate could be delayed, curtailed or terminated, and Infinity may find it difficult to attract a new collaborator for such product candidate.

Disputes and difficulties in these types of relationships are common, often due to priorities changing over time, conflicting priorities or conflicting interests. Merger and acquisition activity may exacerbate these conflicts. Much of the potential revenue from alliances consists of payments contingent upon the achievement of specified milestones and royalties payable on sales of any successfully developed drugs. Any such contingent revenue will depend upon Infinity, and its collaborators', ability to successfully develop, launch, market and sell new drugs. In some cases, Infinity will not be involved in some or all of these processes, and will depend entirely on its collaborators.

If any future collaborator fails to develop or effectively commercialize a product candidate that is the subject of Infinity's strategic alliance with them, it may not be able to develop and commercialize such product candidate independently, and its financial condition and operations would be negatively impacted.

### ***Infinity relies on third parties to conduct its clinical trials, and those third parties may not perform satisfactorily.***

Infinity relies on third parties such as contract research organizations, medical institutions and external investigators to enroll qualified patients, conduct its clinical trials and provide services in connection with such



## [Table of Contents](#)

clinical trials, and it intends to rely on these and other similar entities in the future. Infinity's reliance on these third parties for clinical development activities reduces its control over these activities. Accordingly, these third-party contractors may not complete activities on schedule or conduct its clinical trials in accordance with regulatory requirements or the trial design. If these third parties do not successfully carry out their contractual obligations or meet expected deadlines, Infinity may be required to replace them. Replacing a third-party contractor may result in a delay of the affected trial and unplanned costs. If this were to occur, Infinity's ability to obtain regulatory approval for and to commercialize eganelisib or any product candidate that it may develop in the future could be delayed.

In addition, Infinity is responsible for ensuring that each of its clinical trials are conducted in accordance with the general investigational plan and protocol for the trial. The FDA requires Infinity to comply with certain standards, referred to as good clinical practices, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Infinity's reliance on third parties that it does not control does not relieve it of these responsibilities and requirements. If any of Infinity's trial investigators or third-party contractors does not comply with good clinical practices, Infinity may not be able to use the data and reported results from the trial. If this noncompliance were to occur, Infinity's ability to obtain regulatory approval for and to commercialize its product candidate could be delayed or put at risk.

***Infinity currently relies on third-party manufacturers to produce its preclinical and clinical drug supplies, and it may also rely upon third-party manufacturers to produce commercial supplies of eganelisib.***

Eganelisib requires precise, high quality manufacturing under cGMP. The third-party manufacturers on which Infinity relies on may fail to comply with cGMPs and other applicable government regulations and corresponding foreign standards. These regulations govern manufacturing processes and procedures and the implementation and operation of systems to control and assure the quality of products. The FDA and foreign regulatory authorities may, at any time, audit or inspect a manufacturing facility to ensure compliance with cGMPs and other quality standards. Any failure by Infinity's contract manufacturers to achieve and maintain high manufacturing and quality control standards could result in the inability of eganelisib to be released for use in one or more countries. In addition, such a failure could result in, among other things, patient injury or death, product liability claims, penalties or other monetary sanctions, the failure of regulatory authorities to grant marketing approval of eganelisib, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of eganelisib, operating restrictions and/or criminal prosecution, any of which could significantly and adversely affect supply of eganelisib and seriously hurt Infinity's business.

Contract manufacturers may also encounter difficulties involving production yields or delays in performing their services. Infinity does not have control over third-party manufacturers' performance and compliance with applicable regulations and standards. If, for any reason, including natural disaster, epidemic or pandemic, such as the ongoing COVID-19 pandemic, Infinity's manufacturers cannot perform as agreed, it may be unable to replace such third-party manufacturers in a timely manner, and the production of eganelisib or any future product candidates would be interrupted, resulting in delays in clinical trials and additional costs. Switching manufacturers may be difficult because the number of potential manufacturers is limited, the demand for such services is high and, depending on the type of material manufactured at the contract facility, the change in contract manufacturer must be submitted to and/or approved by the FDA and comparable regulatory authorities outside of the United States. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of Infinity's product candidates after receipt of regulatory approval. It may be difficult or impossible for Infinity to quickly find a replacement manufacturer on acceptable terms, or at all.

To date, eganelisib has been manufactured for preclinical testing and clinical trials primarily by third-party manufacturers. If the FDA or other regulatory agencies approve eganelisib for commercial sale, Infinity expects that it would continue to rely, at least initially, on third-party manufacturers to produce commercial quantities of eganelisib. These manufacturers may not be able to successfully increase the manufacturing capacity for

eganelisib in a timely or economical manner, or at all, particularly if impacted by COVID-19. Significant scale-up of manufacturing might entail changes in the manufacturing process that would have to be submitted to or approved by the FDA or other regulatory agencies. If contract manufacturers engaged by Infinity are unable to successfully increase the manufacturing capacity for eganelisib, or Infinity is unable to establish its own manufacturing capabilities, the commercial launch of any approved products may be delayed or there may be a shortage in supply.

### **Risks Related to Infinity's Intellectual Property**

***If Infinity fails to obtain or maintain necessary or useful intellectual property rights, Infinity could encounter substantial delays in the research, development and commercialization of eganelisib and any product candidates that it may develop in the future.***

Infinity currently has rights to certain intellectual property through the Takeda Agreement to develop eganelisib and other product candidates that it may in the future develop under its PI3K inhibitor program. In addition, Infinity has rights to certain intellectual property through the Takeda Agreement that it has exclusively licensed to Secura Bio pursuant to the Secura Bio Agreement. Infinity may decide to license additional third-party technology that it deems necessary or useful for its business. However, Infinity may be unable to acquire or in-license any compositions, methods of use, processes or other intellectual property rights from third parties that Infinity identifies as necessary for eganelisib at a reasonable cost, or at all. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that Infinity may consider attractive. These established companies may have a competitive advantage over Infinity due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive Infinity to be a competitor may be unwilling to assign or license rights to Infinity.

Infinity sometimes collaborates with non-profit and academic institutions to accelerate its preclinical research or development under written agreements with these institutions. Typically, these institutions provide Infinity with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such option, Infinity may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to it or it may decide not to execute such option if it believes such license is not necessary to pursue its program. If Infinity is unable or opt not to do so, the institution may offer the intellectual property rights to other parties, potentially blocking its ability to pursue its program.

If Infinity does not obtain or maintain these intellectual property rights which it requires, it could encounter substantial delays in developing and commercializing eganelisib or any other potential product candidate while it attempts to develop alternative technologies, methods and product candidates, which it may not be able to accomplish. If Infinity is ultimately unable to do so, it may be unable to develop or commercialize its product candidate, which could harm its business significantly.

***If Infinity fails to comply with its obligations under its existing and any future intellectual property licenses with third parties, it could lose license rights that are important to its business.***

Infinity is a party to several license agreements under which it licenses patent rights and other intellectual property related to its business including the Takeda Agreement, under which it obtained rights to discover, develop and commercialize pharmaceutical products targeting the delta and/or gamma isoforms of PI3K, including eganelisib and duvelisib. Infinity may enter into additional license agreements in the future. For example, pursuant to the Takeda Agreement, Infinity paid a \$2.0 million success-based milestone payment to Takeda in October 2019 associated with MARIO-275. Infinity is obligated to pay Takeda up to \$3.0 million in remaining success-based development milestone payments and up to \$165.0 million in remaining regulatory and commercialization success-based milestone payments for one product candidate other than duvelisib, which could be eganelisib. Infinity's license agreements impose, and it expects that future license agreements will impose, various diligence, milestone payment, royalty, insurance and other obligations on it. If Infinity fails to comply with its obligations under these licenses, its licensors may have the right to terminate these license

agreements, in which event it might not be able to market eganelisib or any other product candidate that is covered by these agreements, or its licensors may convert the license to a non-exclusive license, which could adversely affect the value of eganelisib or any other product candidate being developed under the license agreement. Termination of these license agreements or reduction or elimination of its licensed rights may also result in Infinity having to negotiate new or reinstated licenses with less favorable terms. For example, if Infinity fails to use diligent efforts to develop and commercialize products licensed under the Takeda Agreement, or if Secura Bio materially breaches the Secura Bio Agreement, Infinity could lose its license rights under the Takeda Agreement, including rights to eganelisib.

***Infinity's intellectual property licenses with third parties may be subject to disagreements over contract interpretations, which could narrow the scope of its rights to the relevant intellectual property or technology or increase its financial or other obligations to its licensors.***

The agreements under which Infinity currently licenses intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what Infinity believes to be the scope of its rights to the relevant intellectual property or technology, or increase what Infinity believes to be its financial or other obligations under the relevant agreement, either of which could harm its business, financial condition, results of operations and prospects.

***Infinity's success depends substantially upon its ability to obtain and maintain intellectual property protection for eganelisib.***

Infinity owns or holds exclusive licenses to a number of U.S. and foreign patents and patent applications directed to eganelisib. Infinity's success depends on its ability to obtain patent protection both in the United States and in other countries for eganelisib, its methods of manufacture and its methods of use. Infinity's ability to protect eganelisib from unauthorized or infringing use by third parties depends substantially on Infinity's ability to obtain and enforce its patents.

Due to evolving legal standards relating to the patentability, validity and enforceability of patents covering pharmaceutical inventions and molecular diagnostics and the claim scope of these patents, Infinity's ability to obtain and enforce patents that may issue from any pending or future patent applications is uncertain and involves complex legal, scientific and factual questions. The standards that the United States Patent and Trademark Office ("USPTO"), and its foreign counterparts use to grant patents are not always applied predictably or uniformly and are subject to change. To date, no consistent policy has emerged regarding the breadth of claims allowed in pharmaceutical or molecular diagnostics patents. Thus, Infinity cannot guarantee that any patents will issue from any pending or future patent applications owned by or licensed to it. Even if patents do issue, Infinity cannot guarantee that the claims of these patents will be held valid or enforceable by a court of law, will provide it with any significant protection against competitive products or will afford it a commercial advantage over competitive products.

The Leahy-Smith America Invents Act, or the America Invents Act, reforms United States patent law in part by changing the standard for patent approval for certain patents from a "first to invent" standard to a "first to file" standard and developing a post-grant review system. This new law changes United States patent law in a way that may severely weaken Infinity's ability to obtain patent protection in the United States. Additionally, recent judicial decisions establishing new case law and a reinterpretation of past case law, as well as regulatory initiatives, may make it more difficult for Infinity to protect its intellectual property.

Issued patents that Infinity has or may obtain or license may not provide it with any meaningful protection, prevent competitors from competing with Infinity or otherwise provide it with any competitive advantage. Infinity's competitors may be able to circumvent its patents by developing similar or alternative technologies or products in a non-infringing manner.

If Infinity does not obtain adequate intellectual property protection for its products in the United States, competitors could duplicate them without repeating the extensive testing that Infinity will have been required to undertake to obtain

## [Table of Contents](#)

approval by the FDA. Regardless of any patent protection, under the current statutory framework, the FDA is prohibited by law from approving any generic version of any of Infinity's products for up to five years after it has approved its product. Upon the expiration of that period, or if that time period is altered, the FDA could approve a generic version of Infinity's product unless Infinity has patent protection sufficient for it to block that generic version. Without sufficient patent protection, the applicant for a generic version of Infinity's product would only be required to conduct a relatively inexpensive study to show that its product is bioequivalent to Infinity's product and would not have to repeat the studies that Infinity conducted to demonstrate that the product is safe and effective.

In the absence of adequate patent protection in other countries, competitors may similarly be able to obtain regulatory approval in those countries for products that duplicate egralisib. The laws of some foreign jurisdictions do not protect intellectual property rights to the same extent as in the United States. Many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions. Some of Infinity's development efforts may be performed in China, India and other countries outside of the United States through third-party contractors. Infinity may not be able to monitor and assess intellectual property developed by these contractors effectively; therefore, Infinity may not be able to appropriately protect this intellectual property and could lose valuable intellectual property rights. In addition, the legal protection afforded to inventors and owners of intellectual property in countries outside of the United States may not be as protective of intellectual property rights as in the United States, and Infinity may, therefore, be unable to acquire and protect intellectual property developed by these contractors to the same extent as if these development activities were being conducted in the United States. If Infinity encounters difficulties in protecting its intellectual property rights in foreign jurisdictions, its business prospects could be substantially harmed.

In addition, Infinity relies on intellectual property assignment agreements with its collaborators, vendors, employees, consultants, clinical investigators, scientific advisors and other collaborators to grant it ownership of new intellectual property that is developed by them. These agreements may not result in the effective assignment to Infinity of that intellectual property.

Other agreements through which Infinity licenses patent rights may not give it control over patent prosecution or maintenance, so that Infinity may not be able to control which claims or arguments are presented and may not be able to secure, maintain, or successfully enforce necessary or desirable patent protection from those patent rights. If Infinity is unable to obtain control over patent prosecution in these other agreements, it cannot be certain that patent prosecution and maintenance activities by its licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents.

Infinity, or any future partners, collaborators or licensees, may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection for them. Therefore, Infinity may miss potential opportunities to strengthen its patent position.

It is possible that defects of form in the preparation or filing of Infinity's patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope or patent term adjustments. If Infinity or its partners, collaborators, licensees, or licensors, whether current or future, fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If Infinity's partners, collaborators, licensees or licensors are not fully cooperative or disagree with Infinity as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation, prosecution, or enforcement of Infinity's patents or patent applications, such patents may be invalid and/or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair Infinity's ability to prevent competition from third parties, which may have an adverse impact on its business. As a result, Infinity's ownership of key intellectual property could be compromised.

***Confidentiality agreements may not adequately prevent disclosure of trade secrets and other proprietary information.***

To protect Infinity's proprietary technology, it relies in part on confidentiality agreements with its vendors, collaborators, employees, consultants, scientific advisors, clinical investigators and other collaborators. Infinity generally requires each of these individuals and entities to execute a confidentiality agreement at the commencement of a relationship with it. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure or misuse of confidential information or other breaches of the agreements.

In addition, Infinity may rely on trade secrets to protect its technology, especially where it does not believe patent protection is appropriate or obtainable. Trade secrets are, however, difficult to protect. Others may independently discover Infinity's trade secrets and proprietary information, and in such case Infinity could not assert any trade secret rights against such party. Enforcing a claim that a party illegally obtained and is using Infinity's trade secrets is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, courts outside of the United States may be less willing to protect trade secrets. Costly and time-consuming litigation could be necessary to seek to enforce and determine the scope of Infinity's proprietary rights and could result in a diversion of management's attention, and failure to obtain or maintain trade secret protection could adversely affect Infinity's competitive business position.

***Patent interference, opposition or similar proceedings relating to Infinity's intellectual property portfolio are costly, and an unfavorable outcome could prevent Infinity from commercializing eganelisib.***

Patent applications in the United States are maintained in confidence for up to 18 months after their filing. In some cases, however, patent applications remain confidential in the USPTO for the entire time prior to issuance as a U.S. patent. Similarly, publication of discoveries in the scientific or patent literature often lags behind actual discoveries. Consequently, Infinity cannot be certain that it was the first to invent, or the first to file patent applications on, eganelisib or its therapeutic use. In the event that a third party has also filed a U.S. patent application relating to eganelisib or a similar invention, Infinity may have to participate in interference or derivation proceedings declared by the USPTO or the third party to determine priority of invention in the United States. An adverse decision in an interference or derivation proceeding may result in the loss of rights under a patent or patent application. In addition, the cost of interference proceedings could be substantial.

***Claims by third parties of intellectual property infringement are costly and distracting, and could deprive Infinity of valuable rights it needs to develop or commercialize eganelisib and any product candidate that it might develop in the future or impact the commercialization of duvelisib and the royalties owed to it under the Secura Bio Agreement.***

Infinity's commercial success will depend on whether there are third-party patents or other intellectual property relevant to its potential products that may block or hinder its ability to develop and commercialize eganelisib. Infinity may not have identified all U.S. and foreign patents or published applications that may adversely affect its business either by blocking its ability to manufacture or commercialize its drugs or by covering similar technologies that adversely affect the applicable market. In addition, Infinity may undertake research and development with respect to eganelisib, even when Infinity is aware of third-party patents that may be relevant to eganelisib, on the basis that it may challenge or license such patents. There are no assurances that such licenses will be available on commercially reasonable terms, or at all. If such licenses are not available, Infinity may become subject to patent litigation and, while it cannot predict the outcome of any litigation, it may be expensive and time consuming. If Infinity is unsuccessful in litigation concerning patents owned by third parties, Infinity may be precluded from selling eganelisib.

While Infinity is not currently aware of any litigation or third-party claims of intellectual property infringement related to eganelisib or duvelisib, the biopharmaceutical industry is characterized by extensive litigation regarding patents and other intellectual property rights. Other parties may obtain patents and claim that the use of Infinity's or Secura Bio's technologies infringes these patents or that it or Secura Bio are

## Table of Contents

employing their proprietary technology without authorization. Infinity or Secura Bio could incur substantial costs and diversion of management and technical personnel in defending against any claims that the manufacture and sale of Infinity's potential products or use of its or Secura Bio's technologies infringes any patents, or defending against any claim that Infinity or Secura Bio are employing any proprietary technology without authorization. The outcome of patent litigation is subject to uncertainties that cannot be adequately quantified in advance, including the demeanor and credibility of witnesses and the identity of the adverse party, especially in pharmaceutical patent cases that may turn on the testimony of experts as to technical facts upon which experts may reasonably disagree. In the event of a successful claim of infringement against Infinity, Infinity or Secura Bio may be required to:

- pay substantial damages;
- stop developing, manufacturing and/or commercializing eganelisib or duvelisib (as applicable);
- develop non-infringing product candidates, technologies and methods; and
- obtain one or more licenses from other parties, which could result in Infinity's or Secura Bio paying substantial royalties or the granting of cross-licenses to Infinity's or Secura Bio's technologies.

If any of the foregoing were to occur, Infinity may be unable to commercialize eganelisib, or Infinity may elect to cease certain of its business operations, either of which could severely harm its business.

### ***Infinity may undertake infringement or other legal proceedings against third parties, causing it to spend substantial resources on litigation and exposing Infinity's intellectual property portfolio to challenge.***

Competitors may infringe Infinity's patents. To prevent infringement or unauthorized use, Infinity may need to file infringement suits, which are expensive and time-consuming. In an infringement proceeding, a court may decide that one or more of Infinity's patents is invalid, unenforceable, or both. Even if the validity of Infinity's patents is upheld, a court may refuse to stop the other party from using the technology at issue on the ground that the other party's activities are not covered by Infinity's patents. In this case, third parties may be able to use Infinity's patented technology without paying licensing fees or royalties. Policing unauthorized use of Infinity's intellectual property is difficult, and it may not be able to prevent misappropriation of its proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States. In addition, third parties may affirmatively challenge Infinity's rights to, or the scope or validity of, its patent rights.

### ***Patent terms may be inadequate to protect Infinity's competitive position on its products for an adequate amount of time.***

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Infinity expects to seek extensions of patent terms in the United States and, if available, in other countries where it is prosecuting patents. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the normal expiration of the patent, which is limited to the approved indication (or any additional indications approved during the period of extension). However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with Infinity's assessment of whether such extensions are available, and may refuse to grant extensions to Infinity's patents, or may grant more limited extensions than Infinity requests. If this occurs, Infinity's competitors may be able to take advantage of its investment in development and clinical trials by referencing Infinity's clinical and preclinical data and launch their product earlier than might otherwise be the case.

### ***Infinity may be subject to claims by third parties asserting that Infinity or its employees have misappropriated their intellectual property, or claiming ownership of what Infinity regards as its own intellectual property.***

Many of Infinity's employees and its licensors' employees, including Infinity's senior management, were previously employed at universities or at other biotechnology or pharmaceutical companies, some of which may

be competitors or potential competitors. Some of these employees, including each member of Infinity's senior management, executed proprietary rights, non-disclosure and non-competition agreements, or similar agreements, in connection with such previous employment. Although Infinity tries to ensure that its employees do not use the proprietary information or know-how of others in their work for Infinity, Infinity may be subject to claims that it or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such third party. Litigation may be necessary to defend against such claims. If Infinity fails in defending any such claims, in addition to paying monetary damages, it may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and Infinity could be required to obtain a license from such third party to commercialize its technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if Infinity is successful in defending against such claims, litigation could result in substantial costs and be a distraction to its senior management and scientific personnel.

In addition, while Infinity typically requires its employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to Infinity, Infinity may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that Infinity regards as its own, which may result in claims by or against Infinity related to the ownership of such intellectual property. If Infinity fails in prosecuting or defending any such claims, in addition to paying monetary damages, it may lose valuable intellectual property rights. Even if Infinity is successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to its senior management and scientific personnel.

***If Infinity's trademarks and trade names are not adequately protected, then it may not be able to build name recognition in its markets of interest and its business may be adversely affected.***

Infinity has not yet registered trademarks in its potential markets. Any registered trademarks or trade names may be challenged, circumvented or declared generic or determined to be infringing on other marks. Infinity may not be able to protect its rights to these trademarks and trade names, which it needs to build name recognition among potential partners or customers in its markets of interest. At times, competitors may adopt trade names or trademarks similar to Infinity's, thereby impeding its ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of Infinity's registered or unregistered trademarks or trade names. Over the long term, if Infinity is unable to establish name recognition based on its trademarks and trade names, then it may not be able to compete effectively and its business may be adversely affected. Infinity's efforts to enforce or protect its proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely impact its financial condition or results of operations.

***Obtaining and maintaining Infinity's patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and its patent protection could be reduced or eliminated for non-compliance with these requirements.***

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which non-compliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If Infinity or its sublicensees fail to comply with these requirements, competitors might be able to enter the market earlier than would otherwise have been the case, which could decrease Infinity's revenue from that product.



***Intellectual property rights do not necessarily address all potential threats.***

The degree of future protection afforded by Infinity's intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect its business or permit Infinity to maintain its competitive advantage. For example:

- others may be able to make products that are similar to eganelisib or any future product candidates Infinity may develop but that are not covered by the claims of the patents that it owns or licenses or may own in the future;
- Infinity, or any partners or collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that Infinity licenses or may own in the future;
- Infinity, or any partners or collaborators, might not have been the first to file patent applications covering certain of Infinity's or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of Infinity's technologies without infringing its owned or licensed intellectual property rights;
- it is possible that Infinity's pending licensed patent applications or those that it may own in the future will not lead to issued patents;
- issued patents that Infinity holds rights to may be held invalid or unenforceable, including as a result of legal challenges by its competitors;
- Infinity's competitors might conduct research and development activities in countries where it does not have patent rights and then use the information learned from such activities to develop competitive products for sale in its major commercial markets;
- Infinity may not develop additional proprietary technologies that are patentable;
- the patents of others may have an adverse effect on Infinity's business; and
- Infinity may choose not to file a patent for certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

**Risks Related to Regulatory Approval and Marketing of Eganelisib and Other Legal Compliance Matters**

***Even if Infinity completes the necessary preclinical studies and clinical trials, the regulatory approval process is expensive, time-consuming and uncertain and may prevent Infinity from obtaining approvals for the commercialization of eganelisib. If Infinity or its collaborators are not able to obtain, or if there are delays in obtaining, required regulatory approvals, or if they are not able to successfully commercialize eganelisib, then Infinity's ability to generate revenue will be materially impaired.***

Eganelisib and the activities associated with its development and commercialization, including its design, testing, manufacture, safety, efficacy, record keeping, labeling, storage, approval, advertising, promotion, sale and distribution, export and import, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by the European Medicines Agency (the "EMA") and comparable regulatory authorities in other countries. Failure to obtain marketing approval for eganelisib will prevent Infinity from commercializing eganelisib. Infinity and its collaborators have not received approval to market eganelisib from regulatory authorities in any jurisdiction. Infinity has only limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party contract research organizations to assist Infinity in this process.

Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information, including manufacturing information, to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Eganelisib may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude Infinity from obtaining marketing approval or prevent or limit commercial use.



## Table of Contents

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that Infinity's data is insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of eganelisib. Any marketing approval Infinity or its collaborators ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

Accordingly, if Infinity or its collaborators experience delays in obtaining approval or if Infinity or its collaborators fail to obtain approval of eganelisib, the commercial prospects for eganelisib may be harmed, and Infinity's ability to generate revenues will be materially impaired.

### ***Failure to obtain marketing approval in foreign jurisdictions would prevent eganelisib from being marketed in such jurisdictions.***

In order to market and sell Infinity's medicines in the European Union and many other jurisdictions, Infinity or its third-party collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, a product must be approved for reimbursement before the product can be approved for sale in that country. Infinity or its third-party collaborators may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. Infinity may not be able to file for marketing approvals and may not receive necessary approvals to commercialize eganelisib in any market.

Additionally, Infinity could face heightened risks with respect to seeking marketing approval in the United Kingdom as a result of the withdrawal of the United Kingdom from the EU ("Brexit"). The United Kingdom is no longer part of the European Single Market and European Union Customs Union. As of January 1, 2021, the Medicines and Healthcare products Regulatory Agency (the "MHRA") became responsible for supervising medicines and medical devices in Great Britain, comprising England, Scotland and Wales under domestic law, whereas Northern Ireland will continue to be subject to European Union rules under the Northern Ireland Protocol. The MHRA will rely on the Human Medicines Regulations 2012 (SI 2012/1916) (as amended, the "HMR") as the basis for regulating medicines. The HMR has incorporated into the domestic law of the body of European Union law instruments governing medicinal products that pre-existed prior to the United Kingdom's withdrawal from the European Union. Since a significant proportion of the regulatory framework for pharmaceutical products in the U.K. covering the quality, safety, and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales, and distribution of pharmaceutical products is derived from EU directives and regulations, Brexit may have a material impact upon the regulatory regime with respect to the development, manufacture, importation, approval and commercialization of Infinity's product candidates in the U.K. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, may force Infinity to restrict or delay efforts to seek regulatory approval in the United Kingdom for its product candidates, which could significantly and materially harm its business.

***Infinity may seek certain designations for its product candidates, including Breakthrough Therapy, Fast Track and Priority Review designations in the US, and PRIME Designation in the EU, but it might not receive such designations, and even if it does, such designations may not lead to a faster development or regulatory review or approval process.***

Infinity may seek certain designations for one or more of its product candidates that could expedite review and approval by the FDA. A Breakthrough Therapy product is defined as a product that is intended, alone or in combination with one or more other products, to treat a serious condition, and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For products that have been designated as Breakthrough Therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens.

The FDA may also designate a product for Fast Track review if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. For Fast Track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a Fast Track product's application before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a Fast Track product may be effective.

Infinity may also seek a priority review designation for one or more of its product candidates. If the FDA determines that a product candidate offers major advances in treatment or provides a treatment where no adequate therapy exists, the FDA may designate the product candidate for priority review. A priority review designation means that the goal for the FDA to review an application is six months, rather than the standard review period of ten months.

These designations are within the discretion of the FDA. Accordingly, even if Infinity believes that one of its product candidates meets the criteria for these designations, the FDA may disagree and instead determine not to make such designation. Further, even if Infinity receives a designation, the receipt of such designation for a product candidate may not result in a faster development or regulatory review or approval process compared to products considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of Infinity's product candidates qualifies for these designations, the FDA may later decide that the product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

In the EU, Infinity may seek PRIME designation for its product candidates in the future. PRIME is a voluntary program aimed at enhancing the EMA's role to reinforce scientific and regulatory support in order to optimize development and enable accelerated assessment of new medicines that are of major public health interest with the potential to address unmet medical needs. The program focuses on medicines that target conditions for which there exists no satisfactory method of treatment in the EU or even if such a method exists, it may offer a major therapeutic advantage over existing treatments. PRIME is limited to medicines under development and not authorized in the EU and the applicant intends to apply for an initial marketing authorization application through the centralized procedure. To be accepted for PRIME, a product candidate must meet the eligibility criteria in respect of its major public health interest and therapeutic innovation based on information that is capable of substantiating the claims.

The benefits of a PRIME designation include the appointment of a CHMP rapporteur to provide continued support and help to build knowledge ahead of a marketing authorization application, early dialogue and scientific advice at key development milestones, and the potential to qualify products for accelerated review, meaning reduction in the review time for an opinion on approvability to be issued earlier in the application process. PRIME enables an applicant to request parallel EMA scientific advice and health technology assessment advice to facilitate timely market access. Even if Infinity receives PRIME designation for any of its product candidates,

## Table of Contents

the designation may not result in a materially faster development process, review or approval compared to conventional EMA procedures. Further, obtaining PRIME designation does not assure or increase the likelihood of EMA's grant of a marketing authorization.

***Even if Infinity or its collaborators obtain marketing approvals for eganelisib, the terms of approvals and ongoing regulation of eganelisib may limit how it manufactures and markets eganelisib, which could impair its ability to generate revenue.***

Once marketing approval has been granted, an approved product and its manufacturer and marketer are subject to ongoing review and extensive regulation. Infinity, and any collaborators, must therefore comply with requirements concerning advertising and promotion for eganelisib. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved labeling. Thus, Infinity and any collaborators will not be able to promote any products Infinity develops for indications or uses for which they are not approved.

In addition, manufacturers of approved products and those manufacturers' facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to cGMPs applicable to drug manufacturers or quality assurance standards applicable to medical device manufacturers, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. Infinity, any contract manufacturers Infinity may engage in the future, its current or future collaborators and their contract manufacturers will also be subject to other regulatory requirements, including submissions of safety and other post-marketing information and reports, registration and listing requirements, requirements regarding the distribution of samples to physicians, recordkeeping, and costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product such as the requirement to implement a risk evaluation and mitigation strategy.

Accordingly, assuming Infinity, or any of its collaborators, receive marketing approval for eganelisib, Infinity, its collaborators, and Infinity and their contract manufacturers will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control.

If Infinity, and any collaborators, are not able to comply with post-approval regulatory requirements, Infinity, and its collaborators, could have the marketing approvals for its products withdrawn by regulatory authorities and its, or any collaborators', ability to market any future products could be limited, which could adversely affect Infinity's ability to achieve or sustain profitability. Further, the cost of compliance with post-approval regulations may have a negative effect on Infinity's operating results and financial condition.

***Eganelisib could be subject to restrictions or withdrawal from the market, and Infinity may be subject to substantial penalties, if it or its collaborators fail to comply with regulatory requirements or if Infinity or its collaborators experience unanticipated problems with eganelisib, when and if it is approved.***

Any product candidate for which Infinity or its collaborators obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to quality control and manufacturing, quality assurance and corresponding maintenance of records and documents, and requirements regarding the distribution of samples to physicians and recordkeeping. Even if marketing approval of eganelisib is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the medicine, including the requirement to implement a risk evaluation and mitigation strategy.

## Table of Contents

The FDA and other agencies, including the Department of Justice (the “DOJ”), closely regulate and monitor the post-approval marketing and promotion of products to ensure that they are marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA and DOJ impose stringent restrictions on manufacturers’ communications regarding off-label use and if Infinity does not market its products for their approved indications, Infinity may be subject to enforcement action for off-label marketing. Violations of the FDCA and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription drugs may lead to investigations and enforcement actions alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws.

In addition, later discovery of previously unknown adverse events or other problems with Infinity’s products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on distribution or use of a product;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that Infinity submits;
- recall of products;
- damage to relationships with any potential collaborators;
- unfavorable press coverage and damage to Infinity’s reputation;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of Infinity’s products;
- product seizure;
- injunctions or the imposition of civil or criminal penalties; and
- litigation involving patients using Infinity’s products.

Similar restrictions apply to the approval of Infinity’s products in the EU. The holder of a marketing authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products. These include: compliance with the EU’s stringent pharmacovigilance or safety reporting rules, which can impose post-authorization studies and additional monitoring obligations; the manufacturing of authorized medicinal products, for which a separate manufacturer’s license is mandatory; and the marketing and promotion of authorized drugs, which are strictly regulated in the EU and are also subject to Member State of the European Union (the “EU Member State”) laws.

***Infinity’s relationships with health care providers, physicians and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other health care laws and regulations, which, in the event of a violation, could expose Infinity to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.***

Health care providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which Infinity obtains marketing approval. Infinity’s future arrangements with health care providers, physicians and third-party payors may expose Infinity to broadly applicable fraud and abuse and other health care laws and regulations that may constrain the business or financial

## Table of Contents

arrangements and relationships through which Infinity markets, sells and distributes any products for which it obtains marketing approval. Restrictions under applicable federal and state health care laws and regulations include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation or arranging of, any good or service, for which payment may be made under a federal health care program such as Medicare and Medicaid;
- the federal False Claims Act imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment by a federal health care program or making a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation to pay money to the federal government, with potential liability including mandatory treble damages and significant per-claim penalties;
- the federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) imposes criminal and civil liability for executing a scheme to defraud any health care benefit program or making false statements relating to health care matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal Physician Payments Sunshine Act requires applicable manufacturers of covered drugs to report payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, as well as ownership and investment interests held by physicians and teaching hospitals; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws and transparency statutes, may apply to sales or marketing arrangements and claims involving health care items or services reimbursed by non-governmental third-party payors, including private insurers.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other health care providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

If Infinity’s operations are found to be in violation of any of the laws described above or any governmental regulations that apply to Infinity, it may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of its operations. Any penalties, damages, fines, curtailment or restructuring of its operations could adversely affect its financial results. As Infinity moves toward potential commercialization of eganelisib, any corporate compliance program Infinity designs would be intended to ensure that Infinity will market and sell any future products that it successfully develops from eganelisib or other product candidates it may develop in compliance with all applicable laws and regulations. However, if implemented, Infinity cannot guarantee that such program would protect it from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against Infinity and it is not successful in defending itself or asserting its rights, those actions could have a significant impact on Infinity’s business, including the imposition of significant fines or other sanctions.

Efforts to ensure that Infinity’s business arrangements with third parties will comply with applicable health care laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that Infinity’s business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other health care laws and regulations. If Infinity’s operations are found to be in

## [Table of Contents](#)

violation of any of these laws or any other governmental regulations that may apply to Infinity, it may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of products from government funded health care programs, such as Medicare and Medicaid, and the curtailment or restructuring of its operations. If any of the physicians or other health care providers or entities with whom Infinity expects to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded health care programs.

### ***Existing and future legislation may increase the difficulty and cost for Infinity and any future collaborators to obtain marketing approval of and commercialize eganalisib or any product candidates Infinity may develop and affect the prices it, or they, may obtain.***

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of Infinity's product candidates, restrict or regulate post-approval activities and affect Infinity's ability, or the ability of any future collaborators, to profitably sell any products for which Infinity, or they, obtain marketing approval. Infinity expects that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that it, or any future collaborators, may receive for any approved products.

In March 2010, President Obama signed into law the ACA. In addition, other legislative changes have been proposed and adopted since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2031. These Medicare sequester reductions were suspended and reduced through the end of June 2022, with the full 2% cut resuming thereafter. The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices Infinity may obtain for any of its product candidates for which it may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used. Indeed, under current legislation, the actual reductions in Medicare payments may vary up to 4%.

Since enactment of the ACA, there have been, and continue to be, numerous legal challenges and congressional actions to repeal and replace provisions of the law. For example, with enactment of the Tax Cuts and Jobs Act of 2017 (the "TCJA"), Congress repealed the "individual mandate." The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, became effective in 2019. On December 14, 2018, a U.S. District Court judge in the Northern District of Texas ruled that the individual mandate portion of the PPACA is an essential and inseparable feature of the PPACA, and therefore because the mandate was repealed as part of the TCJA, the remaining provisions of the PPACA are invalid as well. The U.S. Supreme Court heard this case on November 10, 2020 and, on June 17, 2021, dismissed this action after finding that the plaintiffs do not have standing to challenge the constitutionality of the ACA. Litigation and legislation over the PPACA are likely to continue, with unpredictable and uncertain results.

The Trump Administration also took executive actions to undermine or delay implementation of the ACA, including directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. On January 28, 2021, however, President Biden issued a new Executive Order which directs federal agencies to reconsider rules and other policies that limit Americans' access to health care, and consider actions that will protect and strengthen that access. Under this Order, federal agencies are directed to re-examine: policies that undermine protections for people with pre-existing conditions, including

## [Table of Contents](#)

complications related to COVID-19; demonstrations and waivers under Medicaid and the ACA that may reduce coverage or undermine the programs, including work requirements; policies that undermine the Health Insurance Marketplace or other markets for health insurance; policies that make it more difficult to enroll in Medicaid and the ACA; and policies that reduce affordability of coverage or financial assistance, including for dependents. This Executive Order also directs the U.S. Department of Health and Human Services to create a special enrollment period for the Health Insurance Marketplace in response to the COVID-19 pandemic.

Infinity expects that these healthcare reforms, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that it receives for any approved product and/or the level of reimbursement physicians receive for administering any approved product it might bring to market. Reductions in reimbursement levels may negatively impact the prices Infinity receives or the frequency with which its products are prescribed or administered. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. Accordingly, such reforms, if enacted, could have an adverse effect on anticipated revenue from product candidates that Infinity may successfully develop and for which it may obtain marketing approval and may affect its overall financial condition and ability to develop or commercialize product candidates.

***The prices of prescription pharmaceuticals in the United States and foreign jurisdictions is subject to considerable legislative and executive actions and could impact the prices Infinity obtains for its products, if and when licensed.***

The prices of prescription pharmaceuticals have also been the subject of considerable discussion in the United States. There have been several recent U.S. congressional inquiries, as well as proposed and enacted state and federal legislation designed to, among other things, bring more transparency to pharmaceutical pricing, review the relationship between pricing and manufacturer patient programs, and reduce the costs of pharmaceuticals under Medicare and Medicaid. In 2020, President Trump issued several executive orders intended to lower the costs of prescription products and certain provisions in these orders have been incorporated into regulations. These regulations include an interim final rule implementing a most favored nation model for prices that would tie Medicare Part B payments for certain physician-administered pharmaceuticals to the lowest price paid in other economically advanced countries, effective January 1, 2021. That rule, however, has been subject to a nationwide preliminary injunction and, on December 29, 2021, the Centers for Medicare & Medicaid Services (“CMS”) issued a final rule to rescind it. With issuance of this rule, CMS stated that it will explore all options to incorporate value into payments for Medicare Part B pharmaceuticals and improve beneficiaries’ access to evidence-based care.

In addition, in October 2020, the Department of Health and Human Services (“HHS”) and the FDA published a final rule allowing states and other entities to develop a Section 804 Importation Program (“SIP”) to import certain prescription drugs from Canada into the United States. The final rule is currently the subject of ongoing litigation, but at least six states (Vermont, Colorado, Florida, Maine, New Mexico, and New Hampshire) have passed laws allowing for the importation of drugs from Canada with the intent of developing SIPs for review and approval by the FDA. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The final rule would eliminate the current safe harbor for Medicare drug rebates and create new safe harbors for beneficiary point-of-sale discounts and pharmacy benefit manager (“PBM”) service fees. It originally was set to go into effect on January 1, 2022, but with passage of the Inflation Reduction Act (“IRA”), has been delayed by Congress to January 1, 2032.

More recently, on August 16, 2022, the IRA was signed into law by President Biden. The new legislation has implications for Medicare Part D, which is a program available to individuals who are entitled to Medicare Part A or enrolled in Medicare Part B to give them the option of paying a monthly premium for outpatient prescription drug coverage. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap;



## [Table of Contents](#)

imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years.

Specifically, with respect to price negotiations, Congress authorized Medicare to negotiate lower prices for certain costly single-source drug and biologic products that do not have competing generics or biosimilars and are reimbursed under Medicare Part B and Part D. CMS may negotiate prices for ten high-cost drugs paid for by Medicare Part D starting in 2026, followed by 15 Part D drugs in 2027, 15 Part B or Part D drugs in 2028, and 20 Part B or Part D drugs in 2029 and beyond. This provision applies to drug products that have been approved for at least 9 years and biologics that have been licensed for 13 years, but it does not apply to drugs and biologics that have been approved for a single rare disease or condition. Nonetheless, since CMS may establish a maximum price for these products in price negotiations, Infinity would be fully at risk of government action if its products are the subject of Medicare price negotiations. Moreover, given the risk that could be the case, these provisions of the IRA may also further heighten the risk that Infinity would not be able to achieve the expected return on its drug products or full value of its patents protecting its products if prices are set after such products have been on the market for nine years.

Further, the legislation subjects drug manufacturers to civil monetary penalties and a potential excise tax for failing to comply with the legislation by offering a price that is not equal to or less than the negotiated “maximum fair price” under the law or for taking price increases that exceed inflation. The legislation also requires manufacturers to pay rebates for drugs in Medicare Part D whose price increases exceed inflation. The new law also caps Medicare out-of-pocket drug costs at an estimated \$4,000 a year in 2024 and, thereafter beginning in 2025, at \$2,000 a year. In addition, the IRA potentially raises legal risks with respect to individuals participating in a Medicare Part D prescription drug plan who may experience a gap in coverage if they required coverage above their initial annual coverage limit before they reached the higher threshold, or catastrophic period of the plan. Individuals requiring services exceeding the initial annual coverage limit and below the catastrophic period, must pay 100% of the cost of their prescriptions until they reach the catastrophic period. Among other things, the IRA contains many provisions aimed at reducing this financial burden on individuals by reducing the co-insurance and co-payment costs, expanding eligibility for lower income subsidy plans, and price caps on annual out-of-pocket expenses, each of which could have potential pricing and reporting implications.

Accordingly, while it is currently unclear how the IRA will be effectuated, Infinity cannot predict with certainty what impact any federal or state health reforms will have on it, but such changes could impose new or more stringent regulatory requirements on its activities or result in reduced reimbursement for its products, any of which could adversely affect its business, results of operations and financial condition.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care organizations and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for Infinity’s products, once approved, or put pressure on its product pricing. Infinity expects that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for its product candidates or additional pricing pressures.

In the European Union, similar political, economic and regulatory developments may affect Infinity’s ability to profitably commercialize its product candidates, if approved. In markets outside of the United States and the European Union, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. In some countries, particularly the



## Table of Contents

countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, Infinity may be required to conduct a clinical trial that compares the cost-effectiveness of its product candidate to other available therapies. If reimbursement of Infinity's products are unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, its business could be harmed, possibly materially.

***Infinity is subject to U.S. and foreign anti-corruption and anti-money laundering laws with respect to its operations and non-compliance with such laws can subject it to criminal and/or civil liability and harm its business.***

Infinity is subject to the U.S. Foreign Corrupt Practices Act of 1977, as amended (the "FCPA"), the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and possibly other state and national anti-bribery and anti-money laundering laws in countries in which Infinity conducts activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, third-party intermediaries, joint venture partners and collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or benefits to recipients in the public or private sector. Infinity may have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. In addition, Infinity may engage third-party intermediaries to promote its clinical research activities abroad and/or to obtain necessary permits, licenses, and other regulatory approvals. Infinity can be held liable for the corrupt or other illegal activities of these third-party intermediaries, its employees, representatives, contractors, partners, and agents, even if Infinity does not explicitly authorize or have actual knowledge of such activities.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. The FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Infinity cannot ensure that its employees and third-party intermediaries will comply with such anti-corruption laws. Noncompliance with anti-corruption and anti-money laundering laws could subject Infinity to whistleblower complaints, investigations, sanctions, settlements, prosecution, other enforcement actions, disgorgement of profits, significant fines, damages, other civil and criminal penalties or injunctions, suspension and/or debarment from contracting with certain persons, the loss of export privileges, reputational harm, adverse media coverage, and other collateral consequences. If any subpoenas, investigations, or other enforcement actions are launched, or governmental or other sanctions are imposed, or if Infinity does not prevail in any possible civil or criminal litigation, its business, results of operations and financial condition could be materially harmed. In addition, responding to any action will likely result in a materially significant diversion of management's attention and resources and significant defense and compliance costs and other professional fees. In certain cases, enforcement authorities may even cause Infinity to appoint an independent compliance monitor which can result in added costs and administrative burdens.

Further, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order, or use of medicinal products is prohibited in the European Union. The provision of benefits or advantages to physicians is also governed by the national anti-bribery laws of European Union Member States, such as the UK Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment. Payments made to physicians in certain European Union Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization, and/or the regulatory authorities of the individual European Union Member States. These requirements are provided in the national laws, industry codes, or professional codes of conduct applicable in the European Union Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines, or imprisonment.

***Infinity is subject to governmental export and import controls that could impair its ability to compete in international markets due to licensing requirements and subject it to liability if it is not in compliance with applicable laws.***

Infinity's products and solutions are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, and various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls. Exports of Infinity's products and solutions outside of the United States must be made in compliance with these laws and regulations. If Infinity fails to comply with these laws and regulations, Infinity and certain of its employees could be subject to substantial civil or criminal penalties, including the possible loss of export or import privileges; fines, which may be imposed on Infinity and responsible employees or managers; and, in extreme cases, the incarceration of responsible employees or managers.

In addition, changes in Infinity's products or solutions or changes in applicable export or import laws and regulations may create delays in the introduction, provision, or sale of Infinity's products and solutions in international markets, prevent customers from using its products and solutions or, in some cases, prevent the export or import of its products and solutions to certain countries, governments or persons altogether. Any limitation on Infinity's ability to export, provide, or sell its products and solutions could adversely affect its business, financial condition and results of operations.

***If Infinity fails to comply with environmental, health and safety laws and regulations, Infinity could become subject to fines or penalties or incur costs that could harm its business.***

Infinity is subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. From time to time and in the future, its operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. Even if Infinity contracts with third parties for the disposal of these materials and waste products, it cannot completely eliminate the risk of contamination or injury resulting from these materials. In the event of contamination or injury resulting from the use or disposal of Infinity's hazardous materials, Infinity could be held liable for any resulting damages, and any liability could exceed its resources. Infinity also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

Infinity maintains workers' compensation insurance to cover it for costs and expenses it may incur due to injuries to its employees resulting from the use of hazardous materials, as well as other work-related injuries, but this insurance may not provide adequate coverage against potential liabilities. However, Infinity does not maintain insurance for environmental liability or toxic tort claims that may be asserted against it.

In addition, Infinity may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations may impair its research, development or production efforts. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions.

***Infinity's internal computer systems, or those of any collaborators or contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of its product development programs.***

Despite the implementation of security measures and certain data recovery measures, Infinity's internal computer systems and those of third parties with which Infinity contracts are vulnerable to damage from cyber-attacks, computer viruses, unauthorized access, sabotage, natural disasters, terrorism, war, and telecommunication and electrical failures. Any system failure, accident or security breach that causes interruptions in Infinity's operations, for Infinity or those third parties with which it contracts, could result in a material disruption of Infinity's product development programs and business operations, in addition to possibly requiring substantial expenditures of resources to remedy. For example, the loss of clinical trial data from completed clinical trials could result in delays in Infinity's regulatory approval efforts and significantly increase its costs to recover or

## Table of Contents

reproduce the data. To the extent that any disruption or security breach results in a loss of, or damage to, Infinity data or applications, or inappropriate disclosure of confidential or proprietary information, Infinity may incur liabilities and the further development of eGanelisib, or any future product candidates it may develop, may be delayed. In addition, Infinity may not have adequate insurance coverage to provide compensation for any losses associated with such events.

Infinity could be subject to risks caused by misappropriation, misuse, leakage, falsification or intentional or accidental release or loss of information maintained in the information systems and networks of Infinity, including personal information of its employees. In addition, outside parties may attempt to penetrate Infinity's systems or those of its vendors or fraudulently induce its employees or employees of Infinity's vendors to disclose sensitive information to gain access to its data. Like other companies, Infinity may experience threats to its data and systems, including malicious codes and viruses, and other cyber-attacks. The number and complexity of these threats continue to increase over time. If a material breach of Infinity security or that of its vendors occurs, the market perception of the effectiveness of Infinity's security measures could be harmed, Infinity could lose business and its reputation and credibility could be damaged. Infinity could be required to expend significant amounts of money and other resources to repair or replace information systems or networks. Although Infinity develops and maintains systems and controls designed to prevent these events from occurring, and has a process to identify and mitigate threats, the development and maintenance of these systems, controls and processes is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become more sophisticated. Moreover, despite Infinity's efforts, the possibility of these events occurring cannot be eliminated entirely.

***Compliance with global privacy and data security requirements could result in additional costs and liabilities to Infinity or inhibit its ability to collect and process data globally, and the failure to comply with such requirements could have a material adverse effect on Infinity's business, financial condition or results of operations.***

The regulatory framework for the collection, use, safeguarding, sharing, transfer and other processing of information worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. Globally, virtually every jurisdiction in which Infinity operates has established its own data security and privacy frameworks with which Infinity must comply. For example, the European Union's General Data Protection Regulation 2016/679 (the "GDPR") imposes strict obligations on the processing of personal data, including personal health data, and the free movement of such data. The GDPR applies to any company established in the European Union as well as any company outside the European Union that processes personal data in connection with the offering of goods or services to individuals in the European Union or the monitoring of their behavior. The GDPR enhances data protection obligations for processors and controllers of personal data, including, for example, obligations relating to: processing health and other sensitive data; obtaining consent of individuals; providing notice to individuals regarding data processing activities; responding to data subject requests; taking certain measures when engaging third-party processors; notifying data subjects and regulators of data breaches; implementing safeguards to protect the security and confidentiality of personal data; and transferring personal data to countries outside the European Union, including the United States. The GDPR imposes additional obligations and risks upon Infinity's business and substantially increases the penalties to which it could be subject in the event of any non-compliance, including fines of up to €20 million or 4% of total worldwide annual turnover, whichever is higher. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies and obtain compensation for damages. In July 2020, the Court of Justice of the European Union (the "CJEU") invalidated the EU-U.S. Privacy Shield, one of the mechanisms used to legitimize the transfer of personal data from the European Economic Area (the "EEA") to the U.S. The CJEU decision also drew into question the long-term viability of an alternative means of data transfer, the standard contractual clauses, for transfers of personal data from the EEA to the U.S. While Infinity is not self-certified under the Privacy Shield, this CJEU decision may lead to increased scrutiny on data transfers from the EEA to the U.S. generally and increase Infinity's costs of compliance with data privacy legislation as well as Infinity's costs of negotiating appropriate privacy and security agreements with its vendors and business partners. Additionally, in October 2022, President Joe Biden signed an executive order to

implement the EU-U.S. Data Privacy Framework, which would serve as a replacement to the EU-US Privacy Shield. The EC initiated the process to adopt an adequacy decision for the EU-US Data Privacy Framework in December 2022. It is unclear if and when the framework will be finalized and whether it will be challenged in court. The uncertainty around this issue may further impact Infinity's business operations in the EU.

Given the breadth and depth of changes in data protection obligations, preparing for and complying with the GDPR's requirements has required and will continue to require significant time, resources and a review of Infinity's technologies, systems and practices, as well as those of any third-party collaborators, service providers, contractors or consultants that process or transfer personal data collected in the European Union. The GDPR and other changes in laws or regulations associated with the enhanced protection of certain types of sensitive data, such as health care data or other personal information from clinical trials, could require Infinity to change its business practices or lead to government enforcement actions, private litigation or significant fines and penalties against it, reputational harm and could have a material adverse effect on Infinity's business, financial condition or results of operations.

***Infinity's employees may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements, which could cause significant liability for Infinity and harm its reputation.***

Infinity is exposed to the risk of employee fraud or other misconduct, including intentional failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, provide accurate information to the FDA or comparable foreign regulatory authorities, comply with manufacturing standards it has established, comply with federal and state health care fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, report financial information or data accurately or disclose unauthorized activities to Infinity. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to Infinity's reputation. It is not always possible to identify and deter employee misconduct, and the precautions Infinity takes to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting it from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws, standards or regulations. If any such actions are instituted against Infinity, and it is not successful in defending itself or asserting its rights, those actions could have a significant impact on its business and results of operations, including the imposition of significant fines or other sanctions.

#### **Risks Related to Employee Matters and Managing Potential Future Growth**

***If Infinity is not able to retain key personnel and advisors, it may not be able to operate its business successfully.***

Infinity is highly dependent on its executive leadership team. All of these individuals are employees-at-will, which means that neither Infinity nor the employee is obligated to a fixed term of service and that the employment relationship may be terminated by either Infinity or the employee at any time, without notice and whether or not cause or good reason exists for such termination. The loss of the services of any of these individuals might impede the achievement of Infinity's research, development and commercialization objectives. Infinity does not maintain "key person" insurance on any of its employees. Infinity's planned Merger with MEI creates additional risk that its key personnel may explore other opportunities outside of Infinity.

Retaining qualified scientific and business personnel is also critical to Infinity's success. Infinity's industry has experienced a high rate of turnover of management personnel in recent years. If Infinity loses one or more of its executive officers or other key employees, its ability to implement its business strategy successfully could be seriously harmed. This competition is particularly intense near Infinity's headquarters in Cambridge, Massachusetts. Infinity may not be able to attract or retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. In addition,

## [Table of Contents](#)

Infinity may face additional challenges in retaining its existing senior management and key employees for its company as its business needs change.

Infinity also experiences competition in the hiring of scientific personnel from universities and research institutions. In addition, Infinity relies on consultants and advisors, including scientific and clinical advisors, to assist it in formulating its research and development strategy. Infinity's consultants and advisors may be employed by other entities, have commitments under consulting or advisory contracts with third parties that limit their availability to Infinity, or both.

### **Risks Related to Infinity's Common Stock**

#### ***Infinity's common stock may have a volatile trading price and low trading volume.***

The market price of Infinity's common stock has been and Infinity expects it to continue to be subject to significant fluctuations. Some of the factors that may cause the market price of Infinity's common stock to fluctuate include:

- the results of Infinity's current and any future clinical trials of eganelisib;
- future sales of, and the trading volume in, Infinity common stock;
- the impact of the COVID-19 pandemic on the economy or Infinity's business;
- announcements regarding the timing of enrollment and data readouts from Infinity's trials, including any delays;
- announcements of strategic transactions relating to Infinity's programs or the company;
- Infinity's entry into key agreements, including those related to the acquisition or in-licensing of new programs, or the termination of key agreements, including the Takeda Agreement or the Secura Bio Agreement;
- the results and timing of regulatory reviews relating to the approval of eganelisib;
- the initiation of, material developments in, or conclusion of litigation, including but not limited to litigation to enforce or defend any of Infinity's intellectual property rights or to defend product liability claims;
- the failure of eganelisib, if approved, to achieve commercial success;
- the results of clinical trials conducted by others on drugs that would compete with eganelisib;
- the regulatory approval of drugs that would compete with eganelisib;
- issues in manufacturing eganelisib;
- the loss of executive officers or other key employees;
- changes in estimates or recommendations, or publication of inaccurate or unfavorable research about Infinity's business, by securities analysts who cover Infinity's common stock;
- future financings through the issuance of equity or debt securities or otherwise;
- health care reform measures, including changes in the structure of health care payment systems;
- Infinity's cash position and period-to-period fluctuations in Infinity's financial results; and
- general and industry-specific economic and/or capital market conditions.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of Infinity's common stock.

In the past, when the market price of a stock has been volatile, as Infinity's stock price may be, holders of that stock have occasionally brought securities class action litigation against the company that issued the stock. If any

## Table of Contents

of Infinity's stockholders were to bring a lawsuit of this type against Infinity, even if the lawsuit is without merit, negative publicity could be generated, and Infinity could incur substantial costs defending the lawsuit. A stockholder lawsuit could also divert the time and attention of Infinity's management.

***Infinity does not currently meet the requirements for continued listing on the Nasdaq Global Select Market. If Infinity fails to regain compliance with such requirements, its common stock could be delisted from trading, which would decrease the liquidity of Infinity's common stock and Infinity's ability to raise additional capital.***

Infinity's common stock is currently listed on the Nasdaq Global Select Market. Infinity is required to meet specified requirements in order to maintain its listing on the Nasdaq Global Select Market, including, among other things, a minimum bid price of \$1.00 per share (the "Minimum Bid Price") under Nasdaq Listing Rule 5450(a)(1) (the "Minimum Bid Requirement") and a minimum market value of listed securities of \$50,000,000 under Nasdaq Listing Rule 5450(b)(2)(A), or the Minimum MVLS Requirement. On December 28, 2022, Infinity received a deficiency letter (the "December 2022 Bid Price Notice") from the Listing Qualifications Department of the Nasdaq Stock Market, LLC ("Nasdaq"), notifying Infinity that, for the last 30 consecutive business days, the bid price for its common stock was below the Minimum Bid Price required to maintain continued listing on the Nasdaq Global Select Market. The December 2022 Bid Price Notice has no immediate effect on the listing of Infinity's common stock. Infinity has 180 calendar days, or until June 26, 2023, to regain compliance with the Minimum Bid Requirement. If at any time during this 180-day period the closing bid price of Infinity's common stock is at least \$1.00 per share for a minimum of ten consecutive business days, Nasdaq will provide Infinity written confirmation of compliance and the Minimum Bid Requirement matter will be closed. If Infinity fails to satisfy this requirement within the initial 180 calendar day period, it may be eligible for an additional 180 calendar day compliance period if it submits an application to transfer to the Nasdaq Capital Market, then meets specified continued and initial listing standards for the Nasdaq Capital Market and provides written notice of its intention to cure the deficiency during the second compliance period by effecting a reverse stock split if necessary. However, there can be no assurance that Infinity can satisfy all of the requirements to secure such additional compliance period, including without limitation the continued and initial listing standards for the Nasdaq Capital Market, or that it will be able to regain compliance with the Minimum Bid Requirement, or that it can maintain compliance with the other listing requirements even if it successfully transfers to the Nasdaq Capital Market. Infinity currently does not satisfy various specified requirements for listing on the Nasdaq Capital Market.

Even if Infinity successfully transfers to the Nasdaq Capital Market on June 26, 2023, a transfer of Infinity's listing to the Nasdaq Capital Market could adversely affect the liquidity of its common stock. Any such event could make it more difficult to dispose of, or obtain accurate quotations for the price of, Infinity's common stock, and there also would likely be a reduction in its coverage by securities analysts and the news media, which could cause the price of Infinity's common stock to decline further. Infinity may also face other material adverse consequences in such event, such as negative publicity, a decreased ability to obtain additional financing, diminished investor and/or employee confidence, and the loss of business development opportunities, some or all of which may contribute to a further decline in Infinity's stock price.

If Infinity does not regain compliance with the Minimum Bid Requirement by June 26, 2023, and it does not meet the requirements to transfer to the Nasdaq Capital Market at that time, then it will receive written notification that its securities are subject to delisting. At that time, Infinity may appeal the Staff's delisting determination to a Nasdaq Listing Qualifications Panel pursuant to procedures set forth in the applicable Nasdaq Listing Rules.

In addition, on April 4, 2023, Infinity received a deficiency letter (the "April 2023 MVLS Notice") from the Listing Qualifications Department of Nasdaq notifying Infinity that the listing of its common stock was not in compliance with the Minimum MVLS Requirement for the previous 30 consecutive business days required to maintain continued listing on the Nasdaq Global Select Market. The Staff also noted in the April 2023 MVLS Notice that Infinity is not in compliance with Nasdaq Listing Rule 5450(b)(3)(A), which requires listed companies to have total assets and total revenue of at least \$50,000,000 each for the most recently completed

## [Table of Contents](#)

fiscal year or for two of the three most recently completed fiscal years. The April 2023 MVLS Notice has no immediate effect on the listing of Infinity's common stock. Infinity has 180 calendar days, or until October 2, 2023, to regain compliance with the Minimum MVLS Requirement (assuming it has theretofore resolved the Minimum Bid Requirement described in the prior paragraph). If, at any time before October 2, 2023 (assuming it has theretofore resolved the Minimum Bid Requirement described in the prior paragraph), the market value of Infinity's listed securities closes at \$50,000,000 or more for a minimum of ten consecutive business days, the Staff will provide written notification to Infinity that it has regained compliance with the Minimum MVLS Requirement and this matter will be closed. If Infinity does not regain compliance with the Minimum MVLS Requirement by October 2, 2023 (assuming it has theretofore resolved the Minimum Bid Requirement described in the prior paragraph), it will receive written notification that its securities are subject to delisting. At that time, Infinity may appeal the Staff's delisting determination to a Nasdaq Listing Qualifications Panel pursuant to the procedures set forth in the applicable Nasdaq Listing Rules.

***The estimates and judgments Infinity makes, or the assumptions on which it relies, in preparing its consolidated financial statements could prove inaccurate.***

Infinity's consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these consolidated financial statements requires Infinity to make estimates and judgments that affect the reported amounts of its assets, liabilities, revenues and expenses. Such estimates and judgments include those related to revenue recognition, impairment of long-lived assets, accrued expenses, assumptions in the valuation of stock-based compensation and income taxes. Infinity bases its estimates and judgments on historical experience, facts and circumstances known to it and on various assumptions that it believes to be reasonable under the circumstances. These estimates and judgments, or the assumptions underlying them, may change over time or prove inaccurate. If this is the case, Infinity may be required to restate its financial statements, which could in turn subject Infinity to securities class action litigation. Defending against such potential litigation relating to a restatement of its financial statements would be expensive and would require significant attention and resources of Infinity's management. Moreover, Infinity's insurance to cover its obligations with respect to the ultimate resolution of any such litigation may be inadequate. As a result of these factors, any such potential litigation could have a material adverse effect on Infinity's financial results and cause its stock price to decline.

***If Infinity is not able to maintain effective internal control under Section 404 of the Sarbanes-Oxley Act, its business and stock price could be adversely affected.***

Section 404 of the Sarbanes-Oxley Act of 2002 requires Infinity, on an annual basis, to review and evaluate its internal control. Any failure by Infinity to maintain the effectiveness of its internal control in accordance with the requirements of Section 404 of the Sarbanes-Oxley Act, which could be impacted by employee turnover, as such requirements exist today or may be modified, supplemented or amended in the future, could have a material adverse effect on Infinity's business, operating results and stock price.

***Infinity might not be able to utilize a significant portion of its net operating loss carryforwards and research and development tax credit carryforwards.***

Infinity has incurred significant net losses since its inception and cannot guarantee when, if ever, it will become profitable. Unused net operating loss and tax credit carryforwards will carry forward to offset future taxable income, subject to applicable limitations on the use of those losses. Federal net operating losses incurred in taxable years ending on or before December 31, 2017, are eligible to be carried forward for up to 20 years, and to be deducted in full against income for the years to which they may be carried. Federal net operating losses incurred in taxable years ending after December 31, 2017, are eligible to be carried forward indefinitely, but may offset no more than 80% of the taxable income for the years to which they are carried (computed without regard to the deduction for carryovers of net operating losses). To the extent they expire unused, these net operating loss and tax credit carryforwards will not be available to offset future income tax liabilities.



## [Table of Contents](#)

In addition, under Sections 382 and 383 of the Code, and corresponding provisions of state law, if a corporation undergoes an “ownership change,” which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation’s ability to use its pre-change net operating loss and credit carryovers to reduce its tax liability for post-change periods may be limited. Infinity has had ownership changes in the past, expects to experience an ownership change in connection with the Merger, and may experience future ownership changes as a result of subsequent shifts in its stock ownership, some of which may be outside of its control. As a result, Infinity’s ability to use its historical net operating loss and tax credit carryovers to offset future income tax liabilities is limited by prior ownership changes and may become limited by additional ownership changes in the future. In addition, Infinity has not conducted a detailed study to document whether its historical activities qualify to support the research and development credits currently claimed as a carryover. A detailed study could result in adjustment to Infinity’s research and development credit carryovers which adjustment could adversely impact its use of those attributes to offset future income tax liabilities.

### ***Changes in tax laws or in their implementation could adversely affect Infinity’s business and financial condition.***

Changes in tax law may adversely affect Infinity’s business or financial condition. The TCJA, as amended by the Coronavirus Aid, Relief, and Economic Security Act (the “CARES Act”), among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21% and limitation of the deduction for net operating losses to 80% of current year taxable income for losses arising in taxable years beginning after December 31, 2017 (though any such net operating losses may be carried forward indefinitely). In addition, beginning in 2022, the TCJA eliminates the option to deduct research and development expenditures currently and requires corporations to capitalize and amortize them over five years.

In addition to the CARES Act, as part of Congress’ response to the COVID-19 pandemic, economic relief legislation was enacted in 2020 and 2021 containing tax provisions. The IRA, which was signed into law in August 2022, also introduced new tax provisions, including a one percent excise tax imposed on certain stock repurchases by publicly traded corporations. The one percent excise tax generally applies to any acquisition of stock by the publicly traded corporation (or certain of its affiliates) from a stockholder of the corporation in exchange for money or other property (other than stock of the corporation itself), subject to a de minimis exception. Thus, the excise tax could apply to certain transactions that are not traditional stock repurchases.

Regulatory guidance under the TCJA, the IRA, and additional legislation is and continues to be forthcoming, and such guidance could ultimately increase or lessen their impact on Infinity’s business and financial condition. In addition, it is uncertain if and to what extent various states will conform to the TCJA, the IRA and additional tax legislation.

### ***Infinity’s effective tax rate may fluctuate, and it may incur obligations in tax jurisdictions in excess of accrued amounts.***

Infinity’s effective tax rate may be different than experienced in the past due to numerous factors, including as a result of applying the provisions of the TCJA (as such provisions may be elaborated on or further developed in guidance, regulations and technical corrections pertaining to the TCJA), changes in the mix of Infinity’s profitability apportioned to tax jurisdictions in which it may operate, the results of examinations and audits of its tax filings, its inability to secure or sustain acceptable agreements with tax authorities, changes in accounting for income taxes and changes in tax laws. Any of these factors could cause Infinity to experience an effective tax rate significantly different from previous periods or its current expectations and may result in tax obligations in excess of amounts accrued in its financial statements.



## Table of Contents

### ***Because Infinity does not anticipate paying cash dividends, stock price appreciation, if any, will be Infinity's stockholders' sole return on investment.***

Infinity anticipates retaining any future earnings for reinvestment in the infrastructure and personnel necessary to support its development and potential commercialization efforts. Therefore, Infinity does not anticipate paying cash dividends in the future. As a result, only appreciation of the price of its common stock will provide a return to stockholders. Investors seeking cash dividends should not invest in Infinity common stock.

### ***Inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of Infinity's business may rely, which could negatively impact its business.***

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which Infinity's operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect Infinity's business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical employees and stop critical activities and it is possible that the government may shutdown again. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process Infinity's regulatory submissions, which could have a material adverse effect on its business. Further, future government shutdowns could impact Infinity's ability to access the public markets and obtain necessary capital in order to properly capitalize and continue its operations.

### ***Anti-takeover provisions in Infinity's organizational documents and Delaware law may make an acquisition of Infinity difficult.***

Infinity is incorporated in Delaware. Anti-takeover provisions of Delaware law and Infinity's organizational documents may make a change in control more difficult. Also, under Delaware law, Infinity's board of directors may adopt additional anti-takeover measures. For example, Infinity's charter authorizes Infinity's board of directors to issue up to 1,000,000 shares of undesignated preferred stock and to determine the terms of those shares of stock without any further action by Infinity stockholders. If Infinity's board of directors exercises this power, it could be more difficult for a third party to acquire a majority of Infinity's outstanding voting stock. Infinity's charter and Infinity's Amended and Restated Bylaws (the "Infinity Bylaws") also contain provisions limiting the ability of stockholders to call special meetings of stockholders.

Infinity's stock incentive plan generally permits Infinity's board of directors to provide for acceleration of vesting of options granted under that plan in the event of certain transactions that result in a change of control. If Infinity's board of directors uses its authority to accelerate vesting of options, this action could make an acquisition more costly, and it could prevent an acquisition from going forward.

Moreover, because Infinity is incorporated in Delaware, Infinity is governed by the provisions of Section 203 of the DGCL statute, which generally prohibits a person who owns in excess of 15% of Infinity's outstanding voting stock from engaging in a transaction with Infinity for a period of three years after the date on which such person acquired in excess of 15% of Infinity's outstanding voting common stock, unless the transaction is approved by Infinity's board of directors and holders of at least two-thirds of Infinity's outstanding voting stock, excluding shares held by such person. The prohibition against such transactions does not apply if, among other things, prior to the time that such person became an interested stockholder, Infinity's board of directors approved the transaction in which such person acquired 15% or more of Infinity's outstanding voting stock. The existence

of the foregoing provisions could limit the price that investors might be willing to pay in the future for shares of Infinity's common stock.

***Infinity's investments are subject to risks that may cause losses and affect the liquidity of these investments.***

As of December 31, 2022, Infinity had \$38.3 million in cash and cash equivalents. Infinity historically has invested these amounts in money market funds, corporate obligations, U.S. government-sponsored enterprise obligations, and U.S. Treasury securities meeting the criteria of its investment policy, which prioritizes the preservation of Infinity's capital. Corporate obligations may include obligations issued by corporations in countries other than the United States, including some issues that have not been guaranteed by governments and government agencies. Infinity's investments are subject to general credit, liquidity, market and interest rate risks and instability in the financial markets. Infinity may realize losses in the fair value of these investments or a complete loss of these investments. In addition, should Infinity's investments cease paying or reduce the amount of interest paid to Infinity, its interest income would suffer. These market risks associated with Infinity's investment portfolio may have a material adverse effect on Infinity's financial results and the availability of cash to fund its operations.

**Risk Factors of the Combined Company**

***The failure to successfully integrate the businesses and operations of Infinity and MEI in the expected time frame may adversely affect the combined company's future results.***

Infinity and MEI have operated independently and there can be no assurances that the businesses can be integrated successfully. It is possible that the integration process could result in the loss of key Infinity or MEI employees, independent contractors, principal investigators, Clinical Research Organizations ("CROs"), consultants, vendors, and any other third parties, the disruption of our ongoing businesses, inconsistencies in standards, controls, procedures and policies, unexpected integration issues, higher than expected integration costs and an overall integration process that takes longer than originally anticipated. Specifically, the following issues, among others, must be addressed in integrating the operations of Infinity and MEI in order to realize the anticipated benefits of the Merger so the combined company performs as expected:

- combining the companies' operations and corporate functions;
- combining the businesses of Infinity and MEI and meeting the capital requirements of the combined company, in a manner that permits the combined company to achieve any cost savings or other synergies anticipated to result from the Merger, the failure of which would result in the anticipated benefits of the Merger not being realized in the time frame currently anticipated or at all;
- integrating personnel from the two companies, especially in the post-COVID-19 environment which has required many people to work remotely in many locations;
- integrating and unifying Infinity's and MEI's pipeline of product candidates in development;
- identifying and eliminating redundant and underperforming functions and assets;
- harmonizing the companies' operating practices, employee development and compensation programs, internal controls and other policies, procedures and processes;
- maintaining existing agreements with employees, independent contractors, principal investigators, CROs, consultants, vendors, and any other third parties, avoiding delays in entering into new agreements with prospective employees, independent contractors, principal investigators, CROs, consultants, vendors, and any other third parties, and leveraging relationships with such third parties for the benefit of the combined company;
- addressing possible differences in business backgrounds, corporate cultures and management philosophies;
- consolidating the companies' administrative and information technology infrastructure;
- clinical development, coordinating research, commercialization, and marketing efforts;

## Table of Contents

- coordinating geographically dispersed organizations; and
- effecting actions that may be required in connection with obtaining regulatory or other governmental approvals.

In addition, at times the attention our management may be focused on the integration of the businesses of the two companies and diverted from day-to-day business operations or other opportunities that may have been beneficial to us, which may disrupt our ongoing business.

***The market price of the combined company's common stock is expected to be volatile, and the market price of the common stock may drop following the Merger.***

The market price of the combined company's common stock following the Merger could be subject to significant fluctuations. Some of the factors that may cause the market price of the combined company's common stock to fluctuate include:

- results of clinical trials and preclinical studies of the combined company's product candidates, or those of the combined company's competitors or the combined company's existing or future collaborators;
- failure to meet or exceed financial and development projections the combined company may provide to the public;
- failure to meet or exceed the financial and development projections of the investment community;
- if the combined company does not achieve the perceived benefits of the Merger as rapidly or to the extent anticipated by financial or industry analysts;
- announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by the combined company or its competitors;
- actions taken by regulatory agencies with respect to the combined company's product candidates, clinical studies, manufacturing process or sales and marketing terms;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and the combined company's ability to obtain patent protection for its technologies;
- additions or departures of key personnel;
- significant lawsuits, including patent or stockholder litigation;
- if securities or industry analysts do not publish research or reports about the combined company's business, or if they issue adverse or misleading opinions regarding its business and stock;
- changes in the market valuations of similar companies;
- general market or macroeconomic conditions or market conditions in the pharmaceutical and biotechnology sectors;
- sales of securities by the combined company or its securityholders in the future;
- if the combined company fails to raise an adequate amount of capital to fund its operations and continued development of its product candidates;
- trading volume of the combined company's common stock;
- announcements by competitors of new commercial products, clinical progress or lack thereof, significant contracts, commercial relationships or capital commitments;
- adverse publicity relating to precision medicine product candidates, including with respect to other products in such markets;
- the introduction of technological innovations or new therapies that compete with the products and services of the combined company; and
- period-to-period fluctuations in the combined company's financial results.

## Table of Contents

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of the combined company's common stock. In addition, a recession, depression or other sustained adverse market event resulting from the spread of COVID-19 or otherwise could materially and adversely affect the combined company's business and the value of its common stock. In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against such companies. Furthermore, market volatility may lead to increased shareholder activism if the combined company experiences a market valuation that activists believe is not reflective of its intrinsic value. Activist campaigns that contest or conflict with the combined company's strategic direction or seek changes in the composition of its board of directors could have an adverse effect on its operating results and financial condition.

***MEI and Infinity have incurred and will incur substantial direct and indirect costs as a result of the Merger and the combined company will incur substantial direct and indirect costs in connection with combining the business of MEI and Infinity following the Merger.***

MEI and Infinity have incurred and will incur substantial expenses in connection with and as a result of consummating the Merger, and over a period of time following the consummation of the Merger, the combined company also expects to incur substantial expenses in connection with coordinating and, in certain cases, combining the businesses, operations, policies and procedures of MEI and Infinity. A portion of the transaction costs related to the Merger will be incurred regardless of whether the Merger is consummated. While MEI and Infinity have assumed that a certain level of transaction expenses will be incurred, factors beyond MEI's and Infinity's control could affect the total amount or the timing of these expenses. These expenses may exceed the costs historically borne by MEI and Infinity. These expenses could adversely affect the financial condition, results of operations and cash flows of the combined company following the consummation of the Merger.

***The actual financial position and results of operations of the combined company after the Merger may differ materially from the unaudited pro forma condensed combined financial information for the combined company included in this joint proxy statement/prospectus.***

The unaudited pro forma condensed combined financial information included in this joint proxy statement/prospectus is presented for informational purposes only and may not be an indication of what MEI's and/or Infinity's financial position or results of operations would have been had the Merger been consummated on the dates indicated. The unaudited pro forma condensed combined financial information has been derived from the audited and unaudited historical financial statements of Infinity and MEI and certain adjustments and assumptions regarding Infinity and MEI after giving effect to the Merger. The assets and liabilities of MEI and Infinity have been measured at fair value based on various preliminary estimates using assumptions that Infinity and MEI management believes are reasonable, utilizing information currently available. These fair value measurements can be highly subjective and the reasonable application of measurement principles may result in a range of alternative estimates using the same facts and circumstances. These estimates, which require extensive use of accounting estimates and management judgment, may be revised as additional information becomes available and as additional analyses are performed. Differences between preliminary estimates in the unaudited pro forma condensed combined financial information and the final acquisition accounting will occur and could have a material impact on the unaudited pro forma condensed combined financial information and the combined company's financial position and future results of operations.

In addition, the assumptions used in preparing the unaudited pro forma condensed combined financial information may not prove to be accurate, and other factors may affect the combined company's financial condition or results of operations following the consummation of the Merger. Any material variance from the pro forma condensed combined financial information may cause significant variations in the market price of the combined company's common stock. See "*Unaudited Pro Forma Condensed Combined Financial Information*" beginning on page 310 of this joint proxy statement/prospectus.

***Sales of shares of MEI Common Stock after the completion of the Merger may cause the market price of MEI Common Stock to fall.***

Infinity stockholders may decide not to hold the shares of MEI Common Stock they receive in the Merger and other Infinity stockholders, such as funds with limitations on the amount of stock they are permitted to hold in individual issuers, may be required to sell shares of MEI Common Stock that they receive in the Merger. Such sales, or market perception of such sales, of MEI Common Stock could result in higher than average trading volume following the Closing and may cause the market price for MEI Common Stock to decline. Such sales may take place promptly following the Merger or at other times in the future. There is no lock-up in place that would prevent institutional or larger stockholders from selling some or all of their MEI Common Stock after the close of the transaction.

***If third parties threaten to terminate, terminate or alter existing contracts or relationships with MEI or Infinity, MEI's and Infinity's respective businesses may be materially harmed.***

Infinity has contracts with customers, suppliers, vendors, landlords, licensors and other business partners which may require Infinity to obtain consents from these other parties in connection with the Merger. If these consents cannot be obtained, the combined company may suffer a loss of potential future revenues and may lose rights that are material to the business of the combined company. In addition, third parties with whom Infinity or MEI currently have relationships may terminate or otherwise reduce the scope of their relationship with either party in anticipation of the Merger. Any such disruptions could limit the combined company's ability to achieve the anticipated benefits of the Merger. The adverse effect of such disruptions could also be exacerbated by a delay in the completion of the Merger or the termination of the Merger Agreement.

***Both Infinity and MEI have operated with a loss and negative cash flows for the entirety of their existence and it is expected the combined company will have to raise significant capital in the future that could be dilutive to stockholders of the combined company.***

Both Infinity and MEI have operated with a loss and negative cash flows for the entirety of their existence. Infinity and MEI have incurred significant net operating losses in every year since inception and expect to continue to incur significant expenses and operating losses for the foreseeable future. Infinity's net losses were approximately \$44.4 million for the year ended December 31, 2022. MEI's net losses were approximately \$54.5 million for the year ended June 30, 2022 and \$6.4 million for the six months ended December 31, 2022. Based on the combined company's anticipated cash balances, it is anticipated that the combined company will have cash liquidity through mid-2025.

The combined company may not be able to raise capital to continue operations in the future which could result in bankruptcy or liquidation of the combined company. As a result, adequate funding may not be available to the combined company on acceptable terms, or at all.

***MEI and Infinity do not anticipate that the combined company will pay any cash dividends in the foreseeable future.***

The current expectation is that the combined company will retain its future earnings, if any, to fund the growth of the combined company's business as opposed to paying dividends. As a result, capital appreciation, if any, of the common stock of the combined company will be the sole source of gain, if any, for the combined company's stockholders for the foreseeable future.

***The combined company may be exposed to increased litigation, including stockholder litigation, which could have an adverse effect on the combined company's business and operations.***

The combined company may be exposed to increased litigation from stockholders, customers, suppliers, consumers and other third parties due to the combination of MEI's business and Infinity's business following the Merger. Such litigation may have an adverse impact on the combined company's business and results of

## Table of Contents

operations or may cause disruptions to the combined company's operations. In addition, in the past, stockholders have initiated class action lawsuits against biotechnology companies following periods of volatility in the market prices of these companies' stock. Such litigation, if instituted against the combined company, could cause the combined company to incur substantial costs and divert management's attention and resources, which could have a material adverse effect on the combined company's business, financial condition and results of operations.

***After completion of the Merger, the combined company's executive officers, directors and principal stockholders will have the ability to control or significantly influence all matters submitted to the combined company's stockholders for approval.***

Upon the completion of the Merger, it is anticipated that the combined company's executive officers, directors and principal stockholders will, in the aggregate, beneficially own approximately 6.7% of the combined company's outstanding shares of common stock, subject to certain assumptions disclosed elsewhere in this joint proxy statement/prospectus. As a result, if these stockholders were to choose to act together, they would be able to control or significantly influence all matters submitted to the combined company's stockholders for approval, as well as the combined company's management and affairs. For example, these persons, if they choose to act together, would control or significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of the combined company's assets. This concentration of voting power could delay or prevent an acquisition of the combined company on terms that other stockholders may desire.

***If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about the combined company, its business or its market, its stock price and trading volume could decline.***

The trading market for the combined company's common stock will be influenced by the research and reports that equity research analysts publish about it and its business. Equity research analysts may elect not to provide research coverage of the combined company's common stock after the completion of the Merger, and such lack of research coverage may adversely affect the market price of its common stock. In the event it does have equity research analyst coverage, the price of the combined company's common stock could decline if one or more equity research analysts downgrade its stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of the combined company or fails to publish reports on it regularly, demand for its common stock could decrease, which in turn could cause its stock price or trading volume to decline.

***The combined company's ability to utilize its net operating loss carryforwards and tax credit carryforwards may be subject to limitations.***

The combined company's ability to use its federal and state net operating losses ("NOLs") to offset potential future taxable income and related income taxes that would otherwise be due is dependent upon the combined company's generation of future taxable income, and MEI and Infinity cannot predict with certainty when, or whether, the combined company will generate sufficient taxable income to use all of its NOLs. In addition, under Sections 382 and 383 of the Code, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation's ability to use its pre-change net operating loss and credit carryovers to reduce its tax liability for post-change periods may be limited. MEI and Infinity have experienced such ownership changes in the past, and expect that the Merger, if completed, will result in an ownership change of Infinity. The combined company may experience additional ownership changes in the future due to subsequent shifts in its stock ownership (some of which are outside of its control). Consequently, even if the combined company achieves profitability, it may not be able to utilize a material portion of MEI's, Infinity's, or the combined company's NOL carryforwards and other tax attributes, which could have a material adverse effect on cash flow and results of operations. Similar provisions of state tax law may also apply to limit the combined company's use of accumulated state tax attributes. There is also a risk that due to regulatory changes, such as

## Table of Contents

suspensions on the use of NOLs, or other unforeseen reasons, the combined company's existing NOLs could expire or otherwise be unavailable to offset future income tax liabilities.

***If and when the combined company is no longer a smaller reporting company or otherwise no longer qualifies for applicable exemptions, the combined company will be subject to additional laws and regulations affecting public companies that will increase the combined company's costs and the demands on management and could harm the combined company's operating results.***

The combined company will be subject to the reporting requirements of the Exchange Act, which requires, among other things, that the combined company file with the SEC, annual, quarterly and current reports with respect to the combined company's business and financial condition as well as other disclosure and corporate governance requirements. However, as a "smaller reporting company," the combined company may take advantage of some exemptions from disclosure requirements including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002 and reduced disclosure obligations regarding executive compensation in the combined company's periodic reports and proxy statements. Once the combined company is no longer a smaller reporting company or otherwise qualifies for these exemptions, the combined company will be required to comply with these additional legal and regulatory requirements applicable to public companies and will incur significant legal, accounting and other expenses to do so. If the combined company is not able to comply with the requirements in a timely manner or at all, the combined company's financial condition or the market price of the combined company's common stock may be harmed. For example, if the combined company or its independent auditor identifies deficiencies in the combined company's internal control over financial reporting that are deemed to be material weaknesses, the combined company could face additional costs to remedy those deficiencies, the market price of the combined company's stock could decline or the combined company could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources.

***The combined company will have broad discretion in the use of the cash and cash equivalents of the combined company and may invest or spend the proceeds in ways with which you do not agree and in ways that may not increase the value of your investment.***

The combined company will have broad discretion over the use of the cash and cash equivalents of the combined company. You may not agree with the combined company's decisions, and its use of the proceeds may not yield any return on your investment. The combined company's failure to apply these resources effectively could compromise its ability to pursue its growth strategy and the combined company might not be able to yield a significant return, if any, on its investment of these net proceeds. You will not have the opportunity to influence its decisions on how to use the combined company's cash resources.

### **Risks Related to the Merger**

***The Exchange Ratio will not be adjusted based on the market price of MEI Common Stock or Infinity Common Stock, so the merger consideration at the Closing may have a greater or lesser value than at the time the Merger Agreement was signed.***

At the Effective Time, outstanding Infinity Common Stock will be converted into shares of MEI Common Stock. Applying the Exchange Ratio, the former Infinity stockholders immediately before the Merger are expected to own approximately 42% of the outstanding equity of the combined company immediately following the Merger, and MEI stockholders immediately before the Merger are expected to own approximately 58% of the outstanding equity of the combined company immediately following the Merger, subject to certain assumptions.

The number of shares Infinity stockholders will be entitled to receive pursuant to the Merger Agreement will not be affected by changes in the market price of MEI Common Stock or Infinity Common Stock before the completion of the Merger. Therefore, if before the completion of the Merger, the market price of MEI Common Stock increases from the market price on the date of the Merger Agreement and/or the market price of Infinity Common Stock declines from the market price on the date of the Merger Agreement, then Infinity



## [Table of Contents](#)

stockholders could receive merger consideration with substantially more value for their Infinity Common Stock than the parties had negotiated when they established the Exchange Ratio. Similarly, if before the completion of the Merger the market price of MEI Common Stock declines from the market price on the date of the Merger Agreement and/or the market price of Infinity Common Stock increases from the market price on the date of the Merger Agreement, then Infinity stockholders could receive merger consideration with substantially lower value. The Merger Agreement does not include a price-based termination right.

### ***If the conditions to the Merger are not satisfied or waived, the Merger may not occur.***

Even if the Infinity stockholders adopt the Merger Agreement and approve the Infinity Merger Proposal and the MEI stockholders approve the MEI Nasdaq Proposal, specified conditions must be satisfied or waived to complete the Merger. These conditions are set forth in the Merger Agreement and described in the section titled “*The Merger Agreement—Conditions to the Completion of the Merger*” beginning on page 184 of this joint proxy statement/prospectus. MEI and Infinity cannot assure you that all of the conditions to the consummation of the Merger will be satisfied or waived. If the conditions are not satisfied or waived, the Merger may not occur or the Closing may be delayed, and MEI and Infinity each may lose some or all of the intended benefits of the Merger.

### ***The Merger may be completed even though a material adverse effect may result from the announcement of the Merger, industry wide changes or other causes.***

In general, neither MEI nor Infinity is obligated to complete the Merger if there is a continuing material adverse effect affecting the other party between February 22, 2023, the date of the Merger Agreement, and the Closing. However, certain types of changes are excluded from the concept of a “material adverse effect.” Such exclusions include, but are not limited to, changes in general business or economic conditions that generally affect the industry, political conditions, acts of war or terrorism or the outbreak or escalation of armed hostilities, natural disasters, epidemics and pandemics, certain measures and responses with respect to COVID-19, changes in laws or U.S. GAAP, certain changes in the price or trading volume of MEI Common Stock or Infinity Common Stock, certain failures by MEI or Infinity to meet internal or analysts’ expectations or projections or the results of operations, and changes resulting from the announcement, performance or pendency of the Merger. Therefore, if any of these events were to occur, impacting MEI or Infinity, the other party would still be obliged to consummate the closing of the Merger. If any such adverse changes occur and MEI and Infinity consummate the closing of the Merger, the stock price of the combined company may suffer. This in turn may reduce the value of the Merger to the stockholders of MEI, Infinity or both. For a more complete discussion of what constitutes a material adverse effect on MEI or Infinity, see the section titled “*The Merger Agreement—Representations and Warranties*” beginning on page 186 of this joint proxy statement/prospectus.

### ***If MEI and Infinity complete the Merger, the combined company may need to raise additional capital by issuing equity securities or additional debt or through licensing arrangements, which may cause significant dilution to the combined company’s stockholders or restrict the combined company’s operations.***

Additional financing may not be available to the combined company when it is needed or may not be available on favorable terms. To the extent that the combined company raises additional capital by issuing equity securities, such financing will cause additional dilution to all securityholders of the combined company, including MEI’s pre-Merger stockholders and Infinity’s former stockholders. It is also possible that the terms of any new equity securities may have preferences over the combined company’s common stock. Any debt financing the combined company enters into may involve covenants that restrict its operations. These restrictive covenants may include limitations on additional borrowing and specific restrictions on the use of the combined company’s assets, as well as prohibitions on its ability to create liens, pay dividends, redeem its stock or make investments. In addition, if the combined company raises additional funds through licensing arrangements, it may be necessary to grant licenses on terms that are not favorable to the combined company.

## Table of Contents

***MEI and Infinity directors and executive officers have interests in the Merger that are different from yours and that may influence them to support or approve the Merger without regard to your interests.***

Directors and executive officers of MEI and Infinity have interests in the Merger that are different from, or in addition to, the interests of other MEI and Infinity stockholders generally. These interests with respect to MEI's directors and executive officers may include, among others, that Daniel P. Gold, Ph.D., Charles V. Baltic III, Thomas C. Reynolds, and Sujay R. Kango, members of the MEI board of directors, will continue as directors after the Merger. In addition, following the Closing, David Urso (currently MEI's Chief Operating Officer and General Counsel) is expected to serve as Chief Executive Officer of the combined company. These interests with respect to Infinity's directors and executive officers may include, among others, (i) the acceleration of equity award vesting, (ii) that options to purchase shares of Infinity Common Stock will be converted into and become fully vested options to purchase shares of common stock of the combined company, (iii) retention payments for continued services to and through the Closing, (iv) severance payments if employment is terminated in a qualifying termination in connection with the Merger and (v) all of Infinity's directors and executive officers are entitled to certain indemnification and liability insurance coverage pursuant to the terms of the Merger Agreement. In addition, following the Closing, Robert Ilaria, Jr., M.D. (currently Infinity's Chief Medical Officer) is expected to serve as Chief Medical Officer of the combined company and Stéphane Peluso, Ph.D. (currently Infinity's Chief Scientific Officer) is expected to serve as Chief Scientific Officer of the combined company.

Sujay R. Kango serves on the boards of directors of each of MEI and Infinity. The boards of directors of MEI and Infinity considered, among other things, that Mr. Kango holds stock options exercisable for shares of MEI Common Stock and Infinity Common Stock.

Further, the board of directors of the combined company will include certain current directors and executive officers of MEI and Infinity. Following the Closing, the board of directors of the combined company is expected to be composed of eight members, consisting of Norman C. Selby (currently Infinity's Lead Independent Director), who is expected to chair the combined company board, David Urso (currently MEI's Chief Operating Officer and General Counsel), Daniel P. Gold, Ph.D. (currently MEI's Chief Executive Officer), Adelene Q. Perkins (currently Infinity's Chief Executive Officer and Chair of the board of directors of Infinity), Richard Gaynor, M.D. (currently a director of Infinity), Charles V. Baltic III (currently Chair of the board of directors of MEI), Thomas C. Reynolds, M.D., Ph.D. (currently a director of MEI) and Sujay R. Kango (currently a director of MEI and Infinity). The non-employee directors of the combined company will be eligible to be compensated pursuant to the MEI non-employee director compensation policy that is expected to remain in place following the Effective Time.

The MEI and Infinity boards of directors were aware of and considered those interests, among other matters, in reaching their decisions to approve and adopt the Merger Agreement and approve the Merger, and in the case of the Infinity board of directors, recommend the approval of the Merger Agreement to Infinity's stockholders. These interests, among other factors, may have influenced the directors and executive officers of MEI and Infinity to support or approve the Merger.

For more information regarding the interests of MEI and Infinity directors and executive officers in the Merger, please see the sections titled "*The Merger—Interests of MEI Directors and Executive Officers in the Merger*" beginning on page 167 and "*The Merger—Interests of Infinity Directors and Executive Officers in the Merger*" beginning on page 167 of this joint proxy statement/prospectus.

***MEI and Infinity securityholders will have a reduced ownership and voting interest in, and will exercise less influence over the management of, the combined company following the completion of the Merger as compared to their current ownership and voting interests in the respective companies.***

Applying the Exchange Ratio, the former Infinity stockholders immediately before the Merger are expected to own approximately 42% of the outstanding equity of the combined company immediately following the Merger, and MEI stockholders immediately before the Merger are expected to own approximately 58% of the outstanding

## [Table of Contents](#)

equity of the combined company immediately following the Merger, subject to certain assumptions. If the combined company is unable to realize the full strategic and financial benefits currently anticipated from the Merger, MEI and Infinity stockholders will have experienced substantial dilution of their ownership and voting interests in the respective companies without receiving any commensurate benefit, or only receiving part of the commensurate benefit to the extent the combined company is able to realize only part of the strategic and financial benefits currently anticipated from the Merger.

### ***If the Merger is not completed, MEI's and Infinity's stock prices may fluctuate significantly.***

The market price of MEI Common Stock is subject to significant fluctuations. During the 12-month period ended April 14, 2023, the closing sales price of MEI Common Stock on The Nasdaq Capital Market ranged from a high of \$13.00 on June 27, 2022 to a low of \$4.20 on February 24, 2023. The market price of Infinity Common Stock is also subject to significant fluctuations. During the 12-month period ended April 14, 2023, the closing sales price of Infinity's Common Stock on The Nasdaq Global Select Market ranged from a high of \$1.70 on August 24, 2022, to a low of \$0.18 on April 12, 2023.

Market prices for securities of pharmaceutical, biotechnology and other life science companies have historically been particularly volatile. In addition, the market prices of MEI Common Stock and Infinity Common Stock will likely be volatile based on whether stockholders and other investors believe that MEI and Infinity can complete the Merger or otherwise raise additional capital to support the combined company's operations if the Merger is not consummated and another strategic transaction cannot be identified, negotiated and consummated in a timely manner, if at all. The volatility of the market prices of MEI Common Stock and Infinity Common Stock are exacerbated by low trading volume. Additional factors that may cause the market prices of MEI Common Stock and Infinity Common Stock, respectively, to fluctuate include:

- the initiation of, material developments in, or conclusion of litigation to enforce or defend its intellectual property rights or defend against claims involving the intellectual property rights of others;
- the entry into, or termination of, key agreements, including commercial partner agreements;
- announcements by commercial partners or competitors of new commercial products, clinical progress or lack thereof, significant contracts, commercial relationships or capital commitments;
- the introduction of technological innovations or new therapies that compete with its future products;
- the loss of key employees;
- future sales of its common stock;
- general and industry-specific economic conditions that may affect its research and development expenditures;
- the failure to meet industry analyst expectations; and
- period-to-period fluctuations in financial results.

Moreover, the stock markets in general have at times experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading prices of MEI Common Stock and Infinity Common Stock. In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against such companies.

### ***During the pendency of the Merger, MEI and Infinity may not be able to enter into a business combination with another party on more favorable terms because of restrictions in the Merger Agreement, which could adversely affect their respective business prospects.***

Covenants in the Merger Agreement impede the ability of MEI and Infinity to make acquisitions during the pendency of the Merger, subject to specified exceptions. As a result, if the Merger is not completed, the parties

## [Table of Contents](#)

may be at a disadvantage to their competitors during that period. In addition, while the Merger Agreement is in effect, each party is generally prohibited from soliciting, initiating, inducing, encouraging, or facilitating any inquiries, proposals or offers that constitute or could reasonably be expected to lead to certain transactions involving a third party, including a merger, sale of assets or other business combination, subject to specified exceptions. Any such transactions could be favorable to such party's stockholders, but the parties may be unable to pursue them. For more information, see the section titled "*The Merger Agreement—No Solicitation.*"

### ***Certain provisions of the Merger Agreement may discourage third parties from submitting competing proposals, including proposals that may be superior to the Merger.***

The terms of the Merger Agreement prohibit each of MEI and Infinity from soliciting or engaging in discussions with third parties regarding alternative acquisition proposals, except in limited circumstances when such party's board of directors determines in good faith that an unsolicited acquisition proposal constitutes or could reasonably be expected to lead to a superior proposal and that failure to take such action would reasonably be expected to be inconsistent with its fiduciary duties under applicable law, as described in further detail in the section titled "*The Merger Agreement—No Solicitation.*" In addition, if the Merger Agreement is terminated by MEI or Infinity under certain circumstances, including because of a decision by either company's board of directors to accept a superior proposal, such company would be required to pay the other a termination fee. This termination fee may discourage third parties from submitting alternative takeover proposals to either company or its stockholders and may cause such company's board of directors to be less inclined to recommend an alternative proposal.

### ***The financial analyses, estimates and forecasts presented herein and considered by MEI and Infinity in connection with the Merger may not be realized.***

The unaudited prospective financial information of MEI and Infinity presented herein and considered by MEI and Infinity in connection with the Merger was not prepared with a view toward public disclosure, and such information and the estimated synergies were not prepared with a view toward compliance with published guidelines of the SEC or the guidelines established by the American Institute of Certified Public Accountants for preparation and presentation of prospective financial information. The estimates and assumptions underlying the unaudited prospective financial information and estimated synergies involve judgments with respect to, among other things, future economic, competitive, regulatory and financial market conditions, future tax rates and future business decisions which may not be realized and that are inherently subject to significant business, economic, competitive and regulatory uncertainties and contingencies, including, among others, risks and uncertainties described under the sections titled "*Risk Factors*" and "*Cautionary Statement Concerning Forward-Looking Statements and Industry and Market Data,*" all of which are difficult to predict and many of which are beyond the control of MEI and/or Infinity. In addition, the unaudited prospective financial information and estimated synergies will be affected by MEI's or Infinity's, as applicable, ability to achieve strategic goals, objectives and targets over the applicable periods. As a result, there can be no assurance that the underlying assumptions will prove to be accurate or that the projected results or synergies will be realized, and actual results or synergies likely will differ, and may differ materially, from those reflected in the unaudited prospective financial information and the estimated synergies, whether or not the Merger is completed, which could have an adverse effect on MEI's and Infinity's business, financial condition and result of operations.

### ***The announcement and pendency of the Merger, whether or not consummated, may adversely affect the trading price of MEI Common Stock, Infinity Common Stock, and each party's business prospects.***

The announcement and pendency of the Merger, whether or not consummated, may adversely affect the trading price of MEI Common Stock, Infinity Common Stock, and each party's business prospects. In the event that the Merger is not completed, the announcement of the termination of the Merger Agreement may also adversely affect the trading price of MEI Common Stock, Infinity Common Stock, and the business prospects of the respective companies.

## Table of Contents

### ***Failure to consummate the Merger may result in either MEI or Infinity paying a termination fee to the other party and could harm the common stock price of the party obligated to pay the termination fee and such party's future business and operations.***

The Merger will not be consummated if the conditions precedent to the consummation of the transaction are not satisfied or waived, or if the Merger Agreement is terminated in accordance with its terms. If the Merger is not consummated, MEI and Infinity, as applicable, are subject to the following risks:

- if the Merger Agreement is terminated under certain circumstances, MEI may be required to pay Infinity a termination fee of \$4,000,000 and/or reimburse Infinity's reasonable out of pocket fees and expenses incurred in connection with the Merger Agreement and the transaction contemplated thereby up to a maximum of \$1,000,000;
- if the Merger Agreement is terminated under certain circumstances, Infinity may be required to pay MEI a termination fee of \$2,900,000 and/or reimburse MEI's reasonable out of pocket fees and expenses incurred in connection with the Merger Agreement and the transaction contemplated thereby up to a maximum of \$1,000,000; and
- the price of either party's common stock may decline and remain volatile.

If the Merger does not close for any reason, either party's board of directors may elect to, among other things, attempt to complete another strategic transaction, attempt to sell or otherwise dispose of such company's various assets, dissolve or liquidate its assets, declare bankruptcy or seek to continue to operate its business. If either company seeks another strategic transaction or attempts to sell or otherwise dispose of its various assets, there is no assurance that it will be able to do so, that the terms would be equal to or superior to the terms of the Merger or as to the timing of such transaction. If either company decides to dissolve and liquidates its assets, such company would be required to pay all of its debts and contractual obligations, and to set aside certain reserves for potential future claims, and there can be no assurance as to the amount or timing of available cash left to distribute to stockholders after paying its debts and other obligations and setting aside funds for reserves.

### ***If the Merger is not consummated, each of MEI and Infinity would need to determine whether to continue its business, consummate another strategic transaction, or dissolve and liquidate its assets.***

If the Merger is not consummated, MEI and Infinity, as applicable, may be unable to retain the services of key remaining members of its management teams and, as a result, may be unable to seek or consummate another strategic transaction, properly dissolve and liquidate its assets or continue its business. If the Merger is not successfully consummated, the boards of directors of MEI and Infinity may dissolve or liquidate the respective company's assets to pursue a dissolution and liquidation. In such an event, the amount of cash available for distribution to MEI's or Infinity's stockholders, as applicable, will depend heavily on the timing of such transaction or liquidation.

If the Merger does not close for any reason, the board of directors of Infinity may elect to, among other things, dissolve or liquidate its assets, which may include seeking protection from creditors in a bankruptcy proceeding. If Infinity decided to dissolve and liquidate its assets, it would be required to pay all of its debts and contractual obligations, and to set aside certain reserves for potential future claims, and there can be no assurances as to the amount or timing of available cash left to distribute to stockholders after paying its debts and other obligations and setting aside funds for reserves.

In the event of a dissolution and liquidation, the amount of cash available for distribution to MEI's stockholders or Infinity's stockholders, as applicable, will depend heavily on the timing of such decision and, ultimately, such liquidation, since the amount of cash available for distribution continues to decrease as MEI or Infinity, as applicable, fund its operations in preparation for the consummation of the Merger. Further, the Merger Agreement contains certain termination rights for each party, and provides that, upon termination under specified circumstances, either party may be required to pay the other a termination fee, which would further decrease such company's available cash resources. If either party's board of directors were to approve and recommend, and its stockholders were to approve, a dissolution and liquidation, such company would be required under Delaware

corporate law to pay its outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to its stockholders. As applicable, MEI's and Infinity's commitments and contingent liabilities may include (i) regulatory and clinical obligations remaining under its clinical trials; (ii) obligations under its employment, separation and retention agreements with certain employees that provide for severance and other payments following a termination of employment occurring for various reasons, including a change in control; and (iii) potential litigation against such company, and other various claims and legal actions arising in the ordinary course of business. As a result of this requirement, a portion of MEI's assets and Infinity's assets, as applicable, may need to be reserved pending the resolution of such obligations. In addition, either company may be subject to litigation or other claims related to a dissolution and liquidation of such company. If a dissolution and liquidation were pursued, such company's board of directors, in consultation with its advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of MEI Common Stock and Infinity Common Stock, as applicable, could lose all or a significant portion of their investment in the event of its liquidation, dissolution or winding up.

***MEI or Infinity may waive one or more of the conditions to the Merger, and may do so without re-soliciting stockholder approval.***

MEI or Infinity may agree to waive, in whole or in part, some of the conditions to each party's obligations to complete the Merger, to the extent permitted by applicable law. For example, it is a condition to MEI's and Infinity's respective obligations to close the Merger that certain of the representations and warranties of the other party are true and correct in all respects as of the date of the Closing (the "Closing Date"), except where the failure of such representations and warranties to be true and correct would not have a material adverse effect. However, if the board of directors of either party determines that it is in the best interests of the stockholders of that company to waive any such breach by the other party, then such board of directors may elect to waive that condition.

In the event of a waiver of a condition, the boards of directors of MEI and Infinity will evaluate the materiality of any such waiver to determine whether amendment of this joint proxy statement/prospectus and re-solicitation of proxies is necessary. In the event that the boards of directors of the waiving party, in its own reasonable discretion, determines any such waiver is not significant enough to require re-solicitation of its stockholders, it will have the discretion to cause the Merger to be completed without seeking further stockholder approval, which decision may have a material adverse effect on the stockholders of the combined company following the Merger. For example, the market could react negatively to such information, which may cause a substantial decline in the price of the common stock of the combined company following the Merger.

Notwithstanding the foregoing, certain closing conditions may not be waived due to applicable law, or otherwise. The following closing conditions may not be waived: receipt of the requisite stockholder approvals; the effectiveness of the registration statement of which this joint proxy statement/prospectus forms a part; and the absence of any order or injunction that has the effect of prohibiting the consummation of the Merger. The foregoing closing conditions are the only closing conditions to the Merger that may not be waived. All other closing conditions to the Merger may be waived by MEI and/or Infinity, as applicable. See the section "*The Merger Agreement—Conditions to the Completion of the Merger*" for further information.

***The Merger may not qualify as a "reorganization" within the meaning of Section 368(a) of the Code, resulting in recognition of taxable gain or loss by Infinity stockholders in respect of their Infinity Common Stock.***

As discussed in the section titled "*The Merger—Material U.S. Federal Income Tax Consequences of the Merger*," the Merger is intended to qualify as a "reorganization" within the meaning of Section 368(a) Code. However, Infinity has not sought and does not intend to seek a ruling from the IRS or an opinion of counsel regarding the intended tax treatment of the Merger. Consequently, there can be no assurance that the IRS will not challenge the intended tax treatment of the Merger and, if challenged, that a court would not sustain the IRS's position. In the event that the Merger does not qualify as a "reorganization" within the meaning of Section 368(a)

of the Code, each U.S. Holder (as defined in the section titled “*The Merger—Material U.S. Federal Income Tax Consequences of the Merger*”) would recognize gain or loss upon the exchange of shares of Infinity Common Stock for MEI Common Stock in the Merger equal to the difference between the fair market value of the shares of MEI Common Stock received in exchange for the shares of Infinity Common Stock (plus any cash received in lieu of a fractional share) and such U.S. Holder’s adjusted tax basis in the shares of Infinity Common Stock surrendered. Each Infinity stockholder is urged to consult with his, her or its own tax advisor with respect to the tax consequences of the Merger.

***Lawsuits could delay or prevent the Merger.***

Putative stockholder complaints, including stockholder class action complaints, and other complaints may be threatened or filed against MEI, Infinity, and/or their respective boards of directors in connection with the transactions contemplated by the Merger Agreement. MEI, Infinity, and/or their respective boards of directors may not be successful in defending against any such claims. The outcome of litigation is uncertain, and any such lawsuits that may be threatened or filed against MEI, Infinity, and/or their respective boards of directors could delay or prevent the Merger from becoming effective or from becoming effective within the intended timeframe, divert the attention of MEI’s and/or Infinity’s management and employees from their respective day-to-day businesses and otherwise adversely affect their respective financial conditions.



## THE SPECIAL MEETING OF MEI STOCKHOLDERS

### Date, Time, and Place

The MEI Special Meeting will be held at on \_\_\_\_\_, 2023, as a virtual meeting via the Internet at \_\_\_\_\_.

On or about \_\_\_\_\_, 2023, MEI commenced mailing this joint proxy statement/prospectus and the enclosed form of proxy card to its stockholders entitled to vote at the MEI Special Meeting.

### Purposes of the MEI Special Meeting

At the MEI Special Meeting, MEI stockholders will be asked to consider and vote upon the following proposals:

**Proposal No. 1 – The MEI Nasdaq Proposal:** the proposal to approve, for purposes of Nasdaq Listing Rule 5635(a), the issuance of shares of MEI Common Stock, \$0.0000002 par value per share, to stockholders of Infinity pursuant to the terms of the Merger Agreement.

**Proposal No. 2 – The MEI Adjournment Proposal:** the proposal to approve the adjournment of the MEI Special Meeting, from time to time, if necessary or appropriate, including to solicit additional proxies in the event that there are insufficient votes at the time of the MEI Special Meeting or any adjournment or postponement thereof to approve the MEI Nasdaq Proposal.

In accordance with the MEI Bylaws and the DGCL, except as otherwise required by law, business transacted at the MEI Special Meeting will be limited to those matters set forth in the notice of the meeting.

### Recommendation of MEI’s Board of Directors

MEI’s board of directors recommends that the MEI stockholders vote “**FOR**” the MEI Nasdaq Proposal and “**FOR**” the MEI Adjournment Proposal, as required. See “*The Merger—MEI’s Reasons for the Merger; Recommendation of MEI’s Board of Directors*” beginning on page 138 of this joint proxy statement/prospectus.

Assuming a quorum is present, if you mark “**ABSTAIN**” on your proxy card or when voting by Internet or phone, fail to submit a proxy, or fail to vote at the MEI Special Meeting with respect to the MEI Nasdaq Proposal or MEI Adjournment Proposal, it will have “**NO EFFECT**” on the proposal.

### Record Date for the MEI Special Meeting and Quorum

#### MEI Record Date

Only holders of record of shares of MEI Common Stock at the close of business, Pacific Time, on \_\_\_\_\_, 2023, the MEI Record Date for the MEI Special Meeting, will be entitled to receive notice of, and to vote, at the MEI Special Meeting or any postponement or adjournment thereof. Each share of MEI Common Stock entitles the holder thereof to cast one vote on each matter that comes before the MEI Special Meeting.

As of the MEI Record Date for the MEI Special Meeting, there were \_\_\_\_\_ shares of MEI Common Stock outstanding and entitled to vote at the MEI Special Meeting.

#### Quorum

In order for business to be conducted at the MEI Special Meeting, a quorum must be present. A quorum of stockholders is necessary to hold a valid meeting. The presence, in person or by proxy, of the holders of one-third of the shares of the common stock issued and outstanding and entitled to vote, as of the close of business on the MEI Record Date, at the Special Meeting will constitute a quorum. If a quorum is not present at the Special Meeting, we expect that the meeting would be adjourned or postponed to solicit additional proxies. Abstentions and broker non-votes, if any, will be counted towards a quorum.

## Table of Contents

If you hold your shares of MEI Common Stock in a bank, broker or other nominee, your shares of MEI Common Stock will be counted toward determining whether a quorum is present only if you instruct that organization on how to vote your shares with respect to one or more of the proposals. If you do not instruct your bank, broker, or other nominee on how to vote your shares, your shares will not be included in the calculation of the number of shares of MEI Common Stock represented at the MEI Special Meeting for purposes of determining whether a quorum is present.

### **Required Vote, Abstentions and Failure to Vote**

Assuming a quorum is present, the following table presents the votes required for, and the effect of abstentions or a failure to vote on, approval of the MEI Nasdaq Proposal and the MEI Adjournment Proposal.

<u>Proposal</u>	<u>Votes Required</u>	<u>Effect of Abstentions or Failure to Vote</u>	<u>Broker-Non Votes</u>
MEI Nasdaq Proposal	The affirmative vote of a majority of votes cast by MEI stockholders entitled to vote on the proposal.	Abstentions will have “ <b>NO EFFECT</b> ” on the MEI Nasdaq Proposal.	The failure to vote your shares held in “street name” will have “ <b>NO EFFECT</b> ” on the MEI Nasdaq Proposal.
MEI Adjournment Proposal	The affirmative vote of a majority of votes cast by MEI stockholders entitled to vote on the proposal.	Abstentions will have “ <b>NO EFFECT</b> ” on the MEI Adjournment Proposal.	The failure to vote your shares held in “street name” will have “ <b>NO EFFECT</b> ” on the MEI Adjournment Proposal.

### **Voting by MEI’s Directors and Executive Officers**

As of the MEI Record Date, directors and executive officers of MEI and their affiliates owned and were entitled to vote shares of MEI Common Stock, representing approximately % of the shares of MEI Common Stock outstanding on the MEI Record Date. MEI currently expects that MEI’s directors and executive officers will vote any shares of MEI Common Stock they hold in favor of the MEI Nasdaq Proposal and, if necessary, the MEI Adjournment Proposal, although none of them has entered into any agreement obligating him or her to do so. Approval of the MEI Nasdaq Proposal and MEI Adjournment Proposal require the affirmative vote of a majority of votes cast by MEI stockholders entitled to vote on the proposal.

### **Voting of Proxies**

#### *Stockholders of Record*

If you are a stockholder of record of shares of MEI Common Stock as of the MEI Record Date, a proxy card is enclosed with this joint proxy statement/prospectus for your use. MEI requests that MEI stockholders of record submit their proxies over the Internet, by telephone or by completing and signing the accompanying proxy card and returning it promptly. Information and applicable deadlines for authorizing a proxy to vote by telephone or through the Internet are set forth on the enclosed proxy card. When the accompanying proxy card is returned properly executed, the shares of MEI Common Stock represented by it will be voted at the MEI Special Meeting or any adjournment or postponement thereof in accordance with the instructions contained in the proxy card.

If a proxy is signed and returned without an indication as to how the shares of MEI Common Stock represented by the proxy are to be voted with regard to a particular proposal, the shares of MEI Common Stock represented by the proxy will be voted in favor of each such proposal, as applicable, in accordance with the recommendation of MEI’s board of directors.

### **Beneficial Owners of Shares Held by a Bank, Broker or Other Nominee**

If you hold your shares of MEI Common Stock in a brokerage account or if your shares of MEI Common Stock are held by a bank or other nominee (that is, in “street name”), you must provide the bank, broker or other nominee that holds your shares with instructions on how to vote your shares of MEI Common Stock. Please follow the voting instructions provided by your bank, broker, or other nominee. Please note that you are not permitted to vote shares of MEI Common Stock held in “street name” by returning a proxy card directly to MEI or by voting in person at the MEI Special Meeting unless you provide a “legal proxy,” which you must obtain from your bank, broker, or other nominee. Obtaining a legal proxy may take several days.

If your shares of MEI Common Stock are held in “street name,” your bank, broker, or other nominee will only vote your shares if you provide instructions on how to vote on the relevant proposal. Brokers do not have discretionary authority to vote on non-routine matters. A “broker non-vote” occurs when a broker submits a proxy that states that the broker votes for at least one proposal, but does not vote for proposals on non-routine matters because the broker has not received instructions from the beneficial owners on how to vote and thus does not have discretionary authority to vote on those proposals. Because all of the matters to be considered at the MEI Special Meeting are non-routine and brokers will not have discretionary authority to vote on any of the MEI Proposals, MEI does not expect to receive any broker non-votes. If your shares of MEI Common Stock are held in “street name” and you do not instruct your bank, broker, or other nominee on how to vote your shares, your bank, broker, or other nominee will not be permitted to vote your shares of MEI Common Stock on the MEI Nasdaq Proposal or the MEI Adjournment Proposal. Assuming a quorum is present, this failure to instruct your bank, broker, or other nominee will have “**NO EFFECT**” on the MEI Nasdaq Proposal or the MEI Adjournment Proposal.

**Your vote is important. Accordingly, please submit a proxy by telephone, over the Internet, or by signing and returning the enclosed proxy card, or by submitting instructions on how to vote your shares to your broker, bank or other nominee, as soon as possible, whether or not you plan to attend the MEI Special Meeting.**

### **Revocability of Proxies and Changes to an MEI Stockholder’s Vote**

If you are a holder of shares of MEI Common Stock as of the MEI Record Date, you have the power to revoke your proxy at any time before it is voted at the MEI Special Meeting.

If you are a record holder of shares of MEI Common Stock, you can revoke your proxy in one of three ways:

- sending a written notice of revocation that is received by MEI prior to 11:59 p.m. Pacific Time on the day preceding the MEI Special Meeting, stating that you are revoking your proxy, to MEI Corporate Secretary at MEI’s corporate headquarters, 11455 El Camino Real, Suite 250, San Diego, California 92130.
- submitting a new proxy bearing a later date (by Internet, telephone or mail) that is received by MEI prior to 11:59 p.m. Pacific Time on the day preceding the MEI Special Meeting; or
- attending the MEI Special Meeting and voting online or giving a written notice of revocation to the Secretary of MEI prior to the voting at the MEI Special Meeting (your attendance at the meeting will not, by itself, revoke your proxy; you must vote online at the meeting to change your vote or submit a written notice of revocation to revoke your proxy).

**If you wish to change your vote at the MEI Special Meeting, you must vote online at such meeting or give a written notice of revocation to the Secretary of MEI prior to the voting at the MEI Special Meeting.**

The latest dated completed proxy will be the one that counts. Written notices of revocation and other communications with respect to the revocation of any proxies should be addressed to:

MEI Pharma, Inc.  
11455 El Camino Real, Suite 250  
San Diego, California 92130  
Attn: Corporate Secretary

## [Table of Contents](#)

If you are a MEI stockholder whose shares of MEI Common Stock are held in “street name” by a bank, broker, or other nominee, you may revoke your proxy or voting instructions and vote your shares of MEI Common Stock online at the MEI Special Meeting only in accordance with the rules and procedures of your bank, broker, or other nominee. You must follow the directions you receive from your bank, broker, or other nominee in order to change or revoke your proxy or voting instructions and should contact your bank, broker, or other nominee to do so.

### **Solicitation of Proxies**

The MEI board of directors is soliciting your proxy to vote your shares at the MEI Special Meeting. The cost of the solicitation of proxies from MEI stockholders will be borne by MEI. In addition to solicitations by mail, MEI’s directors, officers and employees may solicit proxies personally, by telephone, by facsimile or otherwise, without additional compensation. MEI will also request brokerage firms, nominees, custodians and fiduciaries to forward proxy materials to the beneficial owners of shares of MEI Common Stock held of record on the MEI Record Date and will provide customary reimbursement to such firms for the cost of forwarding these materials. MEI has retained Alliance Advisors, LLC to assist it in soliciting proxies using the means referred to above. MEI will pay the fees of Alliance Advisors, LLC, which MEI expects to be approximately \$35,000, plus reimbursement of out-of-pocket expenses.

### **Adjournments**

Although it is not currently expected, the MEI Special Meeting may, from time to time, if necessary or appropriate, be adjourned for the purpose of soliciting additional proxies, including in the event that there are insufficient votes at the time of the MEI Special Meeting or any adjournment or postponement thereof to approve the MEI Nasdaq Proposal. If a quorum is not present, the holders of record of a majority of the shares present in person or by proxy and entitled to vote at such meeting may adjourn such meeting from time to time. If a quorum is not present at the MEI Special Meeting, each vote cast in favor of the MEI Adjournment Proposal will count as a vote cast in favor of adjourning the meeting. Pursuant to the MEI Bylaws, notice need not be given of any such adjourned meeting if the time and place thereof are announced at the meeting at which adjournment is taken and the adjournment is for not more than 30 days. If the MEI Special Meeting is adjourned, stockholders who have already sent in their proxies will be allowed to revoke them at any time prior to their use.

### **Postponements**

At any time prior to convening the MEI Special Meeting, MEI’s board of directors may postpone the MEI Special Meeting for any reason without the approval of the MEI stockholders. Although it is not currently expected, MEI’s board of directors may postpone the MEI Special Meeting for the purpose of soliciting additional proxies if MEI has not received sufficient proxies to constitute a quorum or sufficient votes for approval of the MEI Nasdaq Proposal. If the MEI Special Meeting is postponed for the purpose of soliciting additional proxies, stockholders who have already sent in their proxies will be allowed to revoke them at any time prior to their use.

### **Attending the MEI Special Meeting**

The MEI Special Meeting will be conducted completely as a virtual meeting via the Internet. MEI believes that holding the MEI Special Meeting completely online will enable greater participation and improved communication. Stockholders may attend the meeting and vote their shares electronically during the meeting via the live webcast by visiting . You will need to have your 16-Digit Control Number included on your Notice or your proxy card (if you received a printed copy of the proxy materials) to join and vote at the MEI Special Meeting. Stockholders may submit questions in advance of the meeting by visiting [www.proxyvote.com](http://www.proxyvote.com). Questions pertinent to matters to be acted upon at the MEI Special Meeting will be answered during the MEI Special Meeting, subject to time constraints. In the interests of time and efficiency, MEI reserves the right to group questions of a similar nature together to facilitate the question and answer portion of the meeting. MEI may not be able to answer all questions submitted in the allotted time.

## [Table of Contents](#)

Even if your shares of MEI Common Stock are held in “street name,” you are welcome to attend the MEI Special Meeting. If your shares of MEI Common Stock are held in “street name,” you may not vote your shares of MEI Common Stock in person at the MEI Special Meeting unless you obtain a proxy, executed in your favor, from the holder of record (*i.e.*, your bank, broker, or other nominee). If you hold your shares of MEI Common Stock in “street name” and wish to vote in person, please contact your bank, broker, or other nominee before the MEI Special Meeting to obtain the necessary proxy from the holder of record.

MEI will have technicians ready to assist you with any technical difficulties you may have in obtaining access to the MEI Special Meeting virtually. If you encounter any difficulties accessing the virtual meeting during check-in or the meeting, please call the technical support number that will be posted on the virtual meeting platform log-in page.

### **Stockholder List**

A list of MEI stockholders entitled to vote at the MEI Special Meeting will be available for inspection at MEI’s principal executive offices, located at 11455 El Camino Real, Suite 250, San Diego, California, 92130, at least ten days prior to the date of the MEI Special Meeting and continuing through the MEI Special Meeting for any purpose germane to the MEI Special Meeting. The list will also be available at the MEI Special Meeting for inspection by any MEI stockholder present at the MEI Special Meeting.

### **Assistance**

If you need assistance in completing your proxy card or have questions regarding the MEI Special Meeting, please contact:

MEI Pharma, Inc.  
11455 El Camino Real, Suite 250  
San Diego, California 92130  
(858) 369-7100  
[investor@meipharma.com](mailto:investor@meipharma.com)

## MATTERS BEING SUBMITTED TO A VOTE OF MEI STOCKHOLDERS

### The MEI Nasdaq Proposal

#### PROPOSAL 1: APPROVAL OF THE ISSUANCE OF MEI COMMON STOCK TO INFINITY STOCKHOLDERS

##### Overview

In connection with the proposed Merger, MEI intends to effect (subject to the terms and conditions of the Merger Agreement), for purposes of complying with the applicable listing rules of the Nasdaq Capital Market, the issuance of up to 4,824,893 shares of MEI Common Stock to Infinity stockholders upon the Closing. For further information, please see the section entitled “*The Merger*,” as well as the annexes to this joint proxy statement/prospectus.

##### Why MEI Needs Stockholder Approval

We are seeking stockholder approval in order to comply with Nasdaq Listing Rule 5635(a).

Under Nasdaq Listing Rule 5635(a), stockholder approval is required prior to the issuance of securities in connection with the acquisition of another company where, due to the present or potential issuance of common stock, other than common stock issued in a public offering (i) the common stock has, or will have upon issuance, voting power equal to or in excess of 20% of the voting power outstanding before the issuance of such securities (or securities convertible into or exercisable for common stock); or (ii) the number of shares of common stock to be issued is or will be equal to or in excess of 20% of the number of shares of common stock outstanding before the issuance of the stock or securities.

##### Effect of Proposal on MEI Stockholders and Infinity Stockholders

If the MEI Nasdaq Proposal is adopted, we will issue up to 4,824,893 shares of MEI Common Stock to Infinity stockholders upon the Closing.

The issuance of the shares of MEI Common Stock described above would result in significant dilution to MEI stockholders and result in MEI stockholders having a smaller percentage interest in the voting power, liquidation value and aggregate book value of MEI.

As of April 23, 2023, MEI had 6,662,857 shares of common stock outstanding. Based upon the initially estimated exchange ratio, following the Merger (i) MEI securityholders immediately before the Merger are expected to own approximately 58% of the aggregate number of outstanding shares of MEI common stock following the Merger and (ii) Infinity securityholders immediately before the Merger are expected to own approximately 42% of the aggregate number of outstanding shares of MEI common stock following the Merger, subject to certain assumptions (including as to the amount of Infinity net cash at Closing, which could be materially different). The foregoing percentages do not give effect to the exercise or conversion of outstanding stock options or warrants.

In the event that this Proposal is not approved by MEI stockholders, the Merger cannot be consummated. In the event that this Proposal is approved by MEI stockholders, but the Merger Agreement is terminated (without the Merger being consummated) prior to the issuance of shares of MEI Common Stock pursuant to the Merger Agreement, MEI will not issue such shares of MEI Common Stock.

### **Resolution to be Voted Upon**

The full text of the resolution to be proposed is as follows:

“RESOLVED, that for the purposes of complying with the applicable provisions of Nasdaq Listing Rule 5635(a), the issuance of shares of MEI Common Stock pursuant to the Merger Agreement, be approved.”

### **Required Vote for Approval**

The approval of the MEI Nasdaq Proposal requires the affirmative vote of a majority of the votes cast by stockholders present in person or represented by proxy and entitled to vote thereon at the MEI Special Meeting (which would include presence by virtual attendance at the MEI Special Meeting). An abstention will be counted towards the quorum requirement but will not count as a vote cast at the MEI Special Meeting and will have “**NO EFFECT**” on the MEI Nasdaq Proposal. A broker non-vote will neither be counted towards the quorum requirement (as the Proposals we believe will be considered as non-discretionary) nor count as a vote cast in the MEI Special Meeting and will have “**NO EFFECT**” on the MEI Nasdaq Proposal.

The MEI Nasdaq Proposal is conditioned on the approval and adoption of the Infinity Merger Proposal.

### **Recommendation of Our Board**

**OUR BOARD OF DIRECTORS RECOMMENDS THAT MEI STOCKHOLDERS  
VOTE “FOR” THE APPROVAL OF THE MEI NASDAQ PROPOSAL (PROPOSAL 1).**

### ***Interests of MEI’s Directors***

The existence of financial and personal interests of one or more of MEI’s directors may result in a conflict of interest on the part of such director(s) between what he, she, or they may believe is in the best interests of MEI and its stockholders and what he, she, or they may believe is best for himself, herself, or themselves in determining to recommend that stockholders vote for the MEI Nasdaq Proposal. In addition, MEI’s directors and officers have interests in the Merger that may conflict with your interests as a stockholder. See the section titled “*The Merger—Interests of MEI’s Directors and Executive Officers in the Merger*” for a further discussion of these considerations.

### **The MEI Adjournment Proposal**

#### **PROPOSAL 2: APPROVAL OF POSSIBLE ADJOURNMENT OF THE MEI SPECIAL MEETING**

The MEI Adjournment Proposal, if adopted, will allow MEI to adjourn the MEI Special Meeting to a later date or dates to permit further solicitation of proxies. The MEI Adjournment Proposal will only be presented to MEI stockholders in the event that, at the time of the MEI Special Meeting, it is necessary or appropriate to solicit additional proxies, including in the event that there are insufficient votes at the time of the MEI Special Meeting or any adjournment or postponement thereof to approve the MEI Nasdaq Proposal.

### **Consequences if the Adjournment Proposal is Not Approved**

If the MEI Adjournment Proposal is presented at the MEI Special Meeting and is not approved by the stockholders of MEI, MEI may not be able to adjourn the MEI Special Meeting to a later date in the event, based on the tabulated votes, that there are not sufficient votes at the time of the MEI Special Meeting to approve the MEI Nasdaq Proposal. In such event, the Merger may not be completed.

### **Resolution to be Voted Upon**

The full text of the resolution to be proposed is as follows:

RESOLVED, the proposal to approve the adjournment of the MEI Special Meeting from time to time, if necessary or appropriate, including to solicit additional proxies in the event that there are insufficient votes at the



---

## [Table of Contents](#)

time of the MEI Special Meeting or any adjournment or postponement thereof to approve the MEI Nasdaq Proposal, is approved and adopted in all respects.

Adoption of the MEI Adjournment Proposal is not conditioned upon the adoption of any of the other Proposals.

### **Required Vote**

The approval of the MEI Adjournment Proposal requires the affirmative vote of a majority of the votes cast by stockholders present in person or represented by proxy and entitled to vote thereon at the MEI Special Meeting (which would include presence by virtual attendance at the MEI Special Meeting). An abstention will be counted towards the quorum requirement but will not count as a vote cast at the MEI Special Meeting and, assuming no quorum is present, will have “**NO EFFECT**” on the MEI Adjournment Proposal. A broker non-vote will neither be counted towards the quorum requirement (as the Proposals we believe will be considered as non-discretionary) nor count as a vote cast in the MEI Special Meeting and will have “**NO EFFECT**” on the MEI Adjournment Proposal.

The approval and adoption of the MEI Adjournment Proposal is not a condition for nor conditioned on the approval of any other Proposal at the MEI Special Meeting.

### **Recommendation of MEI Board**

**IF THE MEI ADJOURNMENT RESOLUTION IS PRESENTED TO MEI STOCKHOLDERS,  
MEI’S BOARD OF DIRECTORS RECOMMENDS THAT ITS STOCKHOLDERS  
VOTE “FOR” THE APPROVAL OF THE MEI ADJOURNMENT PROPOSAL (PROPOSAL 2).**

## THE SPECIAL MEETING OF INFINITY STOCKHOLDERS

### Date, Time, and Place

The Infinity Special Meeting will be held on \_\_\_\_\_, 2023, at \_\_\_\_\_ Eastern Time, unless postponed or adjourned to a later date, as a virtual meeting via the Internet at [www.virtualshareholdermeeting.com/INFI2023SM](http://www.virtualshareholdermeeting.com/INFI2023SM). Infinity is sending this joint proxy statement/prospectus to its stockholders in connection with the solicitation of proxies by Infinity's board of directors for use at the Infinity Special Meeting and any adjournments or postponements thereof. On or about \_\_\_\_\_, 2023, Infinity will commence mailing this joint proxy statement/prospectus and the enclosed form of proxy card to its stockholders entitled to vote at the Infinity Special Meeting.

### Purposes of the Infinity Special Meeting

The Infinity Special Meeting will be held for the following purposes:

1. To approve the adoption of the Merger Agreement, pursuant to which Merger Sub will merge with and into Infinity, with Infinity surviving as a wholly owned subsidiary of MEI, and the surviving company of the Merger, which proposal is referred to as the "Infinity Merger Proposal";
2. To approve, on a non-binding, advisory basis, the compensation that will or may be payable to Infinity's named executive officers in connection with the Merger, which proposal is referred to as the "Infinity Compensation Proposal"; and
3. To approve the adjournment of the Infinity Special Meeting, from time to time, if necessary or appropriate, including to solicit additional proxies in the event that there are insufficient votes at the time of the Infinity Special Meeting or any adjournment or postponement thereof to approve the Infinity Merger Proposal, which proposal is referred to as the "Infinity Adjournment Proposal."

### Recommendation of Infinity's Board of Directors

Infinity's board of directors has determined and believes that it is fair to, in the best interests of, and advisable to, Infinity and its stockholders to approve the adoption of the Merger Agreement. Infinity's board of directors recommends that Infinity's stockholders vote "**FOR**" the Infinity Merger Proposal.

Infinity's board of directors has determined and believes that it is fair to, in the best interests of, and advisable to, Infinity and its stockholders to approve, on a non-binding, advisory basis, the compensation that will or may be payable to Infinity's named executive officers in connection with the Merger. Infinity's board of directors recommends that Infinity's stockholders vote "**FOR**" the Infinity Compensation Proposal.

Infinity's board of directors has determined and believes that it is fair to, in the best interests of, and advisable to, Infinity and its stockholders to approve the possible adjournment of the Infinity Special Meeting. Infinity's board of directors recommends that Infinity's stockholders vote "**FOR**" the Infinity Adjournment Proposal.

### Record Date and Quorum

Infinity's board of directors has fixed \_\_\_\_\_, 2023 as the record date for the determination of stockholders entitled to notice of, and to vote at, the Infinity Special Meeting and any adjournment or postponement thereof (the "Infinity Record Date"). Only holders of record of shares of Infinity Common Stock on the Infinity Record Date are entitled to notice of, and to vote at, the Infinity Special Meeting. On the Infinity Record Date, Infinity had \_\_\_\_\_ shares of common stock outstanding and entitled to vote.

A quorum will be present at the Infinity Special Meeting if the holders of a majority of the Infinity Common Stock issued and outstanding and entitled to vote on the Infinity Record Date is present virtually or represented by proxy. On the Infinity Record Date, there were \_\_\_\_\_ shares of Infinity Common Stock issued and outstanding and

## [Table of Contents](#)

entitled to vote. This means that at least \_\_\_\_\_ shares must be represented virtually or by proxy at the Infinity Special Meeting to have a quorum. Your shares will be counted towards the quorum if you submit a valid proxy or virtually attend the Infinity Special Meeting. Abstentions and broker non-votes, if any, will be included in determining the number of shares present at the meeting for the purpose of determining the presence of a quorum.

### **Required Vote, Abstentions and Failure to Vote**

Approval of the Infinity Merger Proposal is a condition to the completion of the Merger. Therefore, the Merger cannot be completed without the approval of the Infinity Merger Proposal. The Infinity Merger Proposal is described in more detail in the section titled “*Matters Being Submitted To A Vote Of Infinity Stockholders*” in the joint proxy statement/prospectus, which you should read carefully in its entirety before you vote. A copy of the Merger Agreement is attached as Annex A to the accompanying joint proxy statement/prospectus.

Assuming a quorum is present:

- approval of the Infinity Merger Proposal requires the affirmative vote of the holders of a majority of the outstanding shares of Infinity Common Stock entitled to vote thereon. **Abstentions will have the same effect as a vote against this proposal.**
- approval of each of the Infinity Compensation Proposal and the Infinity Adjournment Proposal requires the affirmative vote of the holders of a majority in voting power of the shares of Infinity Common Stock which are present virtually or by proxy and entitled to vote thereon. Abstentions will have the same effect as a vote against such proposals.

### **Voting by Infinity’s Directors and Executive Officers**

As of the Infinity Record Date, directors and executive officers of Infinity and their affiliates owned and were entitled to vote \_\_\_\_\_ shares of Infinity’s Common Stock, representing approximately \_\_\_\_\_ % of the shares of Infinity Common Stock outstanding on the Infinity Record Date. Infinity currently expects that Infinity’s directors and executive officers will vote any shares of Infinity Common Stock they hold in favor of the Infinity Merger Proposal, the Infinity Compensation Proposal and the Infinity Adjournment Proposal, although none of them has entered into any agreement obligating him or her to do so.

### **Voting and Revocation of Proxies**

The proxy accompanying this joint proxy statement/prospectus is solicited on behalf of Infinity’s board of directors for use at the Infinity Special Meeting.

If, as of the Infinity Record Date, your shares were registered directly in your name with the transfer agent for the Infinity Common Stock, American Stock Transfer & Trust Company, then you are a stockholder of record. Whether or not you plan to virtually attend the Infinity Special Meeting, Infinity urges you to fill out and return the proxy card or vote by proxy over the telephone or on the internet as instructed below to ensure your vote is counted.

The procedures for voting are as follows: If you are a stockholder of record, you may vote at the Infinity Special Meeting. Alternatively, you may vote by proxy by using the accompanying proxy card, over the internet or by telephone. Whether or not you plan to virtually attend the Infinity Special Meeting, Infinity encourages you to vote by proxy to ensure your vote is counted. Even if you have submitted a proxy before the Infinity Special Meeting, you may still virtually attend the Infinity Special Meeting and vote online during the meeting. In such case, your previously submitted proxy will be disregarded.

- To vote at the Infinity Special Meeting, attend the Infinity Special Meeting virtually and vote online during the meeting.
- To vote using the proxy card by mail, simply complete, sign and date the accompanying proxy card and return it promptly in the envelope provided. If you return your signed proxy card before the Infinity Special Meeting, Infinity will vote your shares in accordance with the proxy card.

## Table of Contents

- To vote by proxy over the internet, follow the instructions provided on the proxy card.
- To vote by telephone, you may vote by proxy by calling the toll free number found on the proxy card.

If you are a beneficial owner of shares registered in the name of your broker, bank or other nominee, you should have received a voting instruction card and voting instructions with these proxy materials from that organization rather than from us. Simply complete and mail the voting instruction card to ensure that your vote is counted. To vote online during the Infinity Special Meeting, please contact your broker, bank or other nominee for instructions and documents that may be required in order to do so.

Infinity provides internet proxy voting to allow you to vote your shares online, with procedures designed to ensure the authenticity and correctness of your proxy vote instructions. However, please be aware that you must bear any costs associated with your internet access, such as usage charges from internet access providers and telephone companies.

All properly executed proxies that are not revoked will be voted at the Infinity Special Meeting and at any adjournments or postponements of the Infinity Special Meeting in accordance with the instructions contained in the proxy. If a holder of Infinity Common Stock executes and returns a proxy and does not specify otherwise, the shares represented by that proxy will be voted “**FOR**” all of the proposals in accordance with the recommendation of Infinity’s board of directors.

If you are a stockholder of record of Infinity, you may change your vote at any time before your proxy is voted at the Infinity Special Meeting in any one of the following ways:

- You may submit another properly completed proxy with a later date by mail, by telephone or via the internet.
- You may send a written notice that you are revoking your proxy to Infinity’s Corporate Secretary at 1100 Massachusetts Avenue, Floor 4, Cambridge, Massachusetts 02138.
- You may attend the Infinity Special Meeting virtually and vote online during the meeting. Simply attending the Infinity Special Meeting will not, by itself, revoke your proxy.

If your shares are held by your broker, bank or other nominee, you should follow the instructions provided by it.

### **Solicitation of Proxies**

The Infinity board of directors is soliciting your proxy to vote your shares at the Infinity Special Meeting. The cost of the solicitation of proxies from Infinity stockholders will be borne by Infinity. In addition to solicitations by mail, Infinity’s directors, officers and employees may solicit proxies personally, by telephone, by facsimile or otherwise, without additional compensation. Infinity will also request brokerage firms, nominees, custodians and fiduciaries to forward proxy materials to the beneficial owners of shares of Infinity’s Common Stock held of record on the Infinity Record Date and will provide customary reimbursement to such firms for the cost of forwarding these materials. Infinity has retained Morrow Sodali to assist it in soliciting proxies using the means referred to above. Infinity will pay the fees of Morrow Sodali, which Infinity expects to be approximately \$35,000, plus reimbursement of out-of-pocket expenses.

### **Other Matters**

As of the date of this joint proxy statement/prospectus, Infinity’s board of directors does not know of any business to be presented at the Infinity Special Meeting other than as set forth in the notice accompanying this joint proxy statement/prospectus. If any other matters should properly come before the Infinity Special Meeting, it is intended that the shares represented by proxies will be voted with respect to such matters in accordance with the judgment of the persons voting the proxies.

**MATTERS BEING SUBMITTED TO A VOTE OF INFINITY STOCKHOLDERS**

**The Infinity Merger Proposal**

**PROPOSAL 1: APPROVAL OF THE ADOPTION OF THE MERGER AGREEMENT**

Infinity's stockholders are being asked to consider and vote upon a proposal to adopt the Merger Agreement, pursuant to which, among other matters, and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into Infinity, with Infinity continuing as a wholly owned subsidiary of MEI and the surviving corporation of the Merger, which transaction is referred to herein as the Merger. The Merger and the terms of the Merger Agreement are described in more detail under "*The Merger*" and "*The Merger Agreement*," beginning on pages 122 and 180, respectively, of this joint proxy statement/prospectus, and Infinity's stockholders are encouraged to read the full text of the Merger Agreement, which is attached as Annex A hereto. It is a condition to the completion of the Merger that Infinity's stockholders approve the Infinity Merger Proposal.

The Infinity board of directors, after due and careful discussion and consideration, approved and declared advisable the Merger Agreement and the Merger and determined that the Merger Agreement and the Merger are fair to and in the best interests of Infinity and its stockholders. The Infinity board of directors accordingly recommends that Infinity's stockholders adopt the Merger Agreement.

**THE INFINITY BOARD OF DIRECTORS RECOMMENDS THAT YOU VOTE "FOR" THE INFINITY MERGER PROPOSAL (PROPOSAL 1).**

## The Infinity Compensation Proposal

### **PROPOSAL 2: TO APPROVE, ON A NON-BINDING, ADVISORY BASIS, THE COMPENSATION THAT WILL OR MAY BE PAYABLE TO INFINITY'S NAMED EXECUTIVE OFFICERS IN CONNECTION WITH THE MERGER**

Pursuant to Section 14A of the Exchange Act and Rule 14a-21(c) thereunder, Infinity is seeking the approval of its stockholders, on a non-binding, advisory basis, of the compensation that will or may be payable to Infinity's named executive officers in connection with the Merger as disclosed in the section titled "*The Merger—Compensation Payable to Infinity Named Executive Officers*" beginning on page 172 of this joint proxy statement/prospectus. The Infinity Compensation Proposal gives Infinity's stockholders the opportunity to express their views on the merger-related compensation of Infinity's named executive officers.

Accordingly, Infinity is asking its stockholders to vote "**FOR**" the adoption of the following resolution, on a non-binding, advisory basis:

"RESOLVED, that the compensation that will or may be paid or become payable to Infinity's named executive officers in connection with the Merger, and the agreements or understandings pursuant to which such compensation will or may be paid or become payable, in each case as disclosed pursuant to Item 402(t) of Regulation S-K in the section titled "*The Merger—Compensation Payable to Infinity Named Executive Officers*" of the joint proxy statement/prospectus for this meeting is hereby APPROVED."

The vote on the Infinity Compensation Proposal is a vote separate and apart from the vote to adopt the Merger Agreement. Accordingly, if you are a stockholder, you may vote to approve the Infinity Merger Proposal and vote not to approve the Infinity Compensation Proposal, and vice versa. Because the vote on the Infinity Compensation Proposal is advisory only, it will not be binding on Infinity. If the Merger is completed, the merger-related compensation may be paid to Infinity's named executive officers to the extent payable in accordance with the terms of the compensation agreements and arrangements even if stockholders fail to approve the Infinity Compensation Proposal.

**THE INFINITY BOARD OF DIRECTORS RECOMMENDS THAT YOU VOTE "FOR" THE INFINITY COMPENSATION PROPOSAL (PROPOSAL 2).**

**Infinity Adjournment Proposal**

**PROPOSAL 3: APPROVAL OF POSSIBLE ADJOURNMENT OF THE INFINITY SPECIAL MEETING**

If Infinity fails to receive a sufficient number of votes to approve the Infinity Merger Proposal or the Infinity Compensation Proposal, Infinity may propose to adjourn the Infinity Special Meeting, for a period of not more than 60 days, for the purpose of soliciting additional proxies to approve the Infinity Merger Proposal or the Infinity Compensation Proposal. Infinity currently does not intend to propose adjournment at the Infinity Special Meeting if there are sufficient votes to approve the Infinity Merger Proposal and the Infinity Compensation Proposal. Additionally, pursuant to Article II, Section 9 of the Infinity Bylaws, except to the extent inconsistent with any rules and regulations adopted by Infinity's board of directors for conduct at the Infinity Special Meeting, the person presiding over any meeting of Infinity's stockholders shall have the right and authority to convene and (for any or no reason) to adjourn the meeting as, in the judgment of such presiding person, is appropriate for the proper conduct of the meeting.

**THE INFINITY BOARD OF DIRECTORS RECOMMENDS THAT YOU VOTE "FOR" THE INFINITY ADJOURNMENT PROPOSAL (PROPOSAL 3).**



## THE MERGER

*This section of the proxy statement/prospectus describes certain material aspects of the proposed Merger. This section may not contain all of the information that is important to you. You should carefully read this entire proxy statement/prospectus and the documents incorporated herein by reference, including the full text of the Merger Agreement, which is attached as Annex A, for a more complete understanding of the Merger. In addition, (i) important business and financial information about MEI is incorporated into this proxy statement/prospectus by reference and (ii) important business and financial information about Infinity is incorporated into this proxy statement/prospectus by reference. See also “Where You Can Find More Information” beginning on page 338 of this proxy statement/prospectus.*

### General Description of the Merger

MEI Pharma, Inc., which is referred to as MEI, Infinity Pharmaceuticals Inc., which is referred to as Infinity, and Meadow Merger Sub, Inc., a wholly-owned subsidiary of MEI, which is referred to as Merger Sub, have entered into the Agreement and Plan of Merger, dated as of February 22, 2023 (as it may be amended from time to time), which is referred to as the merger agreement, which provides for the merger of Merger Sub, with and into Infinity. As a result of the merger, the separate existence of Merger Sub will cease and Infinity will continue its existence under the laws of the State of Delaware as the surviving corporation and as a wholly-owned subsidiary of MEI. It is expected that the name of the combined company will be changed to “Kimbrx Therapeutics, Inc.” after completion of the Merger.

### Consideration to be Received by the Infinity Stockholders

At the effective time, by virtue of the merger and without any further action on the part of the parties, holders of any securities of Infinity, Merger Sub or of any other person, each share of Infinity common stock that is issued and outstanding immediately prior to the effective time (other than shares of Infinity common stock owned by Infinity or MEI) will be automatically converted into and become exchangeable for 0.052245 shares of MEI common stock, which we refer to as the exchange ratio, and cash in lieu of any fractional shares of MEI common stock any former holder of Infinity common stock would otherwise be entitled to receive.

The exchange ratio is fixed, which means that it will not change between now and the date of the merger, regardless of whether the market price of either MEI common stock or Infinity common stock changes. Therefore, the value of the merger consideration will depend on the market price of MEI common stock at the effective time. The market price of MEI common stock has fluctuated since the date of the announcement of the merger agreement and may continue to fluctuate from the date of this joint proxy statement/prospectus to the date of the special meetings, the date the merger is completed and thereafter. The market price of MEI common stock, when received by Infinity stockholders after the merger is completed, could be greater than, less than or the same as the market price of MEI common stock on the date of this joint proxy statement/prospectus or at the time of the special meeting. Accordingly, you should obtain current market quotations for MEI common stock and Infinity common stock before deciding how to vote with respect to any of the proposals described in this joint proxy statement/prospectus. MEI common stock is traded on the Nasdaq Capital Market under the symbol “MEIP” and Infinity common stock is traded on the Nasdaq Global Market under the symbol “INFI.”

At the effective time, all shares of Infinity common stock owned by MEI or Infinity will be cancelled and will cease to exist, and no consideration will be delivered in exchange for such shares.

### Background of the Merger

Each of the MEI board of directors and the Infinity board of directors, together with members of the management teams of their respective companies, regularly reviews and assesses the opportunities and risks associated with their respective development programs and their respective company’s overall performance, future growth prospects and associated capital needs, business plans and overall direction, and considers a variety of strategic alternatives that may be available to their respective companies, including continuing to pursue its strategy as a

## [Table of Contents](#)

standalone company or pursuing potential strategic or financing transactions with third parties, in each case with the goal of maximizing stockholder value.

From July 2021 through June 2022, the Infinity board of directors and members of Infinity management engaged in efforts to explore potential strategic relationships that would provide funding sufficient to enable the continued development of eganelisib and its advancement into additional clinical studies. These efforts primarily included evaluation of potential licensing and strategic collaboration opportunities with pharmaceutical or biotech companies and discussions on potential broad clinical development plans that were intended to capitalize on the breadth of data generated with eganelisib in multiple settings.

On May 23, 2022, the MEI board of directors formed an Ad Hoc Strategic Transactions Committee (the “MEI Ad Hoc Strategy Committee”) to assist the MEI board of directors in considering and evaluating potential strategic alternatives available to MEI in light of the FDA’s earlier decision to discourage the pursuit of a marketing authorization for MEI’s product candidate, zandelisib, via the accelerated approval pathway based on data generated by the single arm Phase 2 study in subjects with follicular lymphoma or marginal zone lymphoma after failure of two or more prior therapies. The MEI Ad Hoc Strategy Committee consisted of Ms. Cheryl Cohen, Dr. Nick Glover, Ms. Tamar Howson and Mr. Sujay Kango, with Ms. Cohen serving as Chair.

On June 16, 2022, the Infinity board of directors held a meeting, with members of Infinity management participating, to discuss, among other things, the pathway for continued development of eganelisib. Infinity management and the Infinity board of directors concluded that a strategic partnership remained the most attractive pathway for continued development of eganelisib given the higher cost of the later stage clinical trials needed for eganelisib’s continued development, the relatively high infrastructure costs that must be borne by a public pharmaceutical company with a single product candidate such as Infinity and the general deterioration of biotech market conditions including decreases in valuations and financings, Federal Reserve interest rate increases and concerns regarding government price setting under the Inflation Reduction Act. As part of this discussion, members of Infinity management shared with the Infinity board of directors that, in accordance with direction from the Infinity board of directors, Infinity management had contacted approximately 25 larger, commercial stage, profitable, public pharmaceutical and biotechnology companies, each with an oncology focus, that Infinity management perceived as having sufficient financial resources to either acquire Infinity for cash, license eganelisib or fund continued development of eganelisib to assess potential interest in entering into a strategic relationship to acquire rights to eganelisib. We refer to this group of companies as “Group A.” Members of Infinity management also discussed with the Infinity board of directors a potential engagement of Aquilo Partners, referred to herein as “Aquilo,” an investment banking firm that Infinity previously engaged in connection with other matters. In connection with this discussion, Infinity management proposed for the Infinity board’s consideration a list of smaller, development stage private and public oncology-focused biotech companies that Infinity management and Aquilo were evaluating for suitability as potential partners in a strategic transaction, including a merger of equals transaction, rather than a cash-based license of eganelisib or an acquisition of Infinity for cash consideration, because Infinity management perceived this group to be less likely to have sufficient cash resources to make the related payments required for such a transaction. We refer to this group of companies as “Group B.” After considering the information presented by Infinity management, the Infinity board of directors determined to continue the parallel evaluation of strategic partnering opportunities with Group A companies, and those Group B companies that Infinity management determined to be suitable to assess interest in a possible business combination, and continue to identify additional companies to include in Group A and Group B at the discretion of Infinity management.

On June 30, 2022, Adelene Perkins, Chief Executive Officer of Infinity, held an introductory call with the Chief Executive Officer of an oncology development-focused biotech company that we refer to as “Party A1,” one of the Group A companies. The Chief Executive Officer of Party A1 expressed interest in evaluating an option to license eganelisib and exploring other potential strategic transactions.

On July 20, 2022, the Infinity board of directors held a meeting, with members of Infinity management participating, to discuss the status of Infinity’s efforts to explore strategic opportunities with potential pharmaceutical or biotech

## Table of Contents

company partners that could advance efforts to develop eganelisib. As part of the discussion, Infinity management updated the Infinity board of directors on the status of discussions with five parties with which Infinity management had ongoing discussions regarding various types of strategic transactions, including three Group A companies, including Party A1, and two Group B companies. Additionally, Infinity management updated the Infinity board of directors on the status of its efforts to work with Aquilo to contact over 25 Group B companies in addition to the two referenced above to assess their interest in a possible business combination. The Infinity board of directors directed Infinity management to assess whether any Group A companies that had previously declined interest generally in a strategic transaction could potentially be interested in acquiring Infinity and to reapproach such companies to solicit offers for such an acquisition and to otherwise continue its general efforts to seek strategic opportunities, including by continuing its related discussions with Party A1.

On August 4, 2022, Infinity entered into an engagement letter with Aquilo as its financial advisor. Infinity's decision to engage Aquilo as its advisor was based on Aquilo's experience and expertise as a financial and strategic advisor in a wide variety of transactions, including transactions in the life sciences industry, and its familiarity with Infinity's business. Pursuant to its engagement, Aquilo continued to work with Infinity management to identify potential candidates for a strategic transaction.

On September 13, 2022, Party A1 submitted a non-binding term sheet to Infinity for an exclusive option for the exclusive license of eganelisib. From September until November of 2022, Party A1 conducted due diligence on the eganelisib program, and Infinity and Party A1 continued discussions regarding the terms of the proposed option to license eganelisib.

On September 22, 2022, Ms. Perkins held an introductory phone call with the Chief Executive Officer of a Group B company we refer to as "Party B1" to discuss the potential interest level in evaluating a merger of Infinity and Party B1.

On September 26, 2022, Ms. Perkins reached out to Mr. Kango, who, in addition to being a member of the MEI board of directors, is also a member of the Infinity board of directors, to request an introduction to Dr. Gold from MEI.

On September 28, 2022, a Group A company that we refer to as "Party A2" contacted Infinity expressing interest in evaluating the eganelisib program for a potential strategic partnership. During October and November 2022, Infinity and Party A2 held discussions relating to a potential strategic relationship between their two companies.

On September 28, 2022, Mr. Kango introduced Ms. Perkins and Dr. Daniel P. Gold, Ph.D., the President and Chief Executive Officer of MEI, by email and on September 30, 2022, Ms. Perkins and Dr. Gold held an introductory phone call to discuss potential interest in evaluating a combination of Infinity and MEI. Mr. Kango was not otherwise involved in the introductory call. During September and October 2022, Infinity and MEI held discussions relating to a potential combination between Infinity and MEI.

Beginning October, 2022, Mr. Kango resigned from the MEI Ad Hoc Strategy Committee, recused himself from any meetings of the MEI board of directors in which a potential transaction with Infinity would be discussed and recused himself from any meeting of the Infinity board of directors in which a potential transaction with MEI would be discussed because he sat on both the MEI board of directors and the Infinity board of directors.

On October 4, 2022, Infinity and MEI entered into a mutual confidential disclosure agreement to enable discussions and the exchange of business and technical diligence materials on a confidential basis. No confidential disclosure agreement entered into by Infinity or MEI with respect to a potential acquisition of, or business combination or strategic relationship with, Infinity or MEI, as applicable, including the mutual confidential disclosure agreement between Infinity and MEI, contains any standstill provision. In October and November 2022, representatives of Infinity and MEI had numerous preliminary discussions about a potential transaction and conducted due diligence of each other's programs and businesses. MEI's due diligence of Infinity primarily focused on Infinity's strategic fit for a potential business combination transaction with MEI, including

## Table of Contents

the focus of each on oncology and domain knowledge of each in kinase biology and tumor inhibition, and particularly Infinity's clinical-stage product candidate, eganelisib, including potential commercial opportunities for eganelisib in conjunction with MEI's internal pipeline strategy with respect to MEI's existing pipeline programs. MEI's due diligence of Infinity also focused on the potential for the two organizations' culture fit. Infinity's due diligence of MEI primarily focused on assessing whether MEI would have sufficient cash resources to enable continued development of eganelisib after completion of a business combination and a review of MEI's existing pipeline programs as well as the two organizations' culture fit.

On October 19, 2022, Ms. Perkins and Dr. Gold had an initial conversation regarding the possible management of the combined company. The parties agreed that the composition of the potential management team would need to be reviewed by each company's board of directors in the context of the overall organization size and structure as well as the final development pipeline of the combined company.

On October 25, 2022, the Infinity board of directors held a meeting at which members of Infinity management participated. Mr. Kango recused himself from this board meeting. As part of the meeting, the Infinity board of directors discussed the status of the process undertaken by Infinity to explore a strategic relationship with the Group A and Group B companies to advance the development of eganelisib. Members of Infinity management reviewed a numerical summary of Infinity's outreaches, noting that, as of the October 25 board meeting (i) two of the three Group A companies and one of the two Group B companies that Infinity management had reported to the Infinity board of directors at the July 22, 2022 meeting as being in active discussions with Infinity on the eganelisib program had indicated they were no longer interested in pursuing a transaction with Infinity at that time, (ii) there were two Group A companies in active discussions on the eganelisib program, including Party A1, and (iii) four Group B companies, including MEI and the other Group B company that Infinity management had reported to the Infinity board of directors at the July 22, 2022 meeting as being in active discussions with Infinity on the eganelisib program, were in active discussions on the eganelisib program, and Infinity was awaiting feedback from another three Group B companies following an initial review of the eganelisib program. The other Group A and Group B companies contacted had indicated that they were not interested in pursuing a transaction with Infinity at that time. In addition, Infinity management updated the Infinity board of directors on efforts to identify and contact additional companies that had not been part of the list of companies identified to the Infinity board of directors at the July 20 meeting, as previously directed by the board. Infinity management noted Infinity had contacted 35 Group A companies in total, including an additional 10 larger companies it had contacted following the Infinity meeting held on June 16, 2022, to assess interest in a strategic partnership for the development of eganelisib or sale of Infinity for cash, focusing on oncology companies with checkpoint inhibitor or other immunoncology programs. With respect to the Group B companies, management noted that Aquilo had conducted a screen of over 600 public companies and over 150 private companies to identify additional potential strategic opportunities, and Aquilo and Infinity management had together contacted over 50 of such companies, representing an additional outreach of 22 Group B companies following the July 20, 2022 Infinity meeting. Infinity management noted that, in general, the Group B companies had indicated they were primarily interested in discussing transactions for the acquisition of Infinity for stock consideration or an option to license eganelisib.

Also, at the October 25, 2022 meeting, Ms. Perkins expressed to the Infinity board of directors her view that, based on feedback received to date from Infinity's outreaches to Group A and Group B companies, that a sale of Infinity or strategic partnership that would enable the broad clinical development of eganelisib was less likely to be available at this time, and Infinity would likely need to pursue transactions supporting a narrower clinical development plan. The reasons generally cited by Group A companies declining to pursue a broad strategic transaction included lack of a strategic fit with the priorities of such company, or a desire to see additional eganelisib safety and efficacy data from a randomized, controlled clinical study, before committing to funding, a study which would take several years to complete. Infinity management then described to the Infinity board of directors the latest proposal for an option for an exclusive license to eganelisib received from Party A1 and conveyed that Party A1 was conducting technical diligence. The Infinity board of directors and Infinity management discussed whether the proposed transaction with Party A1 or a business combination with MEI would be more likely to maximize stockholder value. Ms. Perkins noted that although discussions with Party A1

## Table of Contents

were at a more advanced stage than discussions with MEI, she believed a merger with MEI offered a greater opportunity for Infinity's stockholders because they would retain meaningful ownership in the merged company and, therefore, would meaningfully participate in any value created by eganelisib's future development. Ms. Perkins noted that Infinity's grant of an option to acquire an exclusive license to eganelisib to Party A1, on the other hand, would be expected to limit upside potential for Infinity's stockholders to an option exercise fee and would foreclose other strategic opportunities. Following this discussion, the Infinity board of directors directed management to focus efforts on pursuing a potential transaction with MEI while advancing discussions with Party A1, and to also continue to evaluate other reasonably available opportunities. Ms. Perkins noted that members of the MEI management team were scheduled to meet with members of Infinity management the following day and reviewed a proposed agenda.

On October 27, 2022, MEI entered into an engagement letter with Torrey Capital, LLC ("Torrey") for Torrey to act as MEI's advisor for financial and strategic matters. Torrey had been previously identified by the Ad Hoc Strategy Committee as a potential advisor with respect to a strategic transaction involving MEI. MEI's decision to engage Torrey as its advisor was based on Torrey's experience and expertise as a financial and strategic advisor in a wide variety of transactions, including transactions in the life sciences industry, and its familiarity with MEI's business, including having been previously retained by MEI for advisory work.

On October 28, 2022, Infinity held a first meeting with Party B1 to discuss eganelisib.

On November 4, 2022, Party B1 expressed interest in a potential business combination between Infinity and Party B1 and these discussions continued throughout November.

On November 7, 2022, at the direction of the MEI board of directors, Torrey began an assignment to help consider potential strategic alternatives for MEI, which included the option to continue as a standalone company or wind up the operations of MEI and declare a dividend of available cash to MEI's stockholders. With regards to a potential transaction, at the direction of the MEI board of directors, Torrey focused its efforts primarily on strategic or licensing transactions with oncology and/or hematology biotech companies, in each case with a potential strategic partner with one or more commercially viable clinical product candidate(s) with an established proof of concept and a management team and a board of directors with the breadth, skills, experience and sophistication to accomplish the transaction on a reasonable timeline. It was agreed by the MEI Transactions Committee and Torrey that any outreach by Torrey should wait until after the outcome and potential ramifications of the zandelisib FDA meeting at the end of the month were known. At that FDA meeting, the future development pathway of zandelisib would be discussed which could lead to either the determination to continue zandelisib development as planned or, as actually happened, the determination to discontinue MEI's development of zandelisib. Over the next several months, Torrey subsequently contacted or was contacted by 22 companies (not including Infinity), including public biotech companies, private biotech companies and academic institutions regarding a potential strategic or licensing transactions involving MEI.

On November 16, 2022, Dr. Gold and Ms. Perkins had a phone call to discuss details of the potential strategic transaction between MEI and Infinity, including arranging discussions between members of MEI management and Infinity management to produce a non-binding term sheet.

On November 16, 2022, Party A1 informed Infinity that it would not be interested in pursuing a potential transaction for an option for an exclusive license to eganelisib until data from a randomized controlled clinical trial to definitively assess the safety and efficacy profile of eganelisib became available.

On November 17, 2022, a representative of Party A2 communicated to Infinity management that Party A2 no longer intended to pursue a partnership to develop eganelisib.

On November 21, 2022, the Infinity board of directors held a virtual meeting, in which members of Infinity management and, at the invitation of the Infinity board of directors, representatives of Infinity's outside legal counsel, WilmerHale, participated to discuss the status of Infinity's efforts to secure a potential strategic transaction to enable

## Table of Contents

the further development of eganelisib. Consistent with past practice, Mr. Kango recused himself from this board meeting. Ms. Perkins provided an update on Infinity's discussions with MEI and Party B1 as well as the indications from Party A1, Party A2 and the other Group A and Group B companies that Infinity management had reported to the Infinity board of directors at the October 25, 2022 meeting as being in active discussions with Infinity on the eganelisib program that they were no longer interested in pursuing the potential transaction with Infinity at such time. The Infinity board of directors discussed the potential of submitting to MEI a draft non-binding term sheet, prepared by Infinity management with input from WilmerHale and Aquilo and presented to the Infinity board of directors (the "November 21 Proposal"). Such term sheet was for an all-stock merger of equals (the "Potential Transaction") whereby, following the conversion of shares of the applicable company pursuant to the merger, the shares of each company outstanding immediately prior to closing would represent 50% of the issued and outstanding shares of capital stock of the combined company. The Infinity board of directors, Infinity management and WilmerHale also discussed the other terms contained in the November 21 Proposal, including, among other things, (i) governance of the combined post-merger company including a chair of the board of directors to be designated by Infinity subject to MEI's consent and executive officers to be mutually agreed upon by the parties, and an initial board of directors comprised of seven directors, with three directors designated by Infinity, three directors to be designated by MEI and one director to be mutually agreed upon by the parties, (ii) the name and location of the headquarters of the combined company to be determined at a later date, (iii) the combined company's stock to be listed on Nasdaq, (iv) the process and timing for concluding due diligence and negotiating a definitive merger agreement, and (v) the entry by MEI and Infinity into a period of exclusivity, the terms of which would be negotiated in a separate document. The November 21 Proposal also provided that provisions regarding MEI's net cash would be determined following the completion of due diligence. At the conclusion of the discussion, the Infinity board of directors directed Infinity management to submit the November 21 Proposal to MEI and, upon satisfactory agreement on key transaction terms, seek to enter into an exclusivity arrangement with MEI. Additionally, the Infinity board of directors delegated authority to Ms. Perkins to negotiate each term contained in the non-binding term sheet for the November 21 Proposal in her reasonable discretion, provided that Ms. Perkins stay within a prespecified range of percentages of the total outstanding common stock of the combined company that the Infinity stockholders would own following the Potential Transaction.

At the November 21, 2022 meeting of the Infinity board of directors, the Infinity board of directors also resolved to form a transaction committee of the Infinity board of directors composed of Norman Selby, Infinity's lead independent director, David Beier and Anthony Evin (the "Infinity Transaction Committee") with authority to establish, approve, monitor and direct the process and procedures related to the review and evaluation of a possible strategic transaction with a third party; respond to any communications, inquiries or proposals regarding a possible strategic transaction; review, evaluate, investigate, pursue and negotiate the terms and conditions of a possible strategic transaction; solicit expressions of interest or proposals for a possible strategic transactions in connection with any process approved by the Infinity board of directors; recommend to the Infinity board of directors any proposed rejection or approval of a possible strategic transaction; and review, analyze, evaluate and monitor all proceedings and activities of Infinity related to a possible strategic transaction.

Also on November 21, 2022, following the adjournment of the November 21, 2022 meeting of the Infinity board of directors, representatives of Infinity management and MEI management held a virtual meeting wherein Infinity shared the November 21 Proposal with MEI, and the parties discussed the terms reflected therein.

On November 22, 2022, the MEI board of directors held a virtual meeting, together with representatives of MEI's counsel, Morgan, Lewis & Bockius LLP ("Morgan Lewis"). Consistent with past practice, Mr. Kango recused himself from this board meeting. At the meeting, the MEI board of directors dissolved the Ad Hoc Strategy Committee and formed a transactions committee (the "MEI Transactions Committee") for efficiency purposes to assist the board of directors and MEI management in evaluating the Potential Transaction as well as other potential strategic alternatives, which would consist of Mr. Charles Baltic, Mr. Fred Driscoll and Dr. Thomas Reynolds, with Mr. Baltic serving as Chair and Dr. Christine White serving as alternate. The MEI Transactions Committee was empowered to review and evaluate the Potential Transaction and any other strategic alternatives and to make recommendations to the MEI board of directors with respect thereto. The MEI board of directors also discussed the outcome of a recent telephonic meeting with the FDA, at which time the agency



## [Table of Contents](#)

conveyed guidance regarding the design and statistical analysis for MEI's zandelisib trial in combination with rituximab versus standard immunochemotherapy in patients with relapsed indolent non Hodgkin's lymphoma and their decision to deny a request for accelerated approval of MEI's product candidate zandelisib based on a response endpoint using randomized data.

On November 23, 2022, representatives from WilmerHale, Aquilo, Morgan Lewis, Torreya, and members of Infinity and MEI management held a conference call to discuss diligence matters, the timeline for the Potential Transaction and the drafting of definitive agreements. The parties agreed to continue to negotiate key business terms in the November 21 Proposal, while also beginning to draft the definitive merger agreement.

On November 24, 2022, Infinity was contacted by a business development representative from a Group A pharmaceutical company, which had not previously expressed interest in partnering with Infinity, which we refer to as "Party A3," now expressing interest in a potential partnership regarding eganalisib.

On November 25, 2022, the MEI Transactions Committee held a virtual meeting, together with members of MEI management and representatives of Morgan Lewis and Torreya. At the meeting, among other items, the MEI Transactions Committee discussed the Potential Transaction, including Infinity's programs and product candidates, the exchange ratio set forth in the November 21 Proposal and the proposed exclusivity arrangement with Infinity. The MEI Transactions Committee agreed to progress discussions with Infinity regarding the November 21 Proposal and to propose to the MEI board of directors entering into an exclusivity arrangement with Infinity while seeking a more favorable exchange ratio for the stockholders of MEI.

On November 28, 2022, the MEI Transactions Committee held a virtual meeting, together with members of MEI management and representatives of Morgan Lewis and Torreya. At the meeting, among other items, the MEI Transactions Committee discussed the November 21 Proposal and inquiries regarding other potential strategic alternatives that Torreya had received to date. The MEI Transactions Committee agreed to prepare a counterproposal for Infinity that would include, among other things, an exchange ratio resulting in an ownership split between Infinity's stockholders and MEI's stockholders of 40% and 60%, respectively, of the combined company. The MEI Transactions Committee agreed that none of the inquiries regarding other potential strategic alternatives provided to date had risen to the level appropriate for further consideration at that time.

On November 29, 2022, members of MEI management and members of Infinity management had a call to discuss the organizational structure of a combined company.

On November 30, 2022, MEI responded to the November 21 Proposal with a counterproposal (the "November 30 Proposal") that increased the MEI's stockholders' post-transaction ownership of the combined company to 60% of the shares of the combined company on a fully diluted basis and proposed changes to the terms related to the governance and leadership structure of the transaction to provide that (i) the size of the board of directors of the combined company be increased to eight members, with the additional member to be designated by MEI, and (ii) the chief executive officer of the combined company be designated by MEI subject to Infinity consent prior to the signing of a definitive merger agreement and be included as one of MEI's designees on the board of directors of the combined company.

On December 1, 2022, members of Infinity management discussed MEI's November 30 Proposal with Aquilo and WilmerHale. Aquilo, WilmerHale and Infinity management prepared a written response to MEI's counterproposal (the "December 1 Proposal") whereby, following the conversion of shares of the applicable company pursuant to the merger, the shares outstanding of Infinity immediately prior to closing would represent 45% of the combined company on a fully diluted basis and the shares outstanding of MEI immediately prior to closing would represent 55% of the combined company on a fully diluted basis. Additionally, the December 1 Proposal included the issuance of contingent value rights that would have the effect of increasing the ownership of the combined company by Infinity's stockholders to 55%, based on the achievement of either of two prespecified milestones related to the prioritized, randomized, controlled, Phase 2 study of eganalisib in patients

## Table of Contents

with squamous cell cancer of the head and neck cancer or the achievement of a prespecified business development milestone. Infinity also proposed that the exchange ratio be subject to upward or downward adjustment based on any variance in MEI's net cash at the closing of the transaction from \$100 million and that Infinity's obligation to close the transaction be conditioned on MEI having at least a specified amount of minimum net cash at closing, with such amount to be mutually agreed upon by the parties. Aquilo delivered the December 1 Proposal to MEI on December 1, 2022.

On December 2, 2022, the MEI Transactions Committee held a virtual meeting, together with members of MEI management and representatives of Morgan Lewis and Torrey. At the meeting, among other items, the MEI Transactions Committee discussed the December 1 Proposal. The MEI Transactions Committee agreed that representatives of MEI would contact representatives of Infinity to discuss the December 1 Proposal.

Also on December 2, 2022, following the adjournment of the MEI Transactions Committee Meeting, Dr. Gold and Ms. Perkins discussed each of the exchange ratios set forth in the November 21 Proposal, the November 30 Proposal and the December 1 Proposal, and the methodology behind such proposed exchange ratios. As part of this discussion, Ms. Perkins and Dr. Gold discussed the possibility of revising the exchange ratio to reflect a post-merger ownership split of the combined company of 55% in favor of MEI's stockholders and 45% in favor of Infinity's stockholders, with no issuance of contingent value rights to Infinity stockholders, subject to their respective board's approval. Dr. Gold and Ms. Perkins agreed to discuss such revised exchange ratio with the MEI Transactions Committee and the Infinity board of directors, respectively. The parties further discussed but did not determine any mutually acceptable compromises regarding whether the exchange ratio would be subject to any adjustment based on MEI's net cash or whether the merger agreement would contain closing conditions related to either party's net cash at closing.

On December 3, 2022, the MEI Transactions Committee held a virtual meeting, together with members of MEI management and representatives of Morgan Lewis and Torrey. At the meeting, among other items, the MEI Transactions Committee discussed the December 1 Proposal and the outcome of the follow-up discussions between representatives of MEI and Infinity. Dr. Gold updated the MEI Transactions Committee regarding the proposed exchange ratio resulting in an ownership split between Infinity's stockholders and MEI's stockholders of 45% and 55%, respectively, with no issuance of contingent value rights that could alter the exchange ratio, as Dr. Gold had discussed with Ms. Perkins on December 2. The MEI Transactions Committee agreed to discuss such proposal with the MEI board of directors and seek further guidance from the MEI board of directors regarding such proposal and the Potential Transaction generally.

On December 5, 2022, the MEI board of directors held a virtual meeting, together with members of MEI management and representatives of Morgan Lewis. Consistent with past practice, Mr. Kango recused himself from this board meeting. At the meeting, among other items, the MEI board of directors discussed the Potential Transaction, a potential strategic realignment (including a related reduction-in-force) as a result of the FDA determination on November 21, 2022 to deny a request for accelerated approval of MEI's product candidate, zandelisib, based on a response endpoint using randomized data. The MEI board of directors agreed to discontinue the global development of zandelisib outside of Japan and proceed with its strategic realignment (including the related reduction-in-force) as announced publicly later that day.

Also on December 5, 2022, MEI issued a press release, publicly announcing that it planned to discontinue the global development of zandelisib outside of Japan and proceed with its strategic realignment (including the related reduction-in-force), that it had engaged Torrey as financial advisor to help explore additional strategic opportunities and adjourning its annual meeting of stockholders, which had been scheduled for that day, to January 5, 2023.

On December 6, 2022, the MEI board of directors held a virtual meeting, together with members of MEI management and representatives of Morgan Lewis and Torrey. Consistent with past practice, Mr. Kango recused himself from this board meeting. At the meeting, among other items, the MEI board of directors



## Table of Contents

discussed the Potential Transaction and inquiries regarding other potential strategic or licensing alternatives that Torreyia had received as of that date. The MEI board of directors agreed to progress discussions with Infinity regarding the Potential Transaction, and to enter into a limited period of exclusivity with Infinity. The MEI board of directors agreed that the period of exclusivity should terminate shortly before the J.P. Morgan Conference (as defined below) to allow MEI to explore other potential strategic opportunities at the J.P. Morgan Conference if MEI and Infinity had not earlier entered into a binding agreement with respect to the Potential Transaction.

On December 8, 2022, Morgan Lewis and WilmerHale engaged in discussions about the Potential Transaction and confirmed their respective clients' agreement that, absent any additional considerations being identified that would warrant revising the transaction structure, MEI would be the legal acquirer in the merger.

On December 9, 2022, Infinity and MEI executed an Exclusivity Agreement providing for an exclusivity period for the negotiation of the Potential Transaction ending on January 8, 2023 (the "Exclusivity Agreement"). The Exclusivity Agreement included exceptions that allowed each party to arrange meetings with third parties to be held during the J.P. Morgan Conference, provided that neither party would be permitted to disclose to any third party that the purpose of any such meeting would be to discuss a possible merger, acquisition or similar material transaction involving such party.

On December 9, 2022, the MEI Transactions Committee held a virtual meeting, together with members of MEI management and representatives of Morgan Lewis and Torreyia. The MEI Transactions Committee was updated on, among other things, the status and process of due diligence on Infinity, and Torreyia's proposed strategy with respect to identifying and evaluating other potential strategic and licensing opportunities following the conclusion of the proposed period of exclusivity with Infinity.

On December 12, 2022, Dr. Gold and Mr. Urso met with members of the Infinity board of directors and Infinity management at Infinity's headquarters to discuss the proposed clinical plan for eganalisib and proposed plans for the combined company following the closing of the Potential Transaction.

On December 13, 2022, the Infinity board of directors held a virtual meeting in which members of Infinity management, as well as representatives from Aquilo and WilmerHale participated. Consistent with past practice, Mr. Kango recused himself from this board meeting. Mr. Tasker reviewed the terms for the Potential Transaction under consideration based on discussions between Ms. Perkins and Dr. Gold on December 2, including a possible post-merger ownership split of the combined company of 55% for MEI's shareholders and 45% for Infinity's stockholders. Mr. Tasker noted that the prospective board of directors of the combined company could range from seven to eight members, with three or four designated by MEI, three designated by Infinity and one mutually agreed on. Mr. Tasker additionally noted that the structure of the transaction, and name and headquarters of the combined company, had yet to be determined. A representative from WilmerHale reviewed potential considerations for the structure of the merger. Members of Infinity management reviewed the projected asset pipeline of the combined company and a high-level overview of clinical development plans. A representative of Aquilo reviewed Aquilo's methodology for assessing the fairness of the Potential Transaction to Infinity's stockholders and reviewed the methodology of an analysis evaluating the potential business combination compared to alternative financing opportunities, noting that alternative financing opportunities may not be available to Infinity in the current market conditions. Mr. Urso and Dr. Gold were also present for a portion of the meeting as an introduction to the Infinity board of directors.

On December 14, 2022, Morgan Lewis circulated the initial draft of the merger agreement, based on the preliminary terms discussed by Infinity and MEI in connection with their negotiation of the preliminary non-binding term sheet, to WilmerHale. The merger agreement contemplated a "one-step" merger structure, in which a subsidiary of MEI would merge with and into Infinity in a reverse triangular merger, with Infinity surviving such merger. Infinity's stockholders would vote on the proposed merger, and MEI's stockholders would vote on the issuance of shares of MEI common stock pursuant to the terms of the merger agreement (the "MEI Share Issuance"). Consistent with MEI's position during the term sheet discussion, the draft merger agreement did not contain any adjustments to the

## Table of Contents

exchange ratio based on the amount of MEI's net cash as of the closing of the transaction, and the draft conditioned each party's obligation to close on the other party having an amount of net cash at the closing of the transaction in excess of an applicable threshold to be negotiated by the parties.

On December 15, 2022, Mr. Driscoll sent an email to the MEI board of directors whereby he resigned from the MEI Transactions Committee and recused himself from all future discussions and meetings regarding Infinity.

On December 16, 2022, the MEI Transactions Committee held a virtual meeting, together with members of MEI management and representatives of Morgan Lewis and Torrey. At the meeting, among other items, the MEI Transactions Committee discussed that Ms. Cohen, Mr. Driscoll and Ms. Howson would be recused from all future discussions and meetings regarding or implicated by the Potential Transaction by the MEI board of directors (and with respect to Mr. Driscoll, any such discussions by the MEI Transactions Committee as well), and in fact were so recused, because they each served on the boards of other companies involved in head and neck cancer research, and that given Mr. Driscoll's recusal, Mr. Driscoll had resigned from the MEI Transactions Committee and would be replaced by the alternate member of the MEI Transactions Committee, Ms. White. The MEI Transactions Committee also discussed the recent meetings and discussions between management teams with respect to the Potential Transaction, MEI's long-range financial forecasts and MEI's internal pipeline strategy with respect to MEI's two pipeline assets, voruciclib and ME-344.

On December 17, 2022, Ms. Cohen sent an email to Mr. Baltic and Ms. White, confirming that she would be recused from all future discussions and meetings regarding or implicated by a potential strategic transaction, including the Potential Transaction.

On December 20, 2022, the MEI Transactions Committee held a virtual meeting, together with members of MEI management and representatives of Morgan Lewis and Torrey. At the meeting, among other items, the MEI Transactions Committee discussed the financial and staffing needs of the combined company following the closing of the Potential Transaction, the commercial opportunities for Infinity's product candidate, eganelisib, and the status and process of the Potential Transaction. The MEI Transactions Committee was updated on the ongoing negotiations of various definitive transaction documents, including the merger agreement, and certain material issues therein.

On December 21, 2022, after discussing the terms reflected in the initial draft of the merger agreement with Infinity, WilmerHale sent a revised draft of the merger agreement to Morgan Lewis which, among other things, (i) accepted the "one-step" merger structure, in which a subsidiary of MEI would merge with and into Infinity in a reverse triangular merger, with Infinity surviving such merger, as proposed in Morgan Lewis's December 14 draft of the merger agreement, (ii) revised the exchange ratio to include an adjustment mechanism that would have the result of proportionally increasing or decreasing the Infinity stockholders' aggregate ownership of the combined company in the event that MEI's net cash as of the closing of the Potential Transaction is less than \$98 million or greater than \$102 million, respectively (the "Net Cash Adjustment"), (iii) provided that each party would be obligated to pay the other party a termination fee in the event that such party's stockholders do not approve the applicable transactions contemplated by the merger agreement requiring such stockholders' approval and the agreement is terminated pursuant to the related termination right, whether or not such party later participates in an acquisition proposal, which we refer to herein as a "Naked No Vote," and (iv) deleted the condition to MEI's obligation to close the Potential Transaction based on the amount of Infinity's net cash, such that only Infinity would have the benefit of such a condition (based on the amount of MEI's net cash).

On December 26, 2022, WilmerHale and Morgan Lewis had a virtual meeting to discuss the terms of the merger agreement, after which Morgan Lewis sent a further revised draft of the merger agreement to WilmerHale. Among other changes, the revised draft removed the Net Cash Adjustment, removed the termination fees payable upon a Naked No Vote by such party's stockholders, and, consistent with MEI's earlier proposals, provided for a combined company board of directors consisting of eight members, with four members designated by MEI, three members designated by Infinity and one member, Sujay Kango, to be jointly designated.

## Table of Contents

On December 28, 2022, after discussing the proposals reflected in Morgan Lewis's latest draft of the merger agreement with WilmerHale, Infinity management directed WilmerHale to send a further revised draft of the merger agreement to Morgan Lewis which, among other things, reinserted the Net Cash Adjustment and reciprocal termination fees in the event of a termination for a Naked No Vote from Infinity's prior draft, and accepted MEI's proposal regarding the size and composition of the combined company board of directors.

On December 29, 2022, the MEI Transactions Committee held a virtual meeting, together with members of MEI management and representatives of Morgan Lewis and Torreya. At the meeting, among other items, the MEI Transactions Committee discussed unsolicited inquiries regarding other potential strategic and licensing alternatives that Torreya had received to date. There was also an analysis and consideration of the value to MEI's stockholders of the possibility of winding up MEI's operations and declaring a dividend of available cash to MEI's stockholders. The MEI Transactions Committee agreed that none of the inquiries regarding other potential strategic or licensing alternatives had risen to the level appropriate for further consideration by the MEI Transactions Committee, and to continue to progress the Potential Transaction with Infinity.

On December 30, 2022, Infinity and MEI, along with representatives from WilmerHale, Morgan Lewis, Aquilo and Torreya, participated in a virtual meeting in order to attempt to resolve the remaining open issues between the parties as to the terms of the transaction.

On December 31, 2022, the MEI Transactions Committee held a meeting, together with members of MEI management and representatives of Morgan Lewis and Torreya. The MEI Transactions Committee had a discussion regarding certain material issues in the merger agreement, including the parties' disagreement about whether the exchange ratio for the merger would be adjusted based on MEI's net cash, the parties' disagreement over what circumstances would result in payment of reciprocal termination fees and MEI's other potential strategic and licensing alternatives. Following such discussion, the MEI Transactions Committee determined that the parties were at an impasse with respect to these issues, and that MEI should cease negotiations with Infinity regarding the Potential Transaction while it explored other potential strategic or licensing alternatives, including at the J.P. Morgan Conference following the expiration of the exclusivity period set forth in the Exclusivity Agreement.

On December 31, 2022, MEI informed Infinity that the MEI Transactions Committee had instructed MEI management to terminate negotiations regarding a transaction with Infinity based on its determination that the parties were at an impasse with respect to agreeing to satisfactory resolutions on the material unresolved transaction terms, including the adjustments to the exchange ratio based on the parties' net cash and the circumstances that would result in payment of reciprocal termination fees.

On January 2, 2023, the Infinity board of directors held a virtual meeting in which members of Infinity management participated. Ms. Perkins provided an update on Infinity's discussions with MEI. Consistent with past practice, Mr. Kango recused himself from this board meeting. The Infinity board of directors discussed the benefits and risks of continuing with the current period of exclusivity with MEI, seeking an early termination of such period, or extending such period of exclusivity. The Infinity board of directors directed management to seek an extension of the exclusivity period with MEI, and if such extension was not able to be agreed upon, to terminate the current period of exclusivity to allow Infinity to resume its efforts to pursue strategic transaction opportunities with parties other than MEI.

On January 3, 2023, Mr. Baltic contacted Mr. Driscoll and asked if he would be available for a brief update. Mr. Driscoll indicated that he would be available to speak on January 4, 2023. During that conversation, Mr. Baltic inquired if Mr. Driscoll would like an update regarding the MEI Transactions Committee activities with Infinity. Mr. Driscoll asked not to be updated and requested that any communication regarding Infinity, either a completed transaction or one no longer moving forward, be done as part of a formal meeting of the MEI board of directors. Mr. Baltic acceded to that request.

## Table of Contents

On January 4, 2023, after MEI indicated that it would not be willing to extend the exclusivity period, Infinity and MEI agreed to terminate the exclusivity period effective immediately as of such date.

On January 4, 2023, following the termination of the exclusivity period, Infinity concluded that further discussions with Party B1 would not be productive, as Party B1's publicly available financial statements indicated that it did not have enough cash to support the development of both eganelisib and its existing program.

On January 5, 2023, MEI held its annual meeting of stockholders, Dr. White retired as a member of the MEI board of directors (and consequently as a member of the Transactions Committee as well), and Mr. Baltic assumed the role of Chair of the MEI board of directors.

On January 5, 2023, Infinity board member Richard Gaynor reached out to the head of research and development at Party A3 to assess its interest in discussing a strategic transaction to further the development of eganelisib. During January 2023, Party A3 reviewed the eganelisib program and the parties discussed the prospect of a potential strategic transaction.

On January 6, 2023, the Infinity board of directors held a virtual meeting in which members of Infinity management participated. Consistent with past practice, Mr. Kango recused himself from this board meeting. Ms. Perkins informed the Infinity board of directors that MEI had not agreed to an extension of the exclusivity period, and as directed by the Infinity board of directors on January 2, Infinity and MEI agreed on January 4, 2023 to terminate the exclusivity period effective immediately. The Infinity board of directors discussed Infinity's efforts to pursue a potential transaction with Party A3, including assessing Party A3's level of interest in pursuing an acquisition of Infinity with cash and whether such a transaction could be consummated within Infinity's forecasted cash runway.

During the week of January 10, 2023, members of MEI management attended the 2023 J.P. Morgan Healthcare Conference (the "J.P. Morgan Conference"), where such members of MEI management met with eight companies (included in the 22 companies referenced previously as having been identified by Torrey). These eight companies presented their business case and clinical story to MEI management. After review by MEI Management, Torrey and the Transactions Committee, it was determined that each of these companies would not be further considered for a strategic or licensing transaction on the basis presented, and the MEI board of directors was subsequently advised and consulted with respect to each such determination. Six of such companies were very early-stage companies, without proof of concept established in their lead product, and two of such companies had no clinical overlap with MEI, and were deemed unlikely to add strategic value to MEI or a pro forma company.

On January 10, 2023, Ms. Perkins met with Dr. Gold in San Francisco while both were attending the J.P. Morgan Conference and discussed the potential for re-initiation of discussions regarding the Potential Transaction and the continuing merits of a merger between Infinity and MEI. No decision was made at this meeting to resume discussions on the Potential Transaction.

On January 19, 2023, Mr. Selby sent an email to Mr. Baltic describing merits of the Potential Transaction and suggesting that MEI and Infinity re-engage in negotiations regarding a Potential Transaction to determine whether or not the issues outstanding as of late December, 2022 could be satisfactorily resolved.

On January 19, 2023, Mr. Baltic replied to Mr. Selby that MEI had a process in place with MEI Transactions Committee and MEI board meetings early the following week, after which time he would likely be able to revert on the outreach and to determine if it would be appropriate to re-engage in negotiations regarding a Potential Transaction and the terms thereof.

On January 20, 2023, MEI management had a virtual meeting with one other company (included in the 22 companies referenced previously as having been identified by Torrey), a publicly traded biotech company, but it was decided by both parties to not move forward with discussions about a strategic transaction due to such company lacking clinical overlap with MEI and generally being a poor fit for a transaction with MEI.

## Table of Contents

On January 23, 2023, the MEI board of directors held a virtual meeting, together with members of MEI management and representatives of Morgan Lewis and Torrey. Consistent with past practice, Mr. Kango recused himself from this board meeting. At the meeting, among other items, the MEI board of directors discussed MEI's clinical programs for its product candidates voruciclib and ME-344 and other potential strategic or licensing alternatives for MEI identified by Torrey to date. At the meeting, the MEI board of directors also appointed Dr. Glover as an alternate member of the MEI Transactions Committee. The MEI board of directors also discussed the posture of the terminated negotiations with Infinity regarding the Potential Transaction, and the outreach of Mr. Selby to inquire about resuming negotiations.

On January 24, 2023, the MEI Transactions Committee held a virtual meeting, together with members of MEI management and representatives of Morgan Lewis and Torrey. The MEI Transactions Committee agreed that MEI should resume discussions with Infinity and provide Infinity with a revised term sheet proposing revisions to certain key transaction terms for the Potential Transaction (the "January 26 Proposal"). Among other items, the January 26 Proposal highlighted six key points that MEI determined needed to be resolved before it would be willing to proceed with a Potential Transaction: (i) a revised exchange ratio whereby, following the conversion of shares of the applicable company pursuant to the merger, the shares outstanding of MEI immediately prior to closing would represent 60% of the combined company and the shares outstanding of Infinity immediately prior to closing would represent 40% of the combined company, (ii) that the exchange ratio would not be adjusted based on the amount of either party's net cash, (iii) that each party's obligation to close the Potential Transaction would be conditioned on the other party having at least a certain amount of net cash, equal to \$80 million in the case of MEI and \$10 million in the case of Infinity, such conditions referred to herein as the "Minimum Cash Condition" of each party, (iv) a proposed definition of "net cash" for all purposes under the merger agreement, (v) that Infinity would be required to undertake certain obligations to develop egnelisib during the period between the signing of the merger agreement and closing of the merger, and provided MEI the right to terminate the agreement if Infinity failed to comply with such covenants, and (vi) that neither party would be required to pay a termination fee in the event the agreement was terminated due to a Naked No Vote by a party's stockholders.

On January 25, 2023, a member of the MEI board of directors had a virtual meeting with one other company (included in the 22 companies referenced previously as having been identified by Torrey) to evaluate the possibility of a strategic transactions with such company, but such company did not have strategic overlap in oncology, although it did have overlap in hematology. The company indicated interest in only a narrow licensing transaction that did not include control of the technology or assets involved, which MEI determined would not be a good strategic fit for MEI.

On January 26, 2023, MEI sent the January 26 Proposal to Infinity.

On January 27, 2023, the MEI Transactions Committee held a virtual meeting, together with members of MEI management and representatives of Morgan Lewis and Torrey. The MEI Transactions Committee had a discussion regarding the Potential Transaction, including recent discussions between representatives of MEI and representatives of Infinity, and ongoing due diligence of Infinity. The MEI Transactions Committee was updated regarding other potential strategic alternatives identified by Torrey to date.

On January 30, 2023, the Infinity board of directors held a virtual meeting in which members of Infinity management participated. Consistent with past practice, Mr. Kango recused himself from this board meeting. Infinity management and the Infinity board of directors reviewed and discussed the January 26 Proposal from MEI and potential responses. Additionally, the Infinity board of directors reviewed the company's strategic planning. The Infinity board of directors determined that Infinity should continue to negotiate with MEI regarding the Potential Transaction.

On February 1, 2023, Mr. Tasker contacted Party A3 inquiring as to Party A3's level of interest in a strategic transaction. Party A3 responded that it was still collecting feedback from its internal stakeholders and would respond at a later date.

## Table of Contents

On February 2, 2023, representatives of Infinity and MEI held a virtual meeting to review the six key points outlined in MEI's January 26 Proposal and discuss potential solutions.

Also on February 2, 2023, the Infinity Transaction Committee reviewed the updated proposal from MEI, and, after discussing potential ways to resolve the key open issues, directed Infinity management to respond with a counterproposal (the "February 2 Proposal"), which generally accepted the terms proposed by MEI in its January 26 Proposal, except that (i) the exchange ratio would provide that, following the merger, the shares of MEI outstanding immediately prior to closing would represent 58% of the combined company and the shares of Infinity outstanding immediately prior to closing would represent 42% of the combined company, (ii) the amount of cash Infinity was required to have to satisfy MEI's Minimum Cash Condition would be reduced from \$10 million to \$2 million, (iii) Infinity's obligations regarding the development of eganelisib during the period between the signing of the merger agreement and the closing of the merger would be narrowed and the termination right expressly linked to such covenants proposed by MEI would be replaced with a requirement that Infinity use its "commercially reasonable efforts" to achieve such narrowed development obligations, and (iv) in lieu of an obligation to pay a termination fee to the other party following termination for a Naked No Vote by a party's stockholders, each party would be obligated to reimburse the other party's expenses in an amount of up to \$1 million in the event that the merger agreement were to be terminated as a result of a Naked No Vote by such party's stockholders. Additionally, the Infinity Transaction Committee directed Ms. Perkins to further negotiate the terms contained in the February 2 Proposal in her reasonable discretion.

Also on February 2, 2023, following the adjournment of the Infinity Transaction Committee meeting, Ms. Perkins emailed the February 2 Proposal to MEI's representatives, as directed by the Infinity Transaction Committee. Between February 2 and February 9, 2023, various representatives of Infinity and MEI discussed the February 2 Proposal.

On February 3, 2023, members of Infinity and MEI management held a call to discuss the clinical development plan for eganelisib for treatment in patients with squamous cell cancer of the head and neck.

On February 6, 2023, MEI management had a virtual meeting with one other company (included in the 22 companies referenced previously as having been identified by Torrey), but such company did not have strategic overlap in oncology therapeutics. MEI management determined that it was not worthwhile to move forward to further diligence. Of the remaining eleven companies identified by Torrey, five of such companies were too early-stage, and six of such companies did not have strategic overlap with MEI and were thus deemed a poor fit for a strategic transaction with MEI.

On February 9, 2023, Ms. Perkins contacted Dr. Gold to propose revisions to certain terms contained in Infinity's February 2 Proposal based on feedback provided by MEI (the "February 9 Proposal"). The February 9 Proposal revised the parties' Minimum Cash Conditions such that, as a condition to Infinity's obligation to close the transaction, MEI would need to have net cash of (i) at least \$80 million if the transaction were to close on or prior to the end of June, 2023, (ii) at least \$78 million if the transaction were to close on or prior to the end of July, 2023 and (iii) at least \$76 million if the transaction were to close on or prior to the end of August, 2023, and, as a condition to MEI's obligation to close the transaction, Infinity would need to have net cash of (a) at least \$4 million if the transaction were to close on or prior to the end of June, 2023, (b) at least \$3 million if the transaction were to close on or prior to the end of July, 2023 and (c) at least \$2 million if the transaction were to close on or prior to the end of August, 2023. In addition, the February 9 Proposal revised Infinity's commitments for Infinity's development of eganelisib during the period between the signing of the merger agreement and the closing of the Potential Transaction.

Also on February 9, 2023, the MEI Transactions Committee held a virtual meeting, together with members of MEI management and representatives of Morgan Lewis and Torrey. At the meeting, among other items, the MEI Transactions Committee discussed the Potential Transaction and inquiries regarding other potential strategic or licensing alternatives that Torrey had received to date.

## Table of Contents

Between February 9 and February 13, 2023, various representatives of Infinity and MEI discussed the February 2 Proposal.

On February 13, 2023, the MEI Transactions Committee held a virtual meeting, together with members of MEI management and representatives of Morgan Lewis and Torrey. At the meeting, among other items, the MEI Transactions Committee discussed the February 9 Proposal and inquiries regarding other potential strategic or licensing alternatives that Torrey had received to date. The MEI Transactions Committee agreed that none of the inquiries regarding other potential strategic or licensing alternatives had risen to the level appropriate for further consideration by the MEI Transactions Committee, and to continue to progress the Potential Transaction substantially in accordance with the terms reflected in the February 9 Proposal.

Also on February 13, 2023, following the adjournment of the MEI Transactions Committee meeting, Dr. Gold confirmed to Ms. Perkins that the MEI Transactions Committee agreed with the terms reflected in Infinity's February 9 Proposal (subject to the approval of the MEI board of directors) and would instruct Morgan Lewis to update the merger agreement draft to incorporate such terms and share the revised draft with Infinity and its advisors.

On February 14, 2023, Infinity management provided an update to the Infinity Transaction Committee on the status of the negotiations and transaction preparations with MEI as well as the fact that there was a major reorganization at Party A3 such that Infinity management did not expect to hear back from, or be able to advance discussions with, Party A3, on a strategic transaction in a timely manner. Based on Infinity management's recommendation, the Infinity Transaction Committee determined that Infinity should continue to focus on seeking resolution to the negotiations with MEI.

On February 15, 2023, Morgan Lewis sent a revised draft of the merger agreement to WilmerHale. The terms reflected in the draft were generally consistent with the terms reflected in the January 26 Proposal, as modified by the February 2 Proposal and the subsequent agreement regarding the modified minimum cash conditions and Infinity's obligations with respect to the development of eganelisib.

Between February 15, 2023 and the afternoon of February 22, 2023, MEI, through Morgan Lewis, and Infinity, through WilmerHale, continued to engage in ongoing negotiations of various definitive transaction documents, including the merger agreement and other ancillary documents.

On February 17, 2023, the MEI Transactions Committee held a virtual meeting, together with members of MEI management and representatives of Morgan Lewis and Torrey. The MEI Transactions Committee was updated on the ongoing negotiations of various definitive transaction documents, including the merger agreement, and certain material issues therein.

On February 20, 2023, at 7:30 p.m. Eastern Time, the Infinity board of directors held a virtual meeting, at which representatives of Infinity management, Aquilo and WilmerHale were also present, to update the Infinity board of directors regarding the status of the arrangements with respect to the proposed merger with MEI and consider the final terms of the transaction, including the merger agreement. Consistent with past practice, Mr. Kango recused himself from this board meeting. Ms. Perkins provided the Infinity board of directors with an overview of the plan for announcement of the Potential Transaction, if approved, and the plan regarding related communications. Discussion ensued. Representatives from WilmerHale then provided a review for the Infinity board of directors of their fiduciary duties in considering and approving the proposed merger. Representatives from WilmerHale also reviewed for the Infinity board of directors the material terms of the proposed final merger agreement, including (i) the transaction structure, (ii) the exchange ratio, such that each issued and outstanding share of common stock of Infinity (other than shares to be cancelled in accordance with the proposed final merger agreement) would be exchanged for the right to receive 1.0449 shares of MEI Common Stock (which was the exchange ratio prior to MEI's reverse stock split), subject to customary equitable adjustments in the event of any changes to, or exchanges of, the shares of Infinity Common Stock or MEI Common Stock to, or into, a different number of shares or a different class or series of shares, by reason of any stock dividend, subdivision, reclassification,



recapitalization, split, reverse split, combination or exchange of shares or other like change, (iii) the proposed post-closing governance structure, corporate headquarters, stock exchange listing and naming of the combined company, (iv) the treatment of Infinity equity awards in the proposed merger, (v) the required stockholder approvals by MEI's and Infinity's stockholders, (vi) the parties' conditions to closing the merger, including each party's minimum cash conditions, (vii) post-signing non-solicitation covenants, force-the-vote structure and termination provisions, including the \$4 million termination fee that could be owed by MEI and the \$2.9 million termination fee that could be owed by Infinity, respectively, in certain circumstances of termination of the merger agreement, (viii) the treatment of each party's transaction-related expenses, (ix) each party's obligation to complete the merger, (x) provisions concerning director and officer indemnification and insurance and (xi) the representation and warranty package, including the definition of a "material adverse effect." Representatives from Aquilo then presented to the Infinity board of directors the financial analyses of the exchange ratio of 1.0449 shares of MEI common stock to be paid to Infinity stockholders for each share of Infinity common stock in the proposed merger with MEI (which was the exchange ratio prior to MEI's reverse stock split). Discussion ensued. Representatives from WilmerHale then reviewed and summarized resolutions that the Infinity board of directors would be asked to consider and approve at a subsequent meeting in connection with the approval of the merger agreement and transactions contemplated thereby. The Infinity board of directors did not, however, approve the merger agreement at this meeting.

On the morning of February 22, 2023, Morgan Lewis circulated final versions of the merger agreement and the related ancillary documents to the MEI Transactions Committee via email. At 12:03 p.m. Eastern Time on February 22, the MEI Transactions Committee held a virtual meeting, together with members of MEI management and representatives of Morgan Lewis and Torreya. The MEI Transactions Committee discussed the Potential Transaction, and representatives of Torreya gave a presentation to the MEI Transactions Committee regarding Torreya's fairness opinion with respect to the Potential Transaction, dated as of February 22, 2023, which covered, among other things, the background of the Potential Transaction, certain key terms of the Potential Transaction (including structure, economic terms and conditions to closing), financial forecasts, projections and Torreya's value analysis for each of MEI and Infinity underlying the exchange ratio as set forth in the merger agreement. Representatives of Torreya then confirmed on behalf of Torreya that the exchange ratio as set forth in the merger agreement was fair, from a financial point of view, to MEI's stockholders. A discussion was held, during which questions were asked and answered. The MEI Transactions Committee then resolved to recommend that the MEI board of directors authorize, approve, adopt, ratify and confirm the form, terms and provisions of, and the execution, delivery and performance by the Company of, the merger agreement, and all other related agreements, instruments, certificates and documents required to be delivered in connection therewith, in each case substantially in the form presented to the MEI Transactions Committee, and the consummation of the transactions contemplated thereby, including the MEI Share Issuance.

On the afternoon of February 22, 2023, Morgan Lewis circulated final versions of the merger agreement and the related ancillary documents to the MEI board of directors, excluding Mr. Driscoll, Mr. Kango and Ms. Howson, via email. At 4:34 p.m. Eastern Time on February 22, the MEI board of directors, excluding Mr. Driscoll, Mr. Kango and Ms. Howson, held a virtual meeting, together with members of MEI management and representatives of Morgan Lewis and Torreya. The meeting began with a summary of the status of MEI's negotiations with Infinity with respect to the Merger, and the MEI board of directors was informed that the merger agreement and the other definitive transaction documents in respect of the Potential Transaction were in final form, subject to the approval of the MEI board of directors and the Infinity board of directors. Representatives of Torreya gave a presentation to the MEI board of directors regarding the Fairness Opinion. The MEI board of directors discussed that the matters to be voted on included (i) a proposed amendment and restatement of MEI's bylaws, (ii) the adoption of the merger agreement and all other agreements, instruments, certificates and documents required to be delivered in connection therewith, in each case substantially in the form presented to the MEI board of directors, and the consummation of the transactions contemplated thereby, including the MEI Share Issuance. Following a discussion, during which questions were asked and answered, the MEI board of directors authorized, approved, adopted and ratified the amended and restated bylaws. Representatives of Torreya then confirmed on behalf of Torreya that, as provided in its fairness opinion, the exchange ratio set forth in the merger agreement was fair, from a financial point of view, to MEI's stockholders. For more information about Torreya's opinion, see the section entitled "*The Merger — Opinion of MEI Financial Advisor*"

## [Table of Contents](#)

beginning on page 147 of this joint proxy statement/prospectus. Following discussion of the Potential Transaction, the MEI board of directors, among other things, (i) determined that the terms of the merger agreement and the MEI Share Issuance were fair to, and in the best interests of, MEI and its stockholders; (ii) approved and declared advisable the merger agreement, the MEI Share Issuance and the other transaction contemplated by the merger agreement; (iii) directed that the MEI Share Issuance proposal be submitted to the MEI stockholders for approval; and (iv) recommended that MEI's stockholders approve the MEI Share Issuance. Consistent with past practice, Mr. Kango, Mr. Driscoll and Ms. Howson recused themselves from discussions and meetings regarding the merger agreement and the transactions contemplated thereby, including the MEI Share Issuance, and did not participate in the MEI board's approval thereof.

On the afternoon of February 22, 2023, Infinity circulated final versions of the merger agreement and the related ancillary documents to the Infinity board of directors, excluding Mr. Kango, via email. On February 22, 2023, at 7:30 p.m. Eastern Time, the Infinity board of directors held a virtual meeting with representatives of Infinity management, Aquilo and WilmerHale. Consistent with past practice, Mr. Kango recused himself from this board meeting. Representatives of WilmerHale confirmed that the merger agreement and related transaction documents were in final form and that there had been no material changes since the February 20 meeting of the Infinity board of directors. Representatives of Aquilo then confirmed that there had been no material changes to the financial analysis presented to the Infinity board of directors at the February 20 meeting of the Infinity board and directed the Infinity board to a presentation providing further details about its financial analysis. After completing the presentation, representatives from Aquilo orally rendered its opinion, subsequently confirmed by delivery of a written opinion, to the effect that, as of the date of the meeting, and based upon and subject to the various assumptions made, procedures followed, matters considered, and qualifications and limitations on the scope of the review undertaken by Aquilo as set forth in the written opinion, the exchange ratio pursuant to the merger agreement was fair from a financial point of view to Infinity stockholders. For more information about Aquilo's opinion, see the section entitled "*The Merger — Opinion of Infinity Financial Advisor*" beginning on page 156 of this joint proxy statement/prospectus. Following discussion, the Infinity board of directors (with Mr. Kango abstaining), among other things, (i) determined that the terms of the merger agreement and the merger were fair to, and in the best interests of, Infinity and its stockholders; (ii) approved and declared advisable the merger agreement, the merger and the other transaction contemplated by the merger agreement; (iii) directed that the merger agreement be submitted to Infinity stockholders for adoption; and (iv) recommended that Infinity stockholders adopt the merger agreement. Consistent with past practice, Mr. Kango recused himself from discussions and meetings regarding the merger agreement and the transactions contemplated thereby, including the Merger, and did not participate in the Infinity board's approval thereof.

Later on the evening of February 22, 2023, MEI and Infinity executed the merger agreement.

Before the opening of Nasdaq trading on February 23, 2023, both parties issued a joint press release announcing MEI's and Infinity's entry into the merger agreement.

### **MEI's Reasons for the Merger; Recommendation of the MEI Board**

#### **MEI Reasons for the Merger**

At a meeting held on February 22, 2023, among other things, the MEI board of directors (i) determined that the Merger Agreement and all other agreements, instruments, certificates and documents required to be delivered in connection therewith (collectively, the "Transaction Documents"), the Merger and other transactions contemplated by the Merger Agreement (together with the Merger, the "Contemplated Transactions,") including the issuance of shares of MEI common stock pursuant to the terms of the Merger Agreement (the "MEI Share Issuance") were advisable, fair to and in the best interests of MEI and its stockholders, (ii) authorized, approved, adopted, ratified and confirmed the Merger Agreement and the other Transaction Documents, in each case substantially in the form presented to the MEI board of directors, and the consummation of the Merger and the

## Table of Contents

other Contemplated Transactions, including the MEI Share Issuance and (iii) resolved to recommend the approval of the MEI Share Issuance by MEI's stockholders. Consistent with past practice, Mr. Kango, Mr. Driscoll and Ms. Howson recused themselves from discussions regarding the Merger Agreement, the Transaction Documents, the Merger and the other Contemplated Transactions, including the MEI Share Issuance, and did not participate in the MEI board's approval thereof.

During the course of its evaluation of the Merger Agreement and the other Transaction Documents, and the Merger and the other Contemplated Transactions, both the MEI board of directors and the MEI Transactions Committee held numerous meetings, consulted with MEI's senior management and its outside legal counsel and financial advisors, reviewed and assessed a significant amount of information and considered the business, assets, liabilities, results of operations, financial performance, capital needs, strategic direction and prospects of each of MEI and Infinity. In reaching its decision to approve the Merger Agreement and the other Transaction Documents, the Merger and the other Contemplated Transactions, the MEI board of directors considered a number of factors that it viewed as supporting such decision, including:

- the financial condition and regulatory and commercial prospects of MEI, and the risks associated with continuing to operate MEI on a stand-alone basis or the other strategic alternatives available to MEI, including the winding up of MEI's operations and declaring a dividend of available cash to MEI's stockholders in an amount equal to approximately \$80 million;
- the financial condition and commercial prospects of Infinity, and the risks associated with combining Infinity with MEI;
- the financial analyses of Torrey Capital, LLC ("Torreya"), including its opinion to the MEI board of directors, to the effect that, as of such date and based on and subject to various assumptions, matters considered and limitations, conditions and qualifications described in its opinion, the exchange ratio as set forth in the Merger Agreement (the "Exchange Ratio") was fair, from a financial point of view, to MEI's stockholders, as more fully described below under the caption "*The Merger—Opinion of MEI's Financial Advisor*";
- the MEI board's belief, after a thorough review of strategic and licensing alternatives and discussions with MEI's senior management, financial advisor and legal counsel, that the Merger is more favorable to MEI's stockholders than the potential value that might have resulted from other strategic and licensing alternatives available to MEI, including the winding up of MEI's operations and declaring a dividend of available cash to MEI's stockholders;
- the MEI board's belief that, as a result of arm's length negotiations with Infinity, MEI and its representatives negotiated the most favorable terms to MEI in the aggregate to which Infinity was willing to agree;
- the MEI board's view, based on the scientific, regulatory and technical due diligence conducted by MEI management, of the regulatory pathway for, and commercial opportunities of, Infinity's product candidate, eganelisib;
- the MEI board's belief, that prioritizing a randomized, controlled Phase II trial of eganelisib in patients with squamous cell cancer of the head and neck ("HNSCC") over other potential indications, which builds on eganelisib clinical data from Infinity's Phase I/Ib trial evaluating eganelisib as a monotherapy and in combination with Opdivo® (nivolumab) in patients with HNSCC and other solid tumor indications, offers the opportunity for potential near term value creation as well as a favorable potential registration path;
- the MEI board's consideration of the expected cash resources of the combined company as of the closing of the Merger, with at least \$100 million of cash and cash equivalents on a pro forma basis after giving effect to the Merger;

## Table of Contents

- the MEI board's consideration of Infinity's strategic fit with the MEI business after giving effect to the Merger, including with respect to the development of MEI's existing product candidates, voruciclib and ME-344, and Infinity's product candidate, eganelisib;
- the MEI board's view, following a review with MEI's management of Infinity's current development and clinical trial plans for the product candidates of the combined company, including eganelisib, voruciclib, ME-344, of the likelihood that the combined company would possess sufficient cash resources at the closing of the Merger to fund operations and generate meaningful clinical data over the next 24 months;
- the prospects of and risks associated with the other strategic or licensing candidates that had made inquiries for a potential transaction with MEI based on the scientific, technical and other due diligence conducted by MEI management and its advisors;
- the MEI board's view that, as a result of the significant, majority equity interest that the MEI stockholders would have in the post-Merger combined company, MEI stockholders have the opportunity to meaningfully participate in the growth and value creation of the combined company following the closing of the Merger by virtue of their continued ownership of MEI Common Stock;
- the MEI board's view of the combined clinical development and regulatory expertise of Infinity and MEI, which both possess relevant experience in the development of pharmaceutical products to treat cancer, particularly including kinase biology target cancer inhibition;
- the MEI board's confidence in the board of directors of the combined company, with representation from each of the current boards of directors of MEI and Infinity;
- the MEI board's confidence in the management team of the combined company, with members drawn from both MEI and Infinity;
- the MEI board's confidence in Norman C. Selby serving as chair of the board of directors of the combined company, David M. Urso serving as the chief executive officer of the combined company, Robert Ilaria, Jr. serving as the chief medical officer of the combined company and Stéphane Peluso serving as the chief scientific officer of the combined company;
- the MEI board's confidence in Ms. Adelene Q. Perkins serving as chair of the combined company's audit committee, Dr. Thomas Reynolds serving as chair of the combined company's compensation committee and Mr. Charles Baltic serving as chair of the combined company's nominating and corporate governance committee;
- the recommendation of MEI's senior management in favor of the Merger, and Torreya's favorable view of the financial condition and clinical and commercial prospects of the combined company;
- the ability of MEI stockholders to approve or reject the Merger by voting on the MEI Share Issuance;
- the expected treatment of the Merger as a tax-free reorganization under Section 368(a) of the Code for U.S. federal income tax purposes, as more fully described in the section entitled "*Material U.S. Federal Income Tax Consequences to the Merger*" beginning on page 176 of this joint proxy statement/prospectus; and
- the current financial and capital market conditions and historical market prices, volatility and trading information with respect to MEI's Common Stock.

The MEI board of directors also reviewed the terms of the Merger Agreement and related transaction documents, including those described below, and concluded that the terms of the Merger Agreement and related transaction documents, in the aggregate, were reasonable under the circumstances:

- the calculation of the Exchange Ratio and the estimated number of shares of MEI Common Stock to be issued in the Merger;

## Table of Contents

- that the representations and warranties of each of MEI and Infinity, as well as the interim operating covenants requiring the parties to conduct their respective businesses in the ordinary course prior to completion of the Merger, subject to specific limitations, are generally reciprocal;
- that MEI will not be required to consummate the Merger if, prior to the closing of the Merger, Infinity does not have an amount of net cash that exceeds the minimum net cash amount set forth in the Merger Agreement;
- that MEI will not be required to consummate the Merger if prior to closing to the closing of the Merger, Infinity does not achieve certain agreed-upon milestones related to the development of eganelisib;
- the number and nature of the conditions to MEI's and Infinity's respective obligations to complete the Merger and the likelihood that the Merger will be completed on a timely basis, as more fully described below under the caption "*The Merger Agreement — Conditions to the Completion of the Merger*," beginning on page 184 in this proxy statement/prospectus;
- the respective rights of, and limitations on, MEI and Infinity under the Merger Agreement to consider and engage in discussions regarding unsolicited Acquisition Proposals under certain circumstances, and the limitations on the board of directors of each party to change its recommendation in favor of the MEI share Issuance, in the case of the MEI board of directors, and the Merger, in the case of the Infinity board of directors, as more fully described below under the caption "*The Merger Agreement — No Solicitation*," beginning on page 187 in this proxy statement/prospectus;
- the right of each party to terminate the Merger Agreement to accept an unsolicited Acquisition Proposal in certain circumstances, subject to the payment of a termination fee and/or the reimbursement of the other party's expenses up to a maximum of \$1,000,000, as more fully described below under the caption "*The Merger Agreement — Termination Fee and Expense Reimbursement*," beginning on page 195 in this proxy statement/prospectus;
- the conclusion of the MEI board of directors that the potential termination fee of \$4,000,000, payable by MEI, and \$2,900,000, payable by Infinity, in each case to the other party, and the circumstances when such fees may be payable, were reasonable, as more fully described below under the caption "*The Merger Agreement — Termination Fee and Expense Reimbursement*," beginning on page 195 in this proxy statement/prospectus; and
- the conclusion of the MEI board of directors that the potential expense reimbursement up to a maximum of \$1,000,000, payable by MEI or Infinity, and the circumstances when such expense reimbursement may be payable, were reasonable, as more fully described below under the caption "*The Merger Agreement — Termination Fee and Expense Reimbursement*," beginning on page 195 in this proxy statement/prospectus.

In the course of its deliberations, the MEI board of directors also considered a variety of risks and other countervailing factors related to entering into the Merger, including:

- the potential effect of the \$4,000,000 termination fee and the \$1,000,000 maximum expense reimbursement amount payable by MEI upon the occurrence of certain events in deterring other potential acquirors from proposing an alternative Acquisition Proposal that may be more advantageous to MEI stockholders;
- the prohibition on MEI soliciting alternative Acquisition Proposals during the pendency of the Merger;
- the substantial expenses incurred by MEI in connection with the Merger;
- the possible volatility of the trading price of the MEI Common Stock resulting from the announcement, pendency or completion of the Merger;

## Table of Contents

- the difficulties and management challenges inherent in completing the Merger and integrating the business, operations and workforces of MEI and Infinity and the risk that anticipated benefits of the Merger might not be realized;
- the risk that the \$2,900,000 termination fee from Infinity to which MEI may be entitled, subject to the terms and conditions of the Merger Agreement, in connection with termination of the Merger Agreement in certain circumstances may not be sufficient to compensate MEI for the harm that it might suffer as a result of such termination;
- the potential for litigation relating to the Merger and the associated costs, burden and inconvenience involved in defending those proceedings;
- the risk that the Merger might not be consummated in a timely manner or at all, including as a result of the Merger not being consummated by the outside termination date of August 31, 2023;
- the fact that the representations and warranties in the Merger Agreement do not survive the closing of the Merger and the potential risk of liabilities that may arise post-closing;
- the restrictions in the Merger Agreement on the conduct of MEI's business during the period between execution of the Merger Agreement and the consummation of the Merger, including the obligation that MEI must conduct its business only in the ordinary course, subject to specific limitations, which (although substantially reciprocal to those restrictions imposed on Infinity) could negatively impact MEI's ability to pursue certain business opportunities or strategic transactions;
- the risk that MEI stockholders or Infinity stockholders, as applicable, may not approve the proposals at the MEI Special Meeting or the Infinity Special Meeting;
- the scientific, technical, regulatory and other risks and uncertainties associated with development and commercialization of eganelisib;
- the risk that the combined company may not have sufficient sources of financing necessary to fund development of the combined company's product candidates through potential value inflection points;
- the lack of availability of appraisal rights under the DGCL to holders of MEI Common Stock which would not allow holders to seek appraisal of the fair value of their shares of MEI Common Stock; and
- the various other risks associated with the combined company and the transaction, including those described in the sections entitled "*Risk Factors*" and "*Cautionary Statement Concerning Forward-Looking Statements*" in this proxy statement/prospectus.

The foregoing information and factors considered by the MEI board of directors are not intended to be exhaustive but are believed to include all of the material factors considered by the MEI board of directors. In view of the wide variety of factors considered in connection with its evaluation of the Merger and the complexity of these matters, the MEI board of directors did not find it useful, and did not attempt, to quantify, rank or otherwise assign relative weights to these factors. In considering the factors described above, individual members of the MEI board of directors may have given different weight to different factors. The MEI board of directors conducted an overall analysis of the factors described above, including thorough discussions with, and questioning of, the MEI management team and the legal, financial advisors and other professional advisors of MEI, and considered the factors overall to be favorable to, and to support, its determination.

### **Infinity's Reasons for the Merger; Recommendation of the Infinity Board**

At a meeting held on February 22, 2023, the board of directors of Infinity, which is referred to as the Infinity board of directors:

- determined that the Merger Agreement, the Merger and the other transactions contemplated by the Merger Agreement are fair to, and in the best interests of, Infinity and its stockholders;

## Table of Contents

- approved and declared advisable the Merger Agreement, the Merger and the other transactions contemplated by the Merger Agreement;
- directed that the Merger Agreement be submitted for adoption at a meeting of Infinity stockholders; and
- recommended that Infinity stockholders vote in favor of the adoption of the Merger Agreement.

Accordingly, the Infinity board of directors has approved the Merger Agreement and recommends that Infinity stockholders vote “FOR” the Infinity Merger Proposal, “FOR” the Infinity Compensation Proposal, and “FOR” the Infinity Adjournment Proposal.

In reaching its decision to approve and declare advisable the Merger Agreement, the Merger and the other transactions contemplated by the Merger Agreement, the Infinity board of directors, as described in the section entitled “—*Background of the Merger*” beginning on page 122 of this joint proxy statement/prospectus, held a number of meetings, consulted with Infinity’s senior management and its outside legal and financial advisors, and considered the business, assets and liabilities, results of operations, financial performance, strategic direction and prospects of Infinity and MEI. At its meeting held on February 22, 2023, after due consideration and consultation with Infinity’s senior management and outside legal and financial advisors and after receipt of its financial advisor’s opinion, the Infinity board of directors approved and declared advisable the Merger Agreement, the Merger and the other transactions contemplated by the Merger Agreement and recommended that Infinity stockholders vote in favor of the adoption of the Merger Agreement.

In making its determination, the Infinity board of directors focused on a number of factors, including the following:

- the Infinity board of directors’ belief that eganelisib has significant commercial potential and the Merger with MEI would allow for eganelisib’s continued development;
- the Infinity board of directors’ belief that, as a result of arm’s length negotiations with MEI, Infinity, through Infinity’s management team and financial advisor, negotiated the most favorable equity split for its pre-closing stockholders to which MEI was willing to agree, and that the terms of the Merger Agreement include the most favorable terms to Infinity in the aggregate to which MEI was willing to agree;
- the Infinity board of directors’ belief that, as a result of the significant equity interest that the Infinity stockholders would have in the post-merger combined company, the Infinity stockholders could meaningfully participate in potential value creation from successful development of eganelisib;
- the Infinity board of directors’ belief, after a thorough review of strategic alternatives, the financial condition and commercial prospects of Infinity and the risks associated with continuing to operate Infinity on a standalone basis, and discussions with Infinity’s senior management, financial advisor and legal counsel, that the Merger Agreement was more favorable to Infinity’s pre-closing stockholders than the potential value that might have resulted from other strategic and financing options available to Infinity at the time, including financing transactions, strategic transactions with other parties, continuing to operate Infinity on a standalone basis and a liquidation of Infinity and the distribution of any available cash;
- the current financial market conditions and historical market prices, volatility and trading information with respect to Infinity Common Stock;
- the Infinity board of directors’ belief that, following the Merger, the combined company would have adequate cash resources to fund the near-term development of eganelisib, and absent the Merger, Infinity would not have sufficient cash to continue development of eganelisib;
- the Infinity board of directors’ belief, that the prioritized, randomized, controlled Phase 2 trial of eganelisib in patients with squamous cell cancer of the head and neck (“HNSCC”), which builds on eganelisib clinical data in HNSCC from Infinity’s Phase 1/1b trial evaluating eganelisib as a monotherapy and in combination with Opdivo® (nivolumab) in patients with solid tumors, offers the opportunity for potential near term value creation;
- the anticipated combined scientific, clinical development and regulatory expertise of Infinity and MEI, which both possess relevant experience in the development of pharmaceutical products to treat cancer;



## Table of Contents

- the Infinity board of directors' confidence in the management team of the combined company, with members drawn from both Infinity and MEI;
- that Norman C. Selby, the lead independent director of the Infinity board of directors, would become the chair of the board of the directors of the combined company as of the Effective Time and the Infinity board of directors' view of Mr. Selby's strong track record as member of the Infinity board of directors;
- that David M. Urso, the chief operating officer of MEI, with a strong reputation as a leader in the life sciences industry, would be the chief executive officer of the combined company as of the effective time;
- that Robert Ilaria, Jr., the chief medical officer of Infinity, would become the chief medical officer of the combined company as of the effective time and the Infinity board of directors' view of Mr. Ilaria's strong track record as chief medical officer of Infinity;
- that Stéphane Peluso, the chief scientific officer of Infinity, would become the chief scientific officer of the combined company as of the effective time and the Infinity board of directors' view of Mr. Peluso's strong track record as chief scientific officer of Infinity;
- that the board of directors of the combined company would include four designees from MEI, including Mr. Urso and Dr. Daniel P. Gold, the president and chief executive officer of MEI, and three designees from Infinity, including Mr. Selby and Adelene Q. Perkins, Infinity's chief executive officer and the chair of the Infinity board of directors, plus Sujay R. Kango as a joint designee of MEI and Infinity;
- that Ms. Perkins would act as chair of the combined company's audit committee, and designees from MEI would act as chair of the combined company's compensation committee and nominating and corporate governance committee;
- the perceived cultural alignment between Infinity and MEI that would facilitate integration and implementation of the Merger;
- as of the Effective Time, the headquarters of the combined company would be in San Diego, California;
- that the Exchange Ratio of 1.0449 shares of MEI Common Stock for each share of Infinity Common Stock, as it was fixed prior to MEI's reverse stock split (and which is 0.052245 after MEI's reverse stock split), is fixed, subject to equitable adjustments, consistent with the principles underlying the merger of equals structure for the transaction;
- the recommendation of Infinity's senior management in favor of the Merger;
- the fact that the shares of MEI Common Stock that Infinity stockholders would receive pursuant to the Merger Agreement would be issued pursuant to an effective registration statement and freely tradable following the completion of the Merger;
- the ability of Infinity stockholders to approve or reject the Merger by voting on the adoption of the Merger Agreement;
- the impact of the Merger on the employees and other stakeholders of Infinity;
- the oral opinion of Aquilo, subsequently confirmed in writing, to the Infinity board of directors that, as of February 22, 2023, and based upon and subject to the various assumptions made, procedures followed, matters considered and qualifications and limitations on the scope of the review undertaken by Aquilo as set forth in its written opinion, the Exchange Ratio pursuant to the Merger Agreement was fair from a financial point of view to the holders of shares of Infinity Common Stock, other than MEI and its affiliates, as more fully described under the section entitled "*Opinion of Infinity's Financial Advisor*" beginning on page 156 of this joint proxy statement/prospectus and the full text of the written opinion of Aquilo, which is attached as Annex C to this joint proxy statement/prospectus;
- the expected treatment of the Merger as a tax-free reorganization under Section 368(a) of the Code for U.S. federal income tax purposes, as more fully described in the section entitled "Material U.S. Federal Income Tax Consequences to the Merger" beginning on page 22 of this joint proxy statement/prospectus;

## Table of Contents

- the review by the Infinity board of directors with its advisors of the structure of the proposed Merger and the financial and other terms of the Merger Agreement, including the parties' representations, warranties and covenants, the conditions to their respective obligations and the termination provisions as well as the likelihood of consummation of the proposed transactions and the evaluation of the Infinity board of directors of the likely time period necessary to complete the Merger. The Infinity board of directors also considered the following specific aspects of the Merger Agreement:
  - the nature of the closing conditions included in the Merger Agreement, including the reciprocal exceptions to the events that would constitute a material adverse effect on either Infinity or MEI for purposes of the Merger Agreement, as well as the likelihood of satisfaction of all conditions to completion of the transactions;
  - that the representations and warranties of Infinity or MEI, as well as the interim operating covenants requiring the parties to conduct their respective businesses in the ordinary course prior to completion of the Merger, subject to specific limitations, are generally reciprocal;
  - that Infinity will not be required to consummate the Merger if MEI does not have an amount of net cash that exceeds the minimum net cash amount set forth in the Merger Agreement;
  - the restrictions in the Merger Agreement on MEI's ability to respond to and negotiate certain alternative transaction proposals from third parties, the requirement that MEI pay Infinity a \$4,000,000 termination fee or reimburse Infinity's transaction expenses up to a maximum of \$1,000,000 if the Merger Agreement is terminated under certain circumstances and the inability of Infinity to terminate the Merger Agreement in connection with a change of recommendation by the MEI board of directors;
  - Infinity's right to engage in negotiations with, and provide information to, a third party that makes an unsolicited written bona fide proposal relating to an alternative proposal, if the Infinity board of directors has determined in good faith, after consultation with its outside legal counsel and financial advisors, that such proposal constitutes or could reasonably be expected to result in a transaction that is superior to the Merger (although Infinity cannot terminate the Merger Agreement to accept a superior proposal); and
  - the right of the Infinity board of directors, subject to certain conditions, to change its recommendation to Infinity stockholders to vote "FOR" the Infinity Merger Proposal if a superior proposal is available or an intervening event has occurred (although Infinity cannot terminate the Merger Agreement to accept a superior proposal or if an intervening event has occurred).

The Infinity board of directors weighed these advantages and opportunities against a number of potentially negative factors in its deliberations concerning the Merger Agreement and the Merger, including:

- the difficulties and management challenges inherent in completing the Merger and integrating the business, operations and workforces of Infinity and MEI and the risk that anticipated benefits of the Merger might not be realized;
- the amount of time it could take to complete the Merger, including that completion of the Merger depends on factors outside of Infinity's or MEI's control, and the risk that the pendency of the Merger for an extended period of time following the announcement of the execution of the Merger Agreement could have an adverse impact on Infinity or MEI, including their respective business relationships;
- the risk that the cultures of the two companies may not be as compatible as anticipated;
- the possible diversion of management attention for an extended period of time during the pendency of the Merger;
- the risk that, despite the retention efforts of Infinity and MEI prior to the consummation of the Merger, the combined company may lose key personnel;
- the risk that changes in the regulatory landscape or new industry developments may adversely affect the business benefits anticipated to result from the Merger;

## Table of Contents

- the provisions of the Merger Agreement which prohibit Infinity from soliciting or entertaining other acquisition offers, the potential payment to MEI by Infinity of a termination fee of \$2,900,000 or an expense reimbursement payment of up to \$1,000,000, as described in the section entitled “*The Merger Agreement—Termination Fees*” beginning on page 195 of this joint proxy statement/prospectus and the inability of Infinity to terminate the Merger Agreement in connection with a change of recommendation by the Infinity board of directors;
- the risk that the \$4,000,000 termination fee from MEI, or payment from MEI of up to \$1,000,000 for the reimbursement of Infinity’s transaction expenses, in each case to which Infinity may be entitled, subject to the terms and conditions of the Merger Agreement, in connection with termination of the Merger Agreement in certain circumstances may not be sufficient to compensate Infinity for the harm that it might suffer as a result of such termination;
- the potential for litigation relating to the proposed Merger and the associated costs, burden and inconvenience involved in defending those proceedings;
- that certain provisions of the Merger Agreement, although reciprocal, may have the effect of discouraging alternative proposals involving Infinity;
- the restrictions in the Merger Agreement on the conduct of Infinity’s business during the period between execution of the Merger Agreement and the consummation of the Merger, including that Infinity must conduct its business only in the ordinary course, subject to specific limitations, which (although reciprocal to those limitations imposed on MEI) could negatively impact Infinity’s ability to pursue certain business opportunities or strategic transactions;
- the risk that Infinity stockholders or MEI stockholders, as applicable, may not approve the proposals at the Infinity Special Meeting or MEI Special Meeting;
- the fact that the Exchange Ratio is fixed under the Merger Agreement, meaning that the trading value of the Merger consideration upon consummation of the Merger might be more or less than the trading value of such consideration on the date of the execution of the Merger Agreement;
- the possible volatility of the trading price of the Infinity Common Stock resulting from the announcement, pendency or completion of the Merger;
- the substantial transaction costs to be incurred in connection with the proposed Merger; and
- the risks of the type and nature described in the section entitled “*Risk Factors*” beginning on page 26 of this joint proxy statement/prospectus and the matters described in the section entitled “*Cautionary Statement Regarding Forward-Looking Statements*” beginning on page 1 of this joint proxy statement/prospectus.

The Infinity board of directors considered all of these factors as a whole and, on balance, concluded that it supported a favorable determination to approve the Merger Agreement and to make its recommendations to Infinity stockholders.

In addition, the Infinity board of directors was aware of and considered the interests of its directors and executive officers that are different from, or in addition to, the interests of Infinity stockholders generally, including the treatment of equity awards held by such directors and executive officers in the Merger described in the section entitled “*Interests of Infinity Directors and Executive Officers in the Merger*” beginning on page 167 of this joint proxy statement/prospectus, and the obligation of the combined company to indemnify Infinity directors and officers against certain claims and liabilities.

The foregoing discussion of the information and factors that the Infinity board of directors considered is not intended to be exhaustive, but rather is meant to include material factors that the Infinity board of directors considered. The Infinity board of directors collectively reached the conclusion to approve the Merger Agreement, the Merger and the other transactions contemplated by the Merger Agreement in light of the various factors

described above and other factors that the members of the Infinity board of directors believed were appropriate. In view of the complexity and wide variety of factors, both positive and negative, that the Infinity board of directors considered in connection with its evaluation of the Merger, the Infinity board of directors did not find it practical, and did not attempt, to quantify, rank or otherwise assign relative or specific weights or values to any of the factors it considered in reaching its decision and did not undertake to make any specific determination as to whether any particular factor, or any aspect of any particular factor, was favorable or unfavorable to the ultimate determination of the Infinity board of directors. In considering the factors discussed above, individual directors may have given different weights to different factors.

The foregoing description of Infinity's consideration of factors supporting the Merger is forward-looking in nature. This information should be read in light of the factors discussed in the section entitled "*Cautionary Statement Regarding Forward-Looking Statements*" beginning on page 1.

### **Opinion of MEI Financial Advisor**

On October 27, 2022, MEI engaged Torrey Capital, LLC ("Torrey") to serve as an independent financial advisor to the MEI board of directors (solely in their capacity as members of the MEI board of directors) to explore and evaluate potential strategic options to maximize the long-term value for MEI stockholders as well as provide an opinion as to the fairness, from a financial point of view, to the holders of shares of MEI Common Stock of the Exchange Ratio provided for in the Merger Agreement.

MEI retained Torrey based on Torrey's qualifications, reputation, experience in the provision of corporate finance services in the life science's market including the valuation of businesses and their securities, its experience in valuing companies in the biotechnology and biopharmaceutical industry, and its familiarity with MEI's business. Torrey is a global investment bank and corporate finance advisor that is regularly engaged to provide financial advisory services, including fairness opinions and valuation advice in connection with mergers and acquisitions, related party transactions and recapitalization transactions within the healthcare sector.

On February 22, 2023, Torrey delivered its oral opinion to the MEI board of directors, which was subsequently confirmed in written opinion dated February 22, 2023 (the "Torrey Opinion") to the MEI board of directors that, as of that date, the Exchange Ratio provided for in the Merger was fair, from a financial point of view, to the holders of shares of MEI Common Stock. For purposes of the Torrey Opinion and related analyses, "Exchange Ratio" means the ratio obtained by dividing (i) 96.4992 million (calculated as 42% of the total outstanding shares of the pro forma company, representing the number of shares legacy Infinity stockholders will own in the combined company), by (ii) 92.3513 million, the number of fully diluted shares outstanding of Infinity as of the date of the Merger Agreement. As of immediately prior to the execution of the Merger Agreement, the Exchange Ratio was calculated to be 1.0449, subject to customary equitable adjustments including as a result of any reverse split of the shares of MEI Common Stock. The Exchange Ratio was determined through negotiations between MEI and Infinity and was approved by the MEI board of directors. Torrey provided advice to the MEI board of directors during these negotiations. Torrey, however, did not recommend any specific amount of consideration to MEI or the MEI board of directors or that any specific amount of consideration constituted the only appropriate consideration for the Merger.

**The full text of the Torrey Opinion sets forth the assumptions made, procedures followed, matters considered and qualifications and limitations on the review undertaken by Torrey in connection with the Torrey Opinion. The Torrey Opinion is attached as Annex B to this joint proxy statement/prospectus. The summary of the Torrey Opinion set forth in this joint proxy statement/prospectus is qualified in its entirety by reference to the full text of the Torrey Opinion.**

## [Table of Contents](#)

**MEI urges you to read carefully the Torreyra Opinion, together with the summary thereof in this joint proxy statement/prospectus, in its entirety. Torreyra provided its opinion for the information and assistance of the MEI board of directors in connection with its consideration of the Merger. The Torreyra Opinion addressed solely the fairness, from a financial point of view, of the Exchange Ratio in the Merger and does not address any other aspect or implication of the Merger. The Torreyra Opinion was not a recommendation to the MEI board of directors or any stockholder of MEI as to how to vote, make any election or to take any other action in connection with the Merger or any other matter and does not in any manner address the prices at which shares of common stock of MEI or Infinity will trade at any time.**

In connection with Torreyra's review of the Merger and developing the opinion described above, Torreyra:

- i. Reviewed the draft Merger Agreement dated February 22, 2023;
- ii. Reviewed and analyzed certain financial and other information with respect to MEI and Infinity which was publicly available;
- iii. Reviewed diligence findings provided by advisors (Morgan Lewis) instructed by MEI;
- iv. Reviewed and analyzed certain information, including financial forecasts relating to the business, earnings, cash flow, assets, liabilities and prospects of MEI and Infinity, on a stand-alone basis, that were publicly available, as well as those that were provided to Torreyra by MEI;
- v. Held discussions with the senior management team of MEI and Infinity with respect to the matters described in the preceding three bullets, as well as the respective business;
- vi. Also compared the proposed financial terms of the Agreement with other financial studies and analyses and took into account such other information as Torreyra deemed appropriate in evaluating the merger consideration.

In connection with its review and arriving at its opinion, Torreyra did not independently verify any of the foregoing information, relied on such information, assumed that all such information was complete and accurate in all material respects, and relied on assurances of management of MEI and Infinity that they were not aware of any facts that would make such information misleading. With respect to the cash projections of Infinity prepared by management of Infinity, the projected cash balance of MEI prepared by management of MEI, and any other estimates or forward looking information reviewed by Torreyra, Torreyra assumed, with the consent of the MEI board of directors, that such information was reasonably prepared on bases reflecting the best currently available estimates and judgments of management as to the matters covered thereby, and Torreyra relied, at the direction of the MEI board of directors, on such information for purposes of its analysis and opinion. Torreyra expressed no view or opinion as to such information or the assumptions on which it was based. Torreyra also relied on information provided by the management of MEI and Infinity as to the capitalization of MEI and Infinity, respectively, and Torreyra assumed, with the consent of the MEI board of directors, that such information will not vary in any material respect that would be meaningful to Torreyra's analysis.

Torreyra also assumed that (i) the Merger will be consummated upon the terms set forth in the Merger Agreement, without any adjustment to the Exchange Ratio (other than the customary equitable adjustments provided for in the Merger Agreement) or any waiver, modification or amendment of any material term, condition or agreement therein which would be in any way meaningful to Torreyra's analysis, (ii) the representations and warranties made by the parties to the Merger Agreement are and will be true and correct in all respects material to Torreyra's analysis, and (iii) in the course of obtaining necessary governmental, regulatory and third-party approvals and consents for the Merger, no modification, delay, limitation, restriction or conditions will be imposed which would have an adverse effect on MEI or Infinity that would be in any way meaningful to Torreyra's analysis. Torreyra is not a legal, accounting, regulatory or tax expert and relied on the assessments made by MEI and its advisors with respect to such matters. Torreyra's opinion is limited to and addresses only the fairness, from a financial point of view, to the holders of MEI Common Stock of the Exchange Ratio as of the date of the opinion. Torreyra expressed no opinion as to the fairness of the Merger to the holders of

## [Table of Contents](#)

any other class of securities, creditors, or other constituencies of MEI. Torreya's opinion does not address the relative merits of the Merger as compared to other business strategies or transactions that might be available to MEI, nor does it address the underlying business decision of MEI to proceed with the Merger or any view on another term or aspect of the Merger, including, without limitation, the structure or form of the Merger. Torreya did not consider, and did not express an opinion as to, the fairness of the amount or nature of the compensation to any of the officers, directors or employees of MEI or any other party, or class of such persons. Further, Torreya did not express any opinion as to in the future what the value of MEI Common Stock or any other securities will be when issued or the price or range of prices at which MEI Common Stock or any other securities may trade or otherwise be transferable at any time, including following announcement or consummation of the Merger.

Torreya was not requested to conduct, and did not conduct, nor did Torreya rely upon, any independent valuation or appraisal of any of the assets or liabilities (contingent, derivative, off balance sheet or otherwise) of MEI or Infinity. Torreya also did not evaluate nor express any opinion as to the solvency of any party to the Merger Agreement, or the ability of MEI or Infinity to pay its obligations when they become due, or as to the impact of the Merger on such matters, under any state, federal or other laws relating to bankruptcy, insolvency, or similar matters.

### ***Summary of Financial Analysis by Torreya***

Set forth below is a summary of the material financial analyses performed by Torreya in connection with the preparation of the Torreya Opinion. The information set forth below summarizes the material financial and comparative analyses performed by Torreya but does not purport to be a complete description of the financial analyses performed by Torreya or the data considered by it in connection with the Torreya Opinion. The preparation of a financial opinion involves various subjective determinations as to the most appropriate and relevant methods of financial analysis and the application of these methods to circumstances. In arriving at the Torreya Opinion, Torreya considered several analytical methodologies. Each analytical technique has inherent strengths and weaknesses, and the nature of the available information may further affect the strengths and weaknesses of any technique. The conclusion reached by Torreya was based on all analyses and factors taken, as a whole, and on application of Torreya's own experience and judgment. No one method of analysis should be regarded as critical to the overall conclusions. Accordingly, Torreya believes that its analyses must be considered as a whole, and that selecting portions of its analyses and of the factors considered by it, without considering all analyses and factors, could create a misleading or incomplete view of the evaluation process underlying the Torreya Opinion.

Torreya analyzed the Exchange Ratio using a variety of different methodologies, but primarily relied upon the discounted cash flow analysis in coming to its conclusion. However, Torreya also used the comparable companies analysis, as well as historical trading prices in evaluating the relative pro forma ownership split of the pro forma entity. The results of each of these analyses are summarized below.

### *Discounted Cash Flow Analysis*

A risk-adjusted discounted cash flow, or DCF, analysis is designed to provide insight into the intrinsic value of a business based on its projected earnings and capital requirements as well as the net present value of projected free cash flows. Torreya performed a DCF analysis of MEI for the purpose of calculating an equity value of MEI Common Stock both on a stand-alone basis based on the estimated present value of the standalone, after-tax free cash flows that MEI was forecasted to generate during fiscal years ending December 31, 2023 through 2039, as well as on a pro forma basis based on the estimated present value of the pro forma, after-tax free cash flows that the combined pro forma entity of MEI and Infinity was forecasted to generate during the fiscal years ending December 31, 2023 through 2039.

For purposes of the standalone DCF analysis, Torreya used risk-adjusted projections of free cash flows for fiscal years ending December 31, 2023 through 2039 provided by MEI management (the "MEI Projections"). Forecasted

## Table of Contents

free cash flows were calculated by taking revenue, subtracting cost of goods sold and operating expenses, adding tax expense (adjusted for MEI's Net Operating Losses ("NOL") generated to date of \$134 million), depreciation and adjusting for changes in net working capital. The MEI Projections included estimates of revenues for each product in MEI's pipeline, adjusted by the probability of success specified by management.

A summary of the revenue of each product, on an unadjusted basis, is shown below:

(in \$mm)	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E	2036E	2037E	2038E	2039E
<b>Revenue</b>																	
Voruciclib-CLL	—	—	—	—	—	—	—	—	—	\$ 165	\$ 366	\$ 587	\$ 780	\$ 895	\$ 924	\$ 955	\$ 164
ME-344	—	—	—	—	—	\$ 175	\$ 331	\$ 443	\$ 503	\$ 527	\$ 551	\$ 577	\$ 603	\$ 631	\$ 53	\$ 3	\$ 3
Zandelisib JP Royalty	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
<b>Total Revenue</b>	—	—	—	—	—	\$ 175	\$ 331	\$ 443	\$ 503	\$ 692	\$ 917	\$1,164	\$1,383	\$1,526	\$ 977	\$ 957	\$ 167

Torrey a then discounted the projected free cash flows for fiscal years ending December 31, 2023, through 2039 for MEI using a discount rate ranging from 12.0% to 15.7%. The discount rate was supported by a cost of equity calculation using the Capital Asset Pricing Model and information derived from the selected public companies in the biotechnology industry. Torrey a also assumed a terminal value, using a terminal growth rate ranging from -20% to -70%, based on discussions with management. The standalone DCF analysis resulted in implied price per share ranging from \$0.58 to \$0.91 per share, based on the implied fully diluted shares outstanding. This represents a premium of 81%-184% over MEI's closing price on February 17, 2023 of \$0.32 per share.

Given that MEI is projected to generate ~\$500 million of negative free cash flow before turning cash flow positive in 2029, Torrey a also considered the effect that raising capital would have on the implied value from the DCF. To do this, Torrey a assumed \$200 million would be raised in both 2025 and 2027 (the years in which MEI's cash balance was forecasted to decline below \$25 million). Under this hypothetical scenario, Torrey a assumed 200 million shares would be issued at \$1.00 per share (pre-reverse stock split) after discussing with MEI management, given the clinical milestones reached prior to the equity raises. Through this fact pattern, the implied price per share of MEI on a standalone basis was estimated to range from \$0.60-\$0.74, representing a premium of 88%-131% over MEI's closing price on February 17, 2023.

### Pro Forma Forecast

For purposes of the pro-forma DCF analysis, Torrey a used risk-adjusted pro forma projections of free cash flows provided by MEI and Infinity management (the "Pro Forma Projections"). The Pro Forma Projections represent a scenario in which the combined entity would develop and commercialize MEI's pipeline assets and Eganelisib, Infinity's lead asset. The revenue projection of all assets was estimated based on MEI management, and the operating expenses were estimated based on both MEI and Infinity management, with probability of success estimates provided by MEI management. The pro forma DCF assumes a transaction close date of July 1, 2023, discount rate ranging from 12.0% to 15.7%, MEI's NOL balance as of December 31, 2022 of \$134 million, and terminal growth rate ranging from -20% to -70%. The pro forma DCF resulted in implied price per share ranging from \$0.76 to \$1.45. This represents a premium of 31%-59% over the implied price per share range of MEI on a standalone basis, and a premium of 138%-353% compared to MEI's share price on February 17, 2023.

Given the pro forma entity is forecasted to generate ~\$650 million of negative cash flows prior to becoming cash flow positive in 2029, Torrey a also performed a DCF analysis on the pro forma entity assuming financing would be required. In this hypothetical scenario, Torrey a assuming equity raises of \$200 million in 2024, \$250 million in 2026, and \$100 million in 2028, at a price of \$1.00 per share after discussing with MEI management, given the combined entity's clinical milestones reached through turning cash flow positive. In this scenario, the implied price per share of the pro forma entity was estimated to range from \$0.68 to \$0.94, representing a 13%-27% premium to the implied price per share range of the standalone MEI entity assuming financing would be required, and a premium of 113%-194% compared to MEI's share price on February 17, 2023.



## [Table of Contents](#)

### Liquidation Value

The pro forma DCF analyses imply a significant premium to both MEI's standalone DCF valuation range and current trading price. Torreyá also compared the implied value of MEI as presented in the pro forma DCF analyses to the estimated liquidation value of MEI. To calculate the liquidation value, management provided its best estimate for the cash available to shareholders upon a hypothetical liquidation. Based on discussions with management, a hypothetical liquidation could occur in the second quarter of 2023, and after paying all wind-down obligations, a fully wound-down MEI entity would be left with \$82.8 million of available cash. This would imply a liquidation value of \$0.62 per share. Given that the pro forma DCF represents a significant premium of up to 134% to the liquidation value, and up to 52% in the scenarios with required equity fundraising, Torreyá believes the DCF supports their opinion that the exchange ratio is fair to MEI shareholders.

The DCF analysis, like any other analytical technique used by Torreyá, has inherent strengths and weaknesses. The range of valuation indications resulting from any technique, including the DCF analysis, should not be taken in isolation to be Torreyá's view of the valuation for MEI. Accordingly, the valuation range derived from the DCF analysis was not necessarily indicative of MEI's present or future value.

### *Historical Trading Price Analysis*

In addition to the DCF analyses explained previously, Torreyá also explored the relative value of MEI and Infinity as implied by historical trading data. Specifically, Torreyá calculated what the implied pro forma ownership split would be based on market trading prices of MEI and Infinity respectively. Comparing the 30-day trading low of MEI as of February 17, 2023 to the 30-day high of Infinity implies a pro forma ownership split of 36% MEI / 64% Infinity. Comparing the 30-day trading high of MEI to the 30-day low of Infinity implies a pro forma ownership split of 47% MEI / 53% Infinity. Similarly, Torreyá calculated the 30 and 60 day Volume Weighted Average Price ("VWAP") for each company. The relative low and high would imply a pro forma ownership range of 40-45% MEI / 55-60% Infinity. Notably, each of these scenarios imply a pro forma ownership percentage for MEI of less than 50%. Given that legacy MEI shareholders are to own 58% of the pro forma entity, Torreyá believes this supports the fairness of the exchange ratio. A summary of the market data analysis for MEI and Infinity as of February 17, 2023, is shown below:

#### *MEI Trading History:*

	<b>One Month</b>	<b>Two Months</b>	<b>Three Months</b>	<b>LTM</b>
Average Closing Price	\$ 0.32	\$ 0.30	\$ 0.32	\$0.59
Closing High	\$ 0.35	\$ 0.41	\$ 0.41	\$2.17
Closing Low	\$ 0.28	\$ 0.22	\$ 0.22	\$0.22
Average Daily Volume (in mm)	0.62	1.27	1.12	2.82
VWAP	\$ 0.32	\$ 0.30	\$ 0.31	N/A

#### *Infinity Trading History:*

	<b>One Month</b>	<b>Two Months</b>	<b>Three Months</b>	<b>LTM</b>
Average Closing Price	\$ 0.64	\$ 0.58	\$ 0.75	\$0.88
Closing High	\$ 0.74	\$ 0.74	\$ 1.26	\$1.70
Closing Low	\$ 0.57	\$ 0.46	\$ 0.46	\$0.46
Average Daily Volume (in mm)	0.37	0.58	0.56	0.64
VWAP	\$ 0.64	\$ 0.56	\$ 0.67	N/A

### *Comparable Companies Analysis*

As an additional data point noted for reference purposes, Torreyá reviewed publicly available information relating to the enterprise value of certain publicly-traded companies. Specifically, Torreyá reviewed companies

## Table of Contents

whose lead product was in phase 1 or 2 for an oncology indication, had an enterprise value less than \$500 million, and didn't utilize cell therapy or gene therapy technology, given the differences compared to MEI and Infinity's clinical assets. This analysis resulted in 11 companies (the "Comparable Companies"), for which Torreyia researched probability-adjusted peak sales from analyst equity research reports, and then calculated the respective enterprise value / adjusted peak revenue multiple for each company. The first and third quartile multiples of the Comparable Companies were 0.16x and 0.58x, respectively. Based on this range of multiples and the respective adjusted peak revenue of MEI and Infinity of \$194 million and \$230 million, respectively, the implied price per share of MEI was \$0.99 - \$1.59, and \$0.54 - \$1.58 for Infinity. On a relative value-basis, this would indicate a pro forma ownership split range of 13-85% for MEI, and 15-87% for Infinity. A summary of the comparable companies used to support this analysis is below. Note, this reflects market data as of February 17, 2023:

(\$ in mm) Company	Indication	FDSO					EV	POS Adj. Peak Revenue	EV /Adj. Peak Revenue
		Share Price	Market Cap	Cash	Debt				
Janux Therapeutics	mCRPC	\$ 17.66	\$ 783	\$339	\$ 0	\$ 444	\$ 882	0.50x	
PSD Biotechnology	Head and Neck Cencer	\$ 8.81	\$ 270	\$ 72	\$ 25	\$ 223	\$ 830	0.27x	
Biomea Fusion	Leukemia	\$ 11.00	\$ 339	\$134	\$ 0	\$ 205	\$ 128	1.61x	
Nuvectis Pharma	Ovarian Clear Cell Carcinoma	\$ 9.97	\$ 154	\$ 24	\$ 0	\$ 130	\$ 299	0.44x	
Kinnate Biopharma	Solid Tumors and Metastatic Melanoma	\$ 7.36	\$ 327	\$247	\$ 0	\$ 116	\$ 765	0.15x	
PMV Pharmaceuticals	Tumor Agnostic	\$ 7.93	\$ 365	\$260	\$ 0	\$ 105	\$ 175	0.60x	
Prelude Therapeutics	Solid and Hematologic Malignancies	\$ 5.84	\$ 291	\$228	\$ 0	\$ 63	\$ 74	0.85x	
Cue Biopharma	HNSCC	\$ 3.18	\$ 113	\$ 62	\$ 9	\$ 59	\$ 305	0.19x	
ALX Oncology	HNSCC	\$ 7.64	\$ 318	\$285	\$ 0	\$ 33	\$ 1,070	0.03x	
GT Biopharma	Leukemia	\$ 0.82	\$ 27	\$ 21	\$ 0	\$ 6	\$ 831	0.01x	
C4 Therapeutics	Multiple Myeloma & Lymphoma	\$ 6.07	\$ 300	\$317	\$ 13	(\$ 4)	\$ 446	NMF	
<b>MEI</b>	<b>CLL and CRC</b>	<b>\$ 0.32</b>	<b>\$ 43</b>	<b>\$124</b>	<b>—</b>	<b>(\$ 82)</b>	<b>\$ 194</b>		

### Miscellaneous

Other than work associated with this transaction, during the two years preceding the date of the Torreyia Opinion, Torreyia has not been engaged to provide financial advisory services or other services to MEI, and Torreyia has not received any compensation from MEI during such period.

Pursuant to MEI's engagement letter with Torreyia, MEI agreed to pay Torreyia a fee for its services, including \$500,000 of warrants upon execution of the engagement, and \$2.2 million for the strategic transaction, \$600,000 of which became payable upon Torreyia informing the MEI board of directors that it was prepared to deliver its opinion and \$1.6 million that will become payable to Torreyia upon completion of the transaction. MEI also agreed to reimburse Torreyia for its reasonable out-of-pocket expenses incurred in connection with its engagement and to indemnify Torreyia against certain liabilities relating to or arising out of Torreyia's engagement.

### Summary of Certain MEI Unaudited Prospective Financial Information

As a matter of course, MEI does not publicly disclose long-term projections of future financial performance due to among other things, the inherent difficulty of predicting financial performance for future periods and the likelihood that the underlying assumptions and estimates may not be realized. However, in connection with the

## [Table of Contents](#)

exploration of strategic alternatives as described in this joint proxy statement/prospectus, MEI management prepared for Torrey certain non-public, unaudited projections of financial performance for MEI for the fiscal years ending December 31, 2023 through 2039, or the MEI Projections, based on its view of the prospects of MEI, and risk-adjusted these projections for MEI's principal programs consisting of (i) zandelisib, (ii) voruciclib, and (iii) ME-344, as described under the "—Opinion of MEI's Financial Advisor —Torreya Capital, LLC." The MEI Projections were based on certain internal assumptions about the probability of technical success and regulatory approval, launch timing, epidemiology, pricing, sales ramp, market growth, market share, competition, and other relevant factors relating to the commercialization of MEI's product candidates.

The unaudited prospective financial information included in this document has been prepared by, and is the responsibility of, MEI's management. BDO USA, LLP has not audited, reviewed, examined, compiled nor applied agreed-upon procedures with respect to the accompanying unaudited prospective financial information and, accordingly, BDO USA, LLP does not express an opinion or any other form of assurance with respect thereto. The BDO USA, LLP report contained in MEI's Annual Report on Form 10-K for the year ended June 30, 2022, which is included elsewhere in this joint proxy statement/prospectus, relates to MEI's previously issued financial statements. It does not extend to the unaudited prospective financial information and should not be read to do so.

The MEI Projections were developed under the assumption of continued standalone operation and did not give effect to any changes or expenses as a result of the Merger or any other effects of the Merger or any impact should the Merger fail to be consummated. The MEI Projections were prepared solely for internal use and are subjective in many respects. As a result, there can be no assurance that the forecasted results will be realized or that actual results will not be significantly higher or lower than estimated. Since the unaudited forecasted financial information covers multiple years, such information, by its nature, becomes less predictive with each successive year. The estimates and assumptions underlying the unaudited forecasted financial information involve judgments with respect to, among other things, future economic, competitive, regulatory and financial market conditions that may not materialize and are inherently subject to significant uncertainties and contingencies, all of which are difficult to predict and many of which are beyond MEI's control. The MEI Projections also reflect assumptions as to certain business decisions that are subject to change. Important factors that may affect actual results and cause the MEI Projections to not be achieved include, but are not limited to: (1) conditions in the financing markets and MEI's ability to access sufficient capital; (2) the timing of regulatory approvals and introduction of new products; (3) the market acceptance of new products; (4) the success of clinical testing; (5) the availability of third-party reimbursement; (6) the impact of competitive products and pricing; (7) the effect of regulatory actions; (8) the effect of global economic conditions; (9) changes in applicable laws, rules and regulations; (10) the early development stage of MEI's product candidates and the corresponding time horizons to reach market and (11) other risk factors described in MEI's Annual Report on Form 10-K for the fiscal year ended June 30, 2022 and Current Reports on Form 8-K, as well as "*Cautionary Statement Concerning Forward-Looking Statements and Industry and Market Data*" located elsewhere in this joint proxy statement/prospectus. In addition, the MEI Projections may be affected by MEI's ability to achieve strategic goals, objectives and targets over the applicable period. Accordingly, there can be no assurance that the MEI Projections will be realized and actual results may vary materially from those shown.

The prospective financial information included in this joint proxy statement/prospectus was not prepared with a view toward public dissemination or compliance with published guidelines of the SEC or established by the American Institute of Certified Public Accountants for preparation and presentation of prospective financial information or generally accepted accounting principles, or GAAP, but, in the view of MEI's management, was prepared on a reasonable basis, reflected, at the time the prospective financial information was prepared, the best currently available estimates and judgments, and presented, to the best of MEI management's knowledge and belief at that time, the expected course of action and the expected future financial performance of MEI. However, this information is not fact and should not be relied upon as being necessarily indicative of future results and readers of this joint proxy statement/prospectus are cautioned not to place undue reliance, if any, on the prospective financial information.

## Table of Contents

The tables below present a summary of the MEI Projections. The summary below is included solely to give MEI's stockholders access to certain long-term financial analyses and forecasts that were made available to the MEI board of directors and Torrey Capital for purposes of performing analyses underlying Torrey Capital's opinion, and is not included in this joint proxy statement/prospectus to influence an MEI stockholder's decision whether to vote for the MEI Nasdaq Proposal or for any other purpose. The inclusion of a summary of the MEI Projections in this document does not constitute an admission or representation that the information is material. The inclusion of a summary of the MEI Projections should not be regarded as an indication that MEI and/or its affiliates, officers, directors, advisors or other representatives or Infinity and/or its affiliates, officers, directors, advisors or other representatives consider the MEI Projections to be necessarily predictive of actual future events and this information should not be relied upon as such. None of MEI and/or its affiliates, officers, directors, advisors or other representatives or Infinity and/or its affiliates, officers, directors, advisors or other representatives gives any stockholder of MEI, Infinity or any other person any assurance that actual results will not differ materially from the MEI Projections. The MEI Projections do not take into account any circumstances, transactions or events occurring after the date on which they were prepared. Some or all of the assumptions underlying the MEI Projections may have changed since the date the MEI Projections were prepared.

MEI HAS NOT UPDATED AND DOES NOT INTEND TO UPDATE OR OTHERWISE REVISE THE UNAUDITED FORECASTED FINANCIAL INFORMATION TO REFLECT CIRCUMSTANCES EXISTING AFTER THE DATE WHEN MADE OR TO REFLECT THE OCCURRENCE OF FUTURE EVENTS, EVEN IN THE EVENT THAT ANY OR ALL OF THE ASSUMPTIONS UNDERLYING SUCH PROSPECTIVE FINANCIAL INFORMATION ARE NO LONGER APPROPRIATE.

Certain of the measures included in the MEI Projections may be considered non-GAAP financial measures, including free cash flow. Non-GAAP financial measures should not be considered in isolation from, or as a substitute for, financial information presented in compliance with GAAP, and non-GAAP financial measures as used by MEI may not be comparable to similarly titled amounts used by other companies.

Financial measures provided to a financial advisor are excluded from the definition of non-GAAP financial measures and therefore, are not subject to SEC rules regarding disclosures of non-GAAP financial measures, which would otherwise require a reconciliation of a non-GAAP financial measure to a GAAP financial measure. Reconciliations of non-GAAP financial measures were not relied upon by Torrey Capital for purposes of its financial analysis as described above in "*Opinion of MEI's Financial Advisor—Torrey Capital, LLC*" located elsewhere in this joint proxy statement/prospectus or by the MEI board of directors in connection with its consideration of the Merger. Accordingly, MEI has not provided a reconciliation of the non-GAAP financial measures included in the MEI Projections.

For the foregoing and other reasons, readers of this joint proxy statement/prospectus are cautioned that the inclusion of a summary of the MEI Projections in this joint proxy statement/prospectus should not be regarded as a representation or guarantee that the targets will be achieved nor that they should place undue reliance, if any, on the MEI Projections. The MEI Projections constitute forward-looking statements and are subject to risks and uncertainties that could cause actual results to differ materially from the projected results. See also "*Cautionary Statement Concerning Forward-Looking Statements and Industry and Market Data*" located elsewhere in this joint proxy statement/prospectus.

[Table of Contents](#)

**Summary of the MEI Projections**

Set forth below is a summary of the MEI Projections referenced in the Torrey Opinion. The MEI Projections reflect: (1) MEI's management's assessment of the commercial potential and probability of success for MEI's lead product candidates, Voruciclib, ME-344, and Zandelisib; (2) MEI's estimated cost of goods and operational costs, including research and development, sales and marketing, and general and administrative costs; and (3) estimated royalties and milestone payments for MEI.

(in \$mm)	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E	2036E	2037E	2038E	2039E
<b>Revenue</b>																	
Voruciclib-CLL	—	—	—	—	—	—	—	—	—	\$ 165	\$ 366	\$ 587	\$ 780	\$ 895	\$ 924	\$ 955	\$ 164
ME-344	—	—	—	—	—	\$ 175	\$ 331	\$ 443	\$ 503	\$ 527	\$ 551	\$ 577	\$ 603	\$ 631	\$ 53	\$ 3	\$ 3
Zandelisib JP Royalty	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
<b>Total Revenue</b>	—	—	—	—	—	\$ 175	\$ 331	\$ 443	\$ 503	\$ 692	\$ 917	\$ 1,164	\$ 1,383	\$ 1,526	\$ 977	\$ 957	\$ 167
<b>Gross Profit</b>																	
Voruciclib-CLL	—	—	—	—	—	—	—	—	—	\$ 153	\$ 337	\$ 538	\$ 712	\$ 816	\$ 843	\$ 870	\$ 152
ME-344	—	—	—	—	—	\$ 171	\$ 322	\$ 431	\$ 490	\$ 513	\$ 537	\$ 562	\$ 588	\$ 615	\$ 51	\$ 3	\$ 3
Zandelisib JP Royalty	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
<b>Total Gross Profit</b>	—	—	—	—	—	\$ 171	\$ 322	\$ 431	\$ 490	\$ 665	\$ 873	\$ 1,100	\$ 1,300	\$ 1,431	\$ 894	\$ 873	\$ 155
<b>EBIT</b>	(\$ 53)	(\$ 60)	(\$ 79)	(\$ 110)	(\$ 148)	(\$ 25)	\$ 144	\$ 260	\$ 292	\$ 407	\$ 620	\$ 829	\$ 1,085	\$ 1,230	\$ 776	\$ 782	\$ 119

**Summary of the Pro Forma Projections**

Set forth below is a summary of the Pro Forma Projections referenced in the Torrey Opinion. The Pro Forma Projections reflect: (1) MEI and Infinity management's assessment of the commercial potential and probability of success for MEI's product candidates and Infinity's lead product, Eganelisib; (2) the pro forma estimated cost of goods and operational costs, including research and development, sales and marketing, and general and administrative costs; and (3) estimated royalties and milestone payments for the combined entity.

(in \$mm)	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E	2036E	2037E	2038E	2039E
<b>Revenue</b>																	
Eganelisib	—	—	—	—	—	—	—	\$ 16	\$ 393	\$ 748	\$ 983	\$ 1,088	\$ 1,124	\$ 1,160	\$ 1,198	\$ 1,238	\$ 1,278
Voruciclib	—	—	—	—	—	—	—	—	—	\$ 165	\$ 366	\$ 587	\$ 780	\$ 895	\$ 924	\$ 955	\$ 164
ME-344	—	—	—	—	—	\$ 175	\$ 331	\$ 443	\$ 503	\$ 527	\$ 551	\$ 577	\$ 603	\$ 631	\$ 53	\$ 3	\$ 3
Zandelisib JP Royalty	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
<b>Total Net Revenue</b>	—	—	—	—	—	\$ 175	\$ 331	\$ 458	\$ 896	\$ 1,440	\$ 1,900	\$ 2,252	\$ 2,507	\$ 2,687	\$ 2,176	\$ 2,195	\$ 1,446
<b>Gross Profit</b>																	
Eganelisib	—	—	—	—	—	—	—	\$ 15	\$ 367	\$ 699	\$ 918	\$ 1,016	\$ 1,088	\$ 1,124	\$ 1,161	\$ 1,199	\$ 1,238
Voruciclib	—	—	—	—	—	—	—	—	—	\$ 153	\$ 337	\$ 538	\$ 712	\$ 816	\$ 843	\$ 870	\$ 152
ME-344	—	—	—	—	—	\$ 171	\$ 322	\$ 431	\$ 490	\$ 513	\$ 537	\$ 562	\$ 588	\$ 615	\$ 51	\$ 3	\$ 3
Zandelisib JP Royalty	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
<b>Total Gross Profit</b>	—	—	—	—	—	\$ 171	\$ 322	\$ 446	\$ 857	\$ 1,364	\$ 1,791	\$ 2,116	\$ 2,388	\$ 2,555	\$ 2,055	\$ 2,072	\$ 1,393
<b>EBIT</b>	(\$ 71)	(\$ 76)	(\$ 102)	(\$ 141)	(\$ 180)	(\$ 59)	\$ 84	\$ 164	\$ 518	\$ 924	\$ 1,348	\$ 1,668	\$ 1,991	\$ 2,166	\$ 1,742	\$ 1,781	\$ 1,157

## Opinion of Infinity Financial Advisor

Aquilo Partners (“Aquilo”) delivered its oral opinion to the Infinity board of directors, which was subsequently confirmed in writing, that, as of February 22, 2023, and based upon and subject to the qualifications, limitations and assumptions set forth therein, the Exchange Ratio is fair, from a financial point of view, to the holders of Infinity Common Stock. For purposes of Aquilo’s opinion and related analyses, the “Exchange Ratio” means 1.0449, subject to customary equitable adjustments including as a result of any reverse split in MEI Common Stock.

**The opinion addresses only the fairness, from a financial point of view, of the Exchange Ratio to the holders of Infinity Common Stock and does not address any other aspect or implication of the Merger. The opinion relies and is based only on the information available as of February 22, 2023. Aquilo provided its opinion for the information and assistance of the Infinity board of directors in connection with the Infinity board of directors’ consideration of the Merger. Aquilo was not requested to opine as to, and its opinion does not in any manner address, Infinity’s underlying business decision to proceed with or effect the Merger. The summary of Aquilo’s opinion in this joint proxy statement/prospectus is qualified in its entirety by reference to the full text of its written opinion, which is attached as [Annex C](#) and sets forth the procedures followed, assumptions made, matters considered and limitations and qualifications on the review undertaken by Aquilo in connection with the preparation of its opinion. Holders of Infinity Common Stock are urged to read the opinion carefully and in its entirety. However, neither Aquilo’s written opinion nor the summary of its opinion and the related analyses set forth in this joint proxy statement/prospectus is intended to be, and they do not constitute, advice or a recommendation to the Infinity board of directors or any holder of Infinity Common Stock as to how such holder should vote or act on any matter relating to the proposed Merger.**

In arriving at its opinion, Aquilo reviewed and analyzed, among other things:

- the draft Merger Agreement dated February 22, 2023;
- certain publicly available business and financial information relating to Infinity and MEI;
- certain non-public business and financial information relating to Infinity and MEI, including financial and business forecasts and projections prepared by management of Infinity and MEI, respectively;
- certain publicly available market, financial and other data for certain other companies Aquilo deemed relevant for purposes of performing a comparison of those companies against Infinity and MEI;
- the financial position, including projected cash burn rate, of each of Infinity, MEI and the combined company, respectively; and
- such other information that Aquilo has deemed relevant.

In addition, Aquilo discussed with management of Infinity and management of MEI, the business, operations, financial condition and prospects of each of Infinity and MEI on a standalone basis and as a combined company.

In connection with its review and arriving at its opinion, with Infinity’s consent, Aquilo relied upon and assumed the accuracy and completeness of all information provided to, discussed with or reviewed by it, without assuming any responsibility for independent verification thereof. With respect to the financial forecasts for Infinity, MEI and the combined company, the management of each of Infinity and MEI, respectively, advised Aquilo, and Aquilo assumed with Infinity’s consent, that such forecasts were reasonably prepared on bases reflecting the best currently available estimates and judgments of the management of Infinity and MEI, respectively, as to the future financial performance of Infinity and MEI, respectively. Aquilo did not make an independent evaluation or appraisal of the assets or liabilities (contingent or otherwise) of Infinity or MEI and Aquilo was not furnished with any such evaluation or appraisal.

Aquilo relied upon, without independent verification, the assessment of each of Infinity’s management and MEI’s management as to the viability of, and risks associated with, the current and future products of the

## [Table of Contents](#)

combined company following the Merger, including without limitation, the development, testing and marketing of such products, the receipt of all necessary governmental and other regulatory approvals for the development, testing and marketing thereof, and the life and enforceability of all relevant patents and other intellectual and other property rights associated with such products. Aquilo also assumed, with Infinity's consent, that, in the course of obtaining any regulatory or third-party consents, approvals or agreements in connection with the Merger, no delay, limitation, restriction or condition will be imposed that would have an adverse effect on Infinity, MEI or the combined company, or the contemplated benefits of the Merger, and that the Merger will be consummated in accordance with the terms of the Merger Agreement without waiver, modification or amendment of any material term, condition or agreement thereof.

In preparing its opinion, Aquilo performed a number of financial and comparative analyses based on data available as of February 22, 2023. The order in which the analyses are described below does not represent the relative importance or weight given to the analyses by Aquilo. The preparation of a fairness opinion is a complex process and is not necessarily susceptible to partial analysis or summary description. Aquilo believes that its analyses must be considered as a whole and that selecting portions of its analyses and of the factors considered by it, without considering all analyses and factors, could create a misleading view of the processes underlying its opinion. No company or transaction used in the analyses performed by Aquilo as a comparison is identical to Infinity or MEI. In addition, Aquilo may have given some analyses more or less weight than other analyses and may have deemed various assumptions more or less probable than other assumptions, so the valuation range resulting from any particular analysis described below should not be taken to be the only factor in determining the fairness, from a financial point of view, of the Exchange Ratio to the holders of Infinity Common Stock. The analyses performed by Aquilo are not necessarily indicative of actual values or actual future results, which may be significantly more or less favorable than suggested by such analyses. The analyses performed were prepared solely as part of Aquilo's analysis of the fairness, from a financial point of view, of the Exchange Ratio to the holders of Infinity Common Stock and do not address any other aspect or implication of the Merger. Furthermore, Aquilo does not express any opinion herein as to the prices, trading range or volume at which Infinity's or MEI's securities will trade following public announcement of the Merger or at which MEI's securities will trade following consummation of the Merger.

Aquilo's opinion does not address the underlying business decision of Infinity to engage in the Merger, nor does it address any legal, tax or regulatory matters. Aquilo's opinion is necessarily based on economic, market, financial and other conditions as they existed on, and on the information made available to Aquilo by or on behalf of Infinity or its advisors, or information otherwise reviewed by Aquilo as of, the date of its opinion. It is understood that subsequent developments may affect the conclusion reached in its opinion and that Aquilo does not have any obligation to update, revise or reaffirm its opinion.

At a meeting of the Infinity board of directors held on February 22, 2023, Aquilo presented certain financial analyses in connection with the delivery of its oral opinion, subsequently confirmed in writing. The following is a summary of the material financial analyses performed by Aquilo in arriving at its opinion. These summaries of financial analyses alone do not constitute a complete description of the financial analyses Aquilo employed in reaching its conclusions. The order of analyses described does not represent relative importance or weight given to those analyses by Aquilo. Certain of the following summaries of financial analyses include information presented in tabular format. In order to understand fully the material financial analyses that were performed by Aquilo, the tables should be read together with the text of each summary. The tables alone do not constitute a complete description of the material financial analyses. The summary text describing each financial analysis does not constitute a complete description of Aquilo's financial analyses, including the methodologies and assumptions underlying the analyses, and if viewed in isolation could create a misleading or incomplete view of the financial analyses performed by Aquilo. The summary text set forth below does not represent and should not be viewed by anyone as constituting conclusions reached by Aquilo with respect to any of the analyses performed by it in connection with the opinion. Rather, Aquilo made its determination as to the fairness, from a financial point of view, of the Exchange Ratio to the holders of Infinity Common Stock on the basis of its experience and professional judgment after considering the results of all of the analyses performed.



**Summary of Financial Analysis by Aquilo**

*Value of MEI Shares Issued to Infinity Stockholders.* Aquilo analyzed the value of the shares of MEI Common Stock to be issued to the holders of Infinity Common Stock based on the Exchange Ratio and the most recent closing price of both the MEI Common Stock and the Infinity Common Stock prior to the delivery of its opinion. Aquilo noted the closing price per share of the MEI Common Stock was \$0.30 on February 22, 2023, and based on the Exchange Ratio, the resulting value of the shares of MEI Common Stock to be issued to the holders of Infinity Common Stock would be approximately \$0.31 per share, or a 44% discount to the \$0.55 closing price per share of the Infinity Common Stock on February 22, 2023. Aquilo also noted that MEI’s share price implied an equity value of \$39.3 million, despite MEI’s \$124.2 million cash balance against only \$22.7 million of current liabilities as of December 31, 2022 and the closing condition in the Merger Agreement that MEI have at least \$80.0 million of net cash as of the closing date of the Merger (the “Minimum Net Cash Amount”). In light of MEI’s implied equity value being significantly less than the amount of its cash, in conducting its analysis, Aquilo valued MEI based on an assumed amount of MEI’s net cash as of the closing date of the Merger in the range of \$80.0 million to \$92.5 million, estimating an implied valuation for the combined company in the range of \$137.9 million to \$159.5 million. Based on the Exchange Ratio, which allocates approximately 42% of the value of the combined company to Infinity, Aquilo noted that, based on the foregoing assumptions, Infinity’s implied valuation would result in a premium to the Infinity equity value in the range of 14.1% to 31.9% based on the February 22, 2023 price per share of \$0.55 and in the range of (1.3)% to 14.1% based on a trailing 30-day volume weighted average price per share of \$0.64. The following sets forth the Infinity equity value detail:

<b>Premium on Infinity Equity Value (\$ millions)</b>						
MEI Net Cash	\$ 80.0	\$ 82.5	\$ 85.0	\$ 87.5	\$ 90.0	\$ 92.5
Implied Aggregate Valuation	\$137.9	\$142.2	\$146.6	\$150.9	\$155.2	\$159.5
Infinity Allocation Percentage	42.0%	42.0%	42.0%	42.0%	42.0%	42.0%
<b>Infinity Implied Valuation</b>	<b>\$ 57.9</b>	<b>\$ 59.7</b>	<b>\$ 61.6</b>	<b>\$ 63.4</b>	<b>\$ 65.2</b>	<b>\$ 67.0</b>
<b>Premium (Discount) to Infinity Valuation:</b>						
As of February 22, 2023	14.1%	17.6%	21.2%	24.7%	28.3%	31.9%
Trailing 30-Day VWAP	(1.3)%	1.8%	4.8%	7.9%	11.0%	14.1%

*Comparable Public Company Analysis.* Aquilo reviewed, analyzed and compared the enterprise value of Infinity on February 22, 2023 to the enterprise values of 10 U.S.-publicly traded biotechnology companies on February 22, 2023 that had a lead product candidate in oncology, excluding “platform-based” oncology companies, and in which the lead product candidate’s stage was no later than an ongoing Phase 2 clinical trial. The following list sets forth the comparable companies selected by Aquilo and their respective enterprise values on February 22, 2023:

<b>Company</b>	<b>Enterprise Value (\$ millions)</b>
Atossa Therapeutics, Inc.	\$ (26.2)
eFFECTOR Therapeutics, Inc.	\$ 8.2
iTeos Therapeutics, Inc.	\$ (107.6)
Jounce Therapeutics, Inc.	\$ (66.5)
Leap Therapeutics, Inc.	\$ (9.4)
MAIA Biotechnology, Inc.	\$ 34.6
Marker Therapeutics, Inc.	\$ 177.5
Surface Oncology, Inc.	\$ (47.3)
Verastem, Inc.	\$ 27.9
Zentalis Pharmaceuticals, Inc.	\$ 735.7

Aquilo reviewed the enterprise values of the selected companies, which ranged from \$(107.6) million to \$735.7 million. The result of the analysis implied a 1<sup>st</sup> quartile to 3<sup>rd</sup> quartile range of the implied enterprise

## [Table of Contents](#)

values for these comparable companies of \$(42.1) million and \$32.9 million, respectively. Based on the implied enterprise values for the comparable companies and after adjusting for Infinity's estimated net cash of \$38.3 million as of December 31, 2022, Aquilo determined the range of implied equity values for Infinity to be \$(3.7) million to \$71.2 million.

No company used in any analysis as a comparison had a lead product candidate identical to eganelisib and they all differ in material ways. Accordingly, an analysis of the results described above is not mathematical; rather it involves complex considerations and judgments concerning differences in financial and operating characteristics of the companies and other factors that could affect the enterprise value of the selected companies to which they are being compared. This analysis yielded a range of enterprise values, and therefore, such implied enterprise value ranges developed from these analyses were viewed by Aquilo collectively and not individually.

*Comparable Transaction Analysis.* Aquilo reviewed, analyzed and compared the Merger to corresponding publicly available financial information for eight business combinations of biotechnology companies since January 2018 where the acquired company was publicly traded, had a lead product candidate in oncology, excluding "platform-based" oncology companies, and in which the lead product candidate's stage was no later than an ongoing Phase 2 clinical trial. The following list sets forth the total transaction values for each of these business combinations:

<u>Date</u>	<u>Acquirer</u>	<u>Target</u>	<u>Total Transaction Value</u>
Nov-22	Merck & Co., Inc.	Imago Biosciences, Inc.	\$ 1,166.7
Jun-22	Bristol-Myers Squibb Company	Turning Point Therapeutics, Inc.	\$ 3,174.1
Apr-22	Regeneron Pharmaceuticals, Inc.	Checkmate Pharmaceuticals, Inc.	\$ 174.4
Nov-20	Sanofi	Kiadis Pharma N.V.	\$ 305.4
Dec-19	Merck & Co., Inc.	ArQule, Inc.	\$ 2,609.7
Feb-19	Merck & Co., Inc.	Immune Design Corp.	\$ 188.7
Feb-18	Merck & Co., Inc.	Viralytics Limited	\$ 367.9
Jan-18	Seattle Genetics, Inc.	Cascadian Therapeutics, Inc.	\$ 480.6

Although the transactions were used for comparison purposes, none of these transactions is directly comparable to the Merger, none of the acquirers were directly comparable to MEI, none of the acquisition targets were directly comparable to Infinity, and none had a lead product candidate directly comparable to eganelisib. Since the Merger is a merger of similarly sized companies with similar equity values, Aquilo ultimately determined that these transactions were not relevant to its analysis given the size and equity value of the acquirers relative to the acquisition targets.

*Infinity Discounted Cash Flow (DCF) Analysis.* Aquilo reviewed financial projections and estimates prepared by Infinity management to perform a discounted cash flow analysis to calculate a range of implied present values for Infinity. Aquilo based its discounted cash flow analysis on various operating assumptions made by Infinity through 2044, including assumptions relating to, among other items, gross and net sales of eganelisib, research and development costs of eganelisib, and other costs of goods, operating costs, taxes, and working capital associated with eganelisib. This analysis assumed Infinity successfully develops, receives regulatory approval for, and markets eganelisib without a development or corporate partnership, and loses patent protection on eganelisib in 2039.

Aquilo analyzed the discounted cash flows on an adjusted for probability of success and an unadjusted for probability of success basis. To determine the adjustment for the probability of success, Aquilo relied on assumptions provided by Infinity management. Based on these assumptions, Aquilo calculated the present value of the unlevered free cash flows for the relevant projection period.

Aquilo discounted the probability-adjusted free cash flows by a discount rate range of 10% to 14% based on its evaluation of the risk and time value associated with the probability-adjusted projections. This implied a net

## [Table of Contents](#)

present enterprise value range for Infinity of \$69.9 million to \$153.4 million. Based on this analysis and after adjusting for Infinity's estimated net cash of \$38.3 million as of December 31, 2022, Aquilo determined the range of implied equity values for Infinity on a probability-adjusted basis to be \$108.2 million to \$191.7 million.

On a non-probability adjusted basis, the discounted cash flows assume Infinity achieves 100% of the financial projections and estimates as provided to Aquilo. These financial projections and estimates bear inherently more risk than projections adjusted by a probability factor, and therefore Aquilo discounted the non-probability adjusted free cash flows by a higher discount rate range of 30% to 35% based on its evaluation of the risk and time value associated with the non-probability adjusted projections. This implied a net present enterprise value range for Infinity of \$19.8 million to \$85.1 million. Based on this analysis and after adjusting for Infinity's estimated net cash of \$38.3 million as of December 31, 2022, Aquilo determined the range of implied equity values for Infinity on a non-probability adjusted basis to be \$58.1 million to \$123.4 million.

*MEI Discounted Cash Flow (DCF) Analysis.* Aquilo reviewed financial projections and estimates prepared by MEI management to perform a discounted cash flow analysis to calculate a range of implied present values for MEI. Aquilo based its discounted cash flow analysis on various operating assumptions made by MEI through 2039, including assumptions relating to, among other items, gross and net sales of voruciclib and ME-344, research and development costs of voruciclib and ME-344, and other operating costs, taxes, and working capital associated with voruciclib and ME-344. This analysis assumed MEI successfully develops, receives regulatory approvals for, and markets voruciclib and ME-344 without a development or corporate partnership, and loses patent protection on voruciclib and ME-344 in 2038 and 2036, respectively, and excludes potential milestone and royalty revenue that may be derived from development and sales of zandelisib in Japan under the Kyowa Kirin Commercialization Agreement.

Aquilo analyzed the discounted cash flows on an adjusted for probability of success and an unadjusted for probability of success basis. To determine the adjustment for the probability of success, Aquilo relied on assumptions provided by MEI management. Based on these assumptions, Aquilo calculated the present value of the unlevered free cash flows for the relevant projection period.

Aquilo discounted the probability-adjusted free cash flows by a discount rate range of 10% to 14% based on its evaluation of the risk and time value associated with the probability-adjusted projections. Aquilo determined this implied a net present enterprise value range for MEI on a probability-adjusted basis of \$(21.9) million to \$33.9 million.

On a non-probability adjusted basis, the discounted cash flows assume MEI achieves 100% of the financial projections and estimates as provided to Aquilo. These financial projections and estimates bear inherently more risk than projections adjusted by a probability factor, and therefore Aquilo then discounted the non-probability adjusted free cash flows by a higher discount rate range of 30% to 35% based on its evaluation of the risk and time value associated with the non-probability adjusted projections. Aquilo determined this implied a net present enterprise value range for MEI on a non-probability adjusted basis of \$(25.7) million to \$40.4 million.

Aquilo noted that the midpoint of the implied MEI net present enterprise ranges was \$2.2 million on a probability-adjusted basis and \$2.9 million on a non-probability adjusted basis, and the average of these midpoints was \$2.5 million.

*Infinity Stand-alone Cash Forecast.* Infinity developed and provided to Aquilo an estimated cash balance assuming the Merger is not completed. Infinity forecasted that it would have between \$8.5 million and \$12.5 million of cash available in August 2023. Aquilo noted that this level of cash would be insufficient to complete the Phase 2 clinical trial of eganelisib for the potential treatment of HNSCC, as Infinity estimated the total cost to be between \$75 million and \$80 million.

*Equity Financing Analysis.* Aquilo considered the potential dilution to the holders of Infinity Common Stock if Infinity issued shares in an equity financing. Aquilo reviewed and analyzed 21 U.S. publicly-traded

## [Table of Contents](#)

biotechnology companies with an equity market capitalization of \$100 million or less that raised at least \$50 million in one or more equity financings since January 2020. Aquilo reviewed the per share issue price of the equity issued in these transactions and determined the premium (discount) relative to the issuer's closing stock price 1-day, 5-days and 15-days prior to the offering. The 1<sup>st</sup> quartile to 3<sup>rd</sup> quartile range of the premium (discount) ranged from (16.8)% to 0.0% relative to 1-day prior; (21.9)% to 8.7% relative to 5-days prior; and (31.9)% to (0.1)% relative to 15-days prior.

Company	Premium (Discount) to Stock Price Prior to Offering		
	1-Day	5-Day	15-Day
89bio, Inc.	0.0%	4.4%	(6.6)%
aTyr Pharma, Inc.	(5.5)%	0.4%	(1.3)%
ContraFect Corporation	(17.4)%	(22.2)%	(32.3)%
Evelo Biosciences, Inc.	0.0%	(21.1)%	(47.1)%
F-star Therapeutics, Inc.	(21.1)%	(27.7)%	(31.0)%
Genocea Biosciences, Inc.	(12.5)%	23.3%	3.5%
Hepion Pharmaceuticals, Inc.	(32.7)%	(32.9)%	(11.9)%
Jasper Therapeutics, Inc.	(11.2)%	(14.8)%	(45.3)%
KemPharm, Inc.	(21.2)%	(42.0)%	(55.6)%
Larimar Therapeutics, Inc.	0.0%	10.1%	9.8%
Lyra Therapeutics, Inc.	(2.3)%	1.7%	(3.7)%
Moleculin Biotech, Inc.	(25.7)%	(18.8)%	(17.5)%
Precision Biosciences, Inc.	0.0%	14.9%	(17.3)%
Rezolute, Inc.	0.0%	10.9%	0.3%
Savara Inc.	(19.0)%	(15.7)%	(16.2)%
SCYNEXIS, Inc.	(14.7)%	(17.3)%	(8.2)%
Sio Gene Therapies Inc.	(14.4)%	(11.3)%	(3.4)%
Terns Pharmaceuticals, Inc.	0.4%	11.5%	7.6%
Trevi Therapeutics, Inc.	(0.3)%	(40.8)%	(38.5)%
Trevi Therapeutics, Inc.	0.0%	(13.6)%	24.2%
VistaGen Therapeutics, Inc.	(1.1)%	24.3%	19.5%
X4 Pharmaceuticals, Inc.	(8.3)%	(26.7)%	(42.1)%

Aquilo evaluated the expected ownership of existing holders of Infinity Common Stock if Infinity raised \$80.0 million (the Minimum Net Cash Amount) or \$92.8 million (the projected MEI net cash level at June 30, 2023 as provided by MEI management, the "Projected Net Cash Amount") in an equity financing based on the range of discounts/premiums in the analysis. Assuming an \$80.0 million equity financing and based on a range of Infinity's closing stock prices prior to the execution of the Merger Agreement, the result of Aquilo's analysis implied that existing holders of Infinity Common Stock would own, as of immediately following the closing of the assumed equity financing, 35% to 39% of Infinity based on Infinity's closing stock price one day prior to the execution; 33% to 41% of Infinity based on Infinity's closing stock price five days prior to the execution; 30% to 39% of Infinity based on Infinity's closing stock price 15-days prior to the execution; and an overall range of 33% to 39% of Infinity based on the averages of the above-listed ranges. Aquilo compared these ownership ranges to the approximately 42% of the combined company that the existing holders of Infinity Common Stock will own as of immediately following the closing of the Merger based on the Exchange Ratio.

Although the 22 equity financings that Aquilo reviewed and analyzed were for comparison purposes, no equity financing is directly comparable to the Merger, none of the issuers are directly comparable to Infinity, and none of the issuers had a lead product candidate directly comparable to eganalisib. Accordingly, an analysis of the results of such a comparison involves considerations concerning the issuer, market conditions, and other factors that could affect the ability of Infinity to issue equity at such valuations.

*Implied Exchange Ratios.* Aquilo compared each of Infinity's implied equity valuation ranges described above to the valuations of MEI, assuming that MEI has (i) \$80.0 million in cash at the closing of the Merger; (ii) \$92.8 million in cash at the closing of the Merger; and (iii) \$92.8 million in cash at the closing of the Merger, plus the average of the midpoints of the

## Table of Contents

risk and non-risk adjusted MEI discounted cash flow analyses. Aquilo also converted the implied pro forma ownership of existing holders of Infinity Common Stock from the equity financing analysis to exchange ratios as if the Merger resulted in the existing holders of Infinity Common Stock receiving such implied pro forma ownership percentages. The relative equity valuations of Infinity and MEI were used to calculate implied exchange ratios, as summarized in the tables below:

<u>Infinity Valuation Method</u>	<u>Implied Exchange Ratio (\$80.0m Net Cash at Close)</u>	
	<u>Low</u>	<u>High</u>
Equity Financing Analysis: 1-day Prior	0.7626x	0.9162x
Equity Financing Analysis: 5-days Prior	0.7153x	0.9959x
Equity Financing Analysis: 15-days Prior	0.6235x	0.9150x
Comparable Public Company Analysis	(0.0675x)	1.2849x
DCF Analysis: Risk Adjusted	1.9522x	3.4586x
DCF Analysis: Non-Risk Adjusted	1.0479x	2.2263x
<b>Average Implied Exchange Ratio</b>	<b>0.8390x</b>	<b>1.6328x</b>

<u>Infinity Valuation Method</u>	<u>Implied Exchange Ratio (\$92.8m Net Cash at Close)</u>	
	<u>Low</u>	<u>High</u>
Equity Financing Analysis: 1-day Prior	0.6574x	0.7898x
Equity Financing Analysis: 5-days Prior	0.6167x	0.8586x
Equity Financing Analysis: 15-days Prior	0.5375x	0.7888x
Comparable Public Company Analysis	(0.0582x)	1.1077x
DCF Analysis: Risk Adjusted	1.6829x	2.9816x
DCF Analysis: Non-Risk Adjusted	0.9034x	1.9192x
<b>Average Implied Exchange Ratio</b>	<b>0.7233x</b>	<b>1.4076x</b>

<u>Infinity Valuation Method</u>	<u>Implied Exchange Ratio (\$92.8m + DCF Net Cash at Close)</u>	
	<u>Low</u>	<u>High</u>
Equity Financing Analysis: 1-day Prior	0.6574x	0.7898x
Equity Financing Analysis: 5-days Prior	0.6167x	0.8586x
Equity Financing Analysis: 15-days Prior	0.5375x	0.7888x
Comparable Public Company Analysis	(0.0567x)	1.0786x
DCF Analysis: Risk Adjusted	1.6387x	2.9033x
DCF Analysis: Non-Risk Adjusted	0.8797x	1.8689x
<b>Average Implied Exchange Ratio</b>	<b>0.7122x</b>	<b>1.3813x</b>

Aquilo noted that the pre-split Exchange Ratio of 1.0449 is in the range of the average of the low and high implied exchange ratios set forth in the table above.

### *Miscellaneous*

No individual methodology was given a specific weight, nor should any methodology be viewed individually. Additionally, no company, issuer or transaction used in any analysis as a comparison is identical to Infinity or MEI or the Merger, and they all differ in material ways.

The preparation of a fairness opinion is a complex process and is not necessarily susceptible to a partial analysis or summary description. In arriving at its opinion, Aquilo considered the results of all of its analyses as a whole and did not attribute any particular weight to any analysis or factor considered by it. Aquilo believes that the summary provided and the analyses described above must be considered as a whole and that selecting portions of these analyses, without considering all of them, would create an incomplete view of the process underlying Aquilo's analyses and the opinion; therefore, the ranges of valuations and relative valuations resulting from any particular

## [Table of Contents](#)

analysis described above should not be taken to be Aquilo's view of the actual valuation of either Infinity or MEI or their relative valuation. The opinion was reviewed and approved by a fairness committee of Aquilo.

Aquilo is acting as financial advisor to Infinity in connection with the Merger pursuant to an engagement letter dated August 4, 2022. Aquilo was selected by Infinity based on Aquilo's qualifications, expertise and reputation. Aquilo, as part of its investment banking business, is continuously engaged in the valuation of businesses and securities in connection with mergers and acquisitions, private placements and valuations for corporate and other purposes. Infinity paid Aquilo a fee of \$500,000 upon the delivery of the opinion and upon consummation of the Merger, Infinity will pay Aquilo a fee of \$1,450,000. Infinity has also agreed to reimburse Aquilo for its expenses incurred in connection with the engagement and to indemnify Aquilo and its affiliates and their respective officers, directors, employees and agents, against specified liabilities. During the two years preceding the date of the opinion, Aquilo was not engaged by Infinity (other than as described in this joint proxy statement/prospectus) or MEI. Aquilo may seek to provide investment banking or financial advisory services to Infinity, MEI or, following completion of the Merger, the combined company in the future, for which Aquilo would seek customary compensation.

### **Summary of Certain Infinity Unaudited Prospective Financial Information**

Infinity does not as a matter of course make public long-term forecasts or internal projections as to future performance, revenues, production, earnings, or other results due to, among other reasons, the uncertainty of the underlying assumptions and estimates. As a result, Infinity does not endorse the unaudited prospective financial information as a reliable indication of future results. Please see the risk factor "*The financial analyses, estimates and forecasts presented herein and considered by MEI and Infinity in connection with the Merger may not be realized.*" in the section entitled "*Risk Factors*" beginning on page 26 of this joint proxy statement/prospectus. Infinity has prepared this unaudited prospective financial information on a different basis than the selected unaudited pro forma condensed combined financial information included in this joint proxy statement/prospectus and is including certain unaudited prospective financial information in this joint proxy statement/prospectus because it was among the financial information made available to the Infinity board of directors, Infinity's financial advisor, MEI and MEI's financial advisor, in connection with their respective evaluations of the Merger. The unaudited prospective financial information is not being included in this joint proxy statement/prospectus to influence any Infinity or MEI stockholder to make an investment decision with respect to the Merger or to influence any Infinity or MEI stockholder as to whether or how such stockholder should vote with respect to the Infinity Merger Proposal, the MEI Nasdaq Proposal, or any other matter. The unaudited prospective financial information presented below was prepared by Infinity management for internal planning purposes in 2022, prior to discussions with MEI, was updated as of February 2023, and is the responsibility of Infinity management. The unaudited prospective financial information was based solely upon information available to Infinity's management at the time of its preparation. The unaudited prospective financial information was based on estimates and assumptions made by Infinity management prior to and during discussions with MEI and was reviewed by Infinity's board of directors in December 2022 and February 2023.

The unaudited prospective financial information included in this document by Infinity has been prepared by, and is the responsibility of, Infinity's management. Ernst & Young LLP has not audited, reviewed, examined, compiled nor applied agreed-upon procedures with respect to the accompanying unaudited prospective financial information and, accordingly, Ernst & Young LLP does not express an opinion or any other form of assurance with respect thereto. The Ernst & Young LLP report (which contains an explanatory paragraph describing conditions that raise substantial doubt about Infinity's ability to continue as a going concern as described in Note 2 to Infinity's consolidated financial statements) contained in Infinity's Annual Report on Form 10-K for the year ended December 31, 2022, which is included elsewhere in this joint proxy statement/prospectus, relates to Infinity's previously issued financial statements. It does not extend to the unaudited prospective financial information and should not be read to do so.

The inclusion of the unaudited prospective financial information in this joint proxy statement/prospectus should not be regarded as an indication that any of Infinity, MEI, any of their respective affiliates, any of their respective

## [Table of Contents](#)

financial advisors or any other person considered, or now considers, this information (including any probability adjustments) to be necessarily predictive of actual future results or events, and it should not be relied upon as such. There can be no assurance that the prospective results will be realized or that actual results will not be significantly higher or lower than estimated.

Because the unaudited prospective financial information covers multiple years, such information by its nature becomes less predictive with each successive year. Infinity and MEI stockholders are urged to review the description of risk factors with respect to the business of Infinity contained elsewhere in this joint proxy statement/prospectus and in the SEC filings of Infinity incorporated by reference into this joint proxy statement/prospectus. See “*Risk Factors*”, “*Cautionary Statement Concerning Forward-Looking Statements and Industry and Market Data*” and “*Where You Can Find More Information*”. The unaudited prospective financial information of Infinity was not prepared with a view toward public disclosure, and the unaudited prospective financial information was not prepared with a view toward compliance with published guidelines of the SEC or the guidelines established by the American Institute of Certified Public Accountants for preparation and presentation of prospective financial information. Furthermore, the unaudited prospective financial information does not necessarily reflect Infinity’s current estimates and does not take into account any circumstances or events occurring after the date it was prepared, and some or all of the assumptions that have been made regarding, among other things, the timing of certain occurrences or impacts, may have changed since such date. In particular, the unaudited prospective financial information set forth below assumes that Infinity would have access to sufficient resources to achieve these projections, but it does not take into account the effect of any failure of the Merger to occur or other event that could impact Infinity’s ability to access sufficient resources to achieve these projections, and so it should not be viewed as accurate in that context.

The inclusion of the unaudited prospective financial information herein should not be deemed an admission or representation by Infinity, MEI or any of their respective affiliates that it is or they view it as material information of Infinity, and in fact, none of the foregoing view the unaudited prospective financial information as material because of the inherent risks and uncertainties associated with such long-term projections. The unaudited prospective financial information should be evaluated in conjunction with the historical financial statements and other information regarding Infinity contained in this joint proxy statement/prospectus and Infinity’s public filings with the SEC.

Financial measures included in forecasts provided to a financial advisor and a board of directors in connection with a business combination transaction, such as the forecasts provided by Infinity, are excluded from the definition of “non-GAAP financial measures” under the rules of the SEC, and therefore such forecasts are not subject to SEC rules regarding disclosures of non-GAAP financial measures, which would otherwise require a reconciliation of a non-GAAP financial measure to a GAAP financial measure. Reconciliations of non-GAAP financial measures were not provided to or relied upon by the Infinity board of directors or the MEI board of directors or their respective financial advisors in connection with the Merger. Accordingly, no reconciliation of the financial measures included in the forecasts is provided in this joint proxy statement/prospectus.

### ***Certain Projections of Infinity***

On an ongoing basis, in the normal course of business planning, Infinity’s management prepares, for internal use, certain unaudited prospective financial information with respect to Infinity’s business plans and operating plan for future periods. The preparation of these Infinity forecasts is part of Infinity’s internal financial planning processes and is discussed with and reviewed by the Infinity board of directors from time to time.

Throughout 2022, in the normal course of Infinity’s business development activities, Infinity engaged in discussions with several parties related to strategic transactions. In connection with these activities, Infinity management updated its internal forecasts and prepared a forecast (the “Infinity Unadjusted Management Forecast”), which included Infinity’s anticipated worldwide revenue forecasts for sales of eganelisib in HNSCC and anticipated operating expenses related to the product candidate. Infinity management also applied



## Table of Contents

probability-of-success factors to the Infinity Unadjusted Management Forecast per Hay, M., et al. (2014) “Clinical development success rates for investigational drugs” published in Nature Biotechnology, as is customary with drugs in development (the “Infinity Probability-Adjusted Management Forecast”). Per Hay, M., et al., a cumulative probability of success of 14% was assigned to Infinity’s eganelisib program based on historical data for HNSCC oncology clinical trials as appropriate for the program’s stage of development.

The Infinity Unadjusted Management Forecast and the Infinity Probability-Adjusted Management Forecast, both concerning Infinity on a standalone basis, were discussed with and reviewed by the Infinity board of directors on December 29, 2022, and then, after subsequent input from management and members of the Infinity board of directors, were approved by the Infinity board of directors on February 22, 2023. The Infinity Unadjusted Management Forecast and the Infinity Probability-Adjusted Management Forecast were shared with Aquilo, MEI and Torrey Capital, MEI’s financial advisor, in December 2022 and the updated forecasts were shared in February 2023.

Infinity management directed Aquilo to use the Infinity Unadjusted Management Forecast and Infinity Probability-Adjusted Management Forecast, solely for purposes of a discounted cash flow analysis presented at the meeting of the Infinity board of directors on February 22, 2023, as described in the section of this joint proxy statement/prospectus entitled “*The Merger—Opinion of Infinity’s Financial Advisor.*” Aquilo performed a discounted cash flow analysis of Infinity by calculating an estimated present value of the standalone unlevered, after-tax free cash flows that Infinity was forecasted to generate during the fiscal years ending December 31, 2023 through December 31, 2044 based on both the unadjusted and the probability-weighted, tax-affected forecasts (inclusive of Infinity’s net operating loss carryforwards).

The internally prepared Infinity Unadjusted Management Forecast and Infinity Probability-Adjusted Management Forecast summarized below were based on information available to Infinity management and estimates, assumptions and judgments made by Infinity management at the time of their preparation and spoke only as of such time.

*The Infinity Unadjusted Management Forecast is summarized below:*

*Fiscal year ended  
December 31  
\$ in millions*

	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E	2036E	2037E	2038E	2039E	2040E	2041E	2042E	2043E	2044E
Revenue <sup>(1)</sup>	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	\$ 123	\$ 342	\$ 669	\$ 841	\$ 994	\$1,146	\$1,207	\$1,247	\$1,247	\$1,247	\$ 623	\$ 312	\$ 156	\$ 78	\$ 39
EBIT <sup>(2)</sup>	(\$ 33)	(\$ 36)	(\$ 29)	(\$ 46)	(\$ 55)	(\$ 66)	(\$ 54)	\$ 48	\$ 230	\$ 479	\$ 629	\$ 731	\$ 895	\$ 928	\$ 974	\$ 974	\$ 974	\$ 592	\$ 296	\$ 148	\$ 74	\$ 37
Unlevered FCF <sup>(3,4)</sup>	(\$ 33)	(\$ 36)	(\$ 30)	(\$ 47)	(\$ 55)	(\$ 67)	(\$ 54)	\$ 36	\$ 208	\$ 354	\$ 480	\$ 562	\$ 692	\$ 727	\$ 766	\$ 770	\$ 770	\$ 530	\$ 265	\$ 133	\$ 66	\$ 33

(1) Reflects worldwide revenue for eganelisib in HNSCC.

(2) Earnings before interest and taxes.

(3) Unlevered Free Cash Flow is defined as EBIT less income tax expenses, plus depreciation and amortization, less changes in net working capital, less capital expenditures.

(4) EBIT and Unlevered Free Cash Flow are non-GAAP measures and should not be considered as an alternative to operating income or net income as a measure of operating performance or cash flow or as a measure of liquidity.

*The Infinity Probability-Adjusted Management Forecast is summarized below:*

*Fiscal year ended December 31 \$ in millions*

## Table of Contents

	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E	2036E	2037E	2038E	2039E	2040E	2041E	2042E	2043E	2044E
Revenue <sup>(1)</sup>	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	\$ 18	\$ 49	\$ 96	\$ 120	\$ 142	\$ 164	\$ 173	\$ 178	\$ 178	\$ 178	\$ 89	\$ 45	\$ 22	\$ 11	\$ 6
EBIT <sup>(2)</sup>	(\$ 17)	(\$ 18)	(\$ 14)	(\$ 20)	(\$ 23)	(\$ 28)	(\$ 36)	\$ 7	\$ 33	\$ 69	\$ 90	\$ 105	\$ 128	\$ 133	\$ 139	\$ 139	\$ 139	\$ 85	\$ 42	\$ 21	\$ 11	\$ 5
Unlevered FCF <sup>(3,4)</sup>	(\$ 17)	(\$ 18)	(\$ 15)	(\$ 20)	(\$ 24)	(\$ 29)	(\$ 36)	\$ 5	\$ 30	\$ 64	\$ 79	\$ 80	\$ 99	\$ 104	\$ 110	\$ 110	\$ 110	\$ 76	\$ 38	\$ 19	\$ 9	\$ 5

(1) Reflects worldwide eganelisib in HNSCC revenue.

(2) Earnings before interest and taxes.

(3) Unlevered Free Cash Flow is defined as EBIT less income tax expenses, plus depreciation and amortization, less changes in net working capital, less capital expenditures.

(4) EBIT and Unlevered Free Cash Flow are non-GAAP measures and should not be considered as an alternative to operating income or net income as a measure of operating performance or cash flow or as a measure of liquidity.

Though presented with numerical specificity, the unaudited prospective financial information described reflect numerous assumptions and estimates as to future events made by the management of Infinity. In preparing the unaudited prospective financial information, Infinity made certain assumptions and estimates regarding, among other things, as applicable, the commercial launch of Infinity future product candidates, third-party payor reimbursement for Infinity product candidates, the cost to fund development including clinical trial expenses, the completion of and favorable outcomes of clinical trials, the potential market size of treatments for any diseases, interest rates, corporate financing activities, including the amount and timing of the issuance of debt, the timing and amount of equity issuances or repurchases, the effective tax rate, the regulatory and legal environment in which Infinity operates and the amount of general and administrative costs. At the time such unaudited prospective financial information was prepared, Infinity's management believed such assumptions and estimates were reasonable.

The unaudited prospective financial information constitutes forward-looking statements and no assurances can be given that the assumptions made in preparing the unaudited prospective financial information will accurately reflect future conditions. The estimates and assumptions underlying the unaudited prospective financial information involve judgments with respect to, among other things, future economic, competitive, regulatory and financial market conditions, future tax rates and future business decisions which may not be realized and that are inherently subject to significant business, economic, competitive and regulatory uncertainties and contingencies, including, among others, risks and uncertainties described under "Risk Factors" and "Cautionary Statement Concerning Forward-Looking Statements and Industry and Market Data", all of which are difficult to predict and many of which are beyond the control of Infinity and/or MEI and will be beyond the control of the combined company. In addition, the unaudited prospective financial information will be affected by Infinity's or the combined company's, as applicable, ability to achieve strategic goals, objectives and targets over the applicable periods. As a result, there can be no assurance that the underlying assumptions will prove to be accurate or that the projected results will be realized, and actual results likely will differ, and may differ materially, from those reflected in the unaudited prospective financial information, whether or not the Merger is completed.

Infinity and MEI stockholders are urged to review Infinity's most recent SEC filings for a description of Infinity's results of operations and financial condition and capital resources during 2020, 2021 and 2022, including "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Infinity's Annual Report on Form 10-K for the year ended December 31, 2022.

In light of, among other matters, the foregoing factors and the uncertainties inherent in the unaudited prospective financial information, readers of this joint proxy statement/prospectus are cautioned not to place undue, if any, reliance on the unaudited prospective financial information included in this joint proxy statement/prospectus. No representation is made by Infinity, MEI, any of their respective affiliates, any of their respective financial advisors or any other person to any Infinity or MEI stockholder regarding the ultimate performance of Infinity or the combined company compared to the information included in the unaudited prospective financial information. In particular, Infinity has made no representation to MEI or any other party to the Merger Agreement concerning the unaudited prospective financial information. None of Infinity, MEI, any of their respective affiliates or any of their respective financial advisors can provide assurance of the validity, reasonableness, accuracy, or completeness of the unaudited prospective financial information included in this joint proxy statement/prospectus. The inclusion of unaudited prospective financial information in this joint proxy statement/prospectus should not be regarded as an indication that such unaudited prospective financial information will be an accurate prediction of future events, and such information should not be relied on as such.

### **Interests of MEI Directors and Executive Officers in the Merger**

In considering the recommendation of the MEI board of directors with respect to issuing shares of MEI Common Stock in the Merger. The MEI stockholders should be aware that MEI's directors and executive officers have interests in the Merger that are different from, or in addition to, the interests of MEI's stockholders generally. These interests may present them with actual or potential conflicts of interest, and these interests, to the extent material, are described below.

- Daniel P. Gold, Ph.D., Charles V. Baltic III, Thomas C. Reynolds, and Sujay R. Kango, members of the MEI board of directors, will continue as directors after the Merger, and, following the closing of the Merger, Daniel P. Gold, Ph.D., Charles V. Baltic III, Thomas C. Reynolds, and Sujay R. Kango will be eligible to be compensated as directors of MEI pursuant to MEI's compensation policy that is expected to remain in place following the Merger.
- Sujay R. Kango serves on the boards of directors of each of MEI and Infinity and holds stock options exercisable for shares of MEI Common Stock and Infinity Common Stock.
- David M. Urso will continue as an executive officer of the combined company after the Merger.

As of March 31, 2023, the directors and executive officers of MEI owned, in the aggregate, 6.2% of the outstanding voting shares of MEI Common Stock. The MEI board of directors was aware of these interests and considered them, among other matters, in the decision to approve the Merger Agreement.

The MEI board of directors was aware of these potential conflicts of interest and considered them, among other matters, in reaching its decision to approve the Merger and the Merger Agreement.

### **Interests of Infinity Directors and Executive Officers in the Merger**

In considering the recommendations of the Infinity board of directors, Infinity's stockholders should be aware that Infinity's directors and executive officers have interests in the Merger, including financial interests, that may be different from, or in addition to, the interests of the other Infinity stockholders generally. These interests are described in more detail below, and with respect to the named executive officers of Infinity, are quantified in the tables below in the section titled "*The Merger—Compensation Payable to Infinity Named Executive Officers*" beginning on page 172 of this joint proxy statement/prospectus. The Infinity board of directors was aware of and considered these interests, among other matters, in reaching its decisions to adopt the Merger Agreement and approve the transactions contemplated by the Merger Agreement and to recommend the adoption of the Merger Agreement to Infinity's stockholders. See the section titled "*Infinity's Reasons for the Merger; Recommendation of Infinity Board*" beginning on page 142 of this joint proxy statement/prospectus.

For purposes of this disclosure, Infinity's "named executive officers" are (i) Adelene Q. Perkins, Infinity's Chief Executive Officer and Chair of the Infinity board of directors, (ii) Robert Ilaria, Jr., M.D., Infinity's Chief Medical Officer and (iii) Stéphane Peluso, Ph.D., Infinity's Chief Scientific Officer. For purposes of this disclosure, Infinity's "executive officers" are its named executive officers, together with (i) Lawrence E. Bloch, M.D., J.D., Infinity's former President and (ii) Seth Tasker, J.D., Infinity's Senior Vice President, Chief Business Officer and Secretary.

### ***Treatment of Shares of Infinity Common Stock in the Merger; Ownership Interests***

The treatment of Infinity Common Stock in the Merger, including the shares of Infinity Common Stock held by Infinity's directors and executive officers, is described under the section entitled "*The Merger Agreement—Consideration to be Received by the Infinity Stockholders*" beginning on page 122 of this joint proxy statement/prospectus. As of March 31, 2023, Infinity's directors and executive officers beneficially owned, in the aggregate, approximately 11% of the outstanding shares of Infinity Common Stock.

**Treatment of Infinity Stock Options and Restricted Stock Units in the Merger**

The treatment of Infinity Stock Options and Infinity RSUs in the Merger, including such awards held by Infinity’s directors and executive officers, is described under the sections titled “*The Merger Agreement—Treatment of Infinity Stock Options*” and “*The Merger Agreement—Treatment of Infinity RSUs*,” respectively, beginning on page 182 of this joint proxy statement/prospectus. Infinity’s executive officers have executed durable automatic sale instructions with respect to their Infinity RSUs, pursuant to which, upon the vesting of the Infinity RSUs, Infinity will arrange for the sale of such number of shares of Infinity Common Stock issuable with respect to the vested Infinity RSUs as is sufficient to generate net proceeds sufficient to satisfy the minimum statutory withholding obligations with respect to the income recognized by the executive officer upon the vesting of the Infinity RSUs.

The following table sets forth, for each executive officer and director of Infinity, (i) the number and value of Infinity Stock Options that will vest in connection with the Merger, prior to the application of the Exchange Ratio, and (ii) the number and value of Infinity RSUs that will vest prior to the Effective Time (including the number of shares of Infinity Common Stock to be sold to satisfy tax withholding obligations upon the accelerated vesting of such Infinity RSUs). The amounts shown in the following table assume that the Merger closes on June 30, 2023 and that the relevant price per share of Infinity Common Stock prior to the Effective Time is \$0.24, which price equals the average closing price of a share of Infinity Common Stock over the first five business day period following the first public announcement of the Merger (i.e., the five business day period beginning February 23, 2023).

	<b>Number of Infinity Stock Options Subject to Acceleration</b>	<b>Value of Infinity Stock Options Subject to Acceleration (\$)(2)</b>	<b>Number of Infinity RSUs Subject to Acceleration (3)</b>	<b>Value of Infinity RSUs Subject to Acceleration \$(3)</b>
<b>Executive Officers</b>				
Adelene Q. Perkins	607,615	0	768,133	184,352
Robert Ilaria, Jr.	223,420	0	356,747	85,619
Stéphane Peluso	189,809	0	274,267	65,824
Lawrence E. Bloch (1)	—	—	—	—
Seth Tasker	280,729	0	300,000	72,000
<b>Directors</b>				
Samuel Agresta	—	—	—	—
David Beier	—	—	—	—
Anthony B. Evinin	—	—	—	—
Richard Gaynor	—	—	—	—
Sujay Kango	22,500	0	—	—
Brian Schwartz	—	—	—	—
Norman C. Selby	—	—	—	—

- (1) Dr. Bloch’s employment with Infinity was terminated effective March 31, 2023. In connection with his termination of employment under the Infinity Severance Plan, as described below, and following Dr. Bloch’s entry into a binding severance and release agreement with Infinity on March 29, 2023, (i) 246,016 shares subject to the Infinity Stock Options that Dr. Bloch held immediately prior to his termination vested, which was equal to the number of shares subject to such Infinity Stock Options that would have vested within the one-year period following his termination of employment without cause and (ii) 446,667 RSUs granted to Dr. Bloch on August 11, 2022 vested under the terms of the award. Dr. Bloch’s vested Infinity Stock Options cease to be exercisable as of June 30, 2023.
- (2) The value of the Infinity Stock Options subject to acceleration is \$0, as none of the accelerated Infinity Stock Options described in this table are in-the-money.

## Table of Contents

- (3) Includes the number of Infinity RSUs to be sold to satisfy tax withholding obligations upon the accelerated vesting of such Infinity RSUs in accordance with the terms of each executive officer's durable automatic sales instructions.

In addition to the Infinity Stock Options and Infinity RSUs described in the foregoing table, Infinity's directors and officers hold certain previously vested Infinity Stock Options and Infinity RSUs, which are described in greater detail in the section titled "*Infinity Executive Compensation*" beginning on page 204 of this joint proxy statement/prospectus.

### ***Infinity Change in Control Severance Payments in Connection with the Merger***

#### **Infinity Executive Severance Benefits Plan**

Infinity's executive officers are eligible to receive severance benefits under Infinity's Executive Severance Benefits Plan, as amended by (i) Amendment No. 1 to the Executive Severance Benefits Plan, (ii) with respect to each of Ms. Perkins, Dr. Peluso, Dr. Ilaria and Mr. Tasker, the Infinity Retention Agreements described below, and (iii) with respect to Dr. Bloch, his separation agreement entered into with Infinity as of March 29, 2023 (as amended, the "Infinity Severance Plan"). The Infinity Severance Plan provides eligible full-time employees who are duly elected by Infinity's board of directors as "executive officers" of Infinity within the meaning of Rule 3b-7 under the Exchange Act with certain severance benefits upon a termination without cause (as defined in the Infinity Severance Plan) or a resignation for good reason (as defined in the Infinity Severance Plan), including in each case within one year following a change in control (an "Infinity Covered Termination"). Pursuant to the Infinity Severance Plan, each executive who experiences an Infinity Covered Termination is entitled to:

- an amount, payable in a single lump sum for each executive officer, equal to twelve months of the executive's monthly base salary;
- payment by Infinity of a portion of the cost of COBRA continuation of benefits coverage for the executive and his or her applicable dependents for the twelve-month period following such termination or until the executive commences new employment and is eligible for new plan coverage, if sooner, subject to certain conditions set forth in the Infinity Severance Plan;
- at the request of the executive, reasonable outplacement services for up to six months at the discretion of the Infinity Severance Plan's administrator or until the executive commences new employment, if sooner;
- any unpaid annual bonus in respect to any completed bonus period which has ended prior to the date of the executive's termination and which Infinity's board of directors deems granted to the executive in its discretion pursuant to Infinity's contingent compensation program, payable at the same time annual bonuses are paid to other Infinity employees (or, if later, on the release effective date); and
- immediate vesting of the portion of any outstanding equity awards of the executive which would have vested within the one year-period following such Infinity Covered Termination.

The Infinity Severance Plan also provides that the plan administrator may exercise its discretion to pay an executive the pro-rated amount of the executive's minimum bonus amount approved by Infinity's compensation committee for the year of termination. However, in light of the retention payments to each of Ms. Perkins, Dr. Peluso, Dr. Ilaria and Mr. Tasker under the Infinity Retention Agreements that are described below, no such pro-rated minimum bonus amount will be paid.

To receive any benefits under the Infinity Severance Plan, the executive officer must comply with provisions of any applicable noncompetition or non-solicitation agreement to which he or she is a party and must observe any other obligations he or she has to Infinity. The executive officer must also execute, deliver and not revoke a suitable waiver and release under which the executive releases and discharges Infinity and its affiliates from any and all claims arising out of his or her employment relationship with Infinity. Subject to the terms of the Merger Agreement, which would prohibit the amendment of the Infinity Severance Plan without MEI's consent other

## [Table of Contents](#)

than in the ordinary course of business, Infinity's board of directors may amend, modify, or terminate the Infinity Severance Plan at any time in its sole discretion; however, no such amendment, modification or termination may affect the rights of an executive then receiving payments or benefits under the Infinity Severance Plan without the consent of the executive and no such amendment, modification or termination made after a change in control will be effective for one year. The Infinity Severance Plan does not provide any "gross-up" for the amount of excise tax liability, if any, under Section 4999 of the Code, related to the "golden parachute payment" provisions under Section 280G of the Code.

Infinity has structured its severance benefits to apply following a change in control such that benefits are paid upon the occurrence of both a change in control and the termination of the executive during the 12-month period following the change in control. The Infinity Severance Plan does not provide any "gross-up" for the amount of excise tax liability, if any, under Section 4999 of the Code, related to the "golden parachute payment" provisions under Section 280G of the Code.

### **Infinity Retention and Severance Protection Agreements**

On February 22, 2023, Infinity entered into a Retention and Severance Protection Agreement with each of Ms. Perkins, Dr. Peluso, Dr. Ilaria and Mr. Tasker (each, an "Infinity Retention Agreement" and together, the "Infinity Retention Agreements").

Pursuant to the terms of the Infinity Retention Agreement with Ms. Perkins, upon and in connection with the Closing, Ms. Perkins's employment with Infinity will terminate without cause (as defined in the Infinity Retention Agreement) and she will join the MEI board of directors. As an incentive for Ms. Perkins to remain employed with Infinity through the Closing, Ms. Perkins is eligible to receive a retention bonus in the amount of \$250,000, payable in the next payroll the cut-off date for which follows the Closing Date. If Ms. Perkins's employment with Infinity terminates for any reason prior to the Closing Date, no portion of the retention bonus will be paid to Ms. Perkins. In addition to the retention bonus, Ms. Perkins is eligible to receive severance benefits under the Infinity Severance Plan when Infinity terminates Ms. Perkins's employment without cause in connection with the Closing or if Infinity terminates her employment before the Closing Date of the Merger for any reason other than for either cause or disability.

Pursuant to the terms of the Infinity Retention Agreement with Dr. Peluso, as an incentive for Dr. Peluso to remain employed through the Closing and through December 31, 2023, Dr. Peluso is eligible to receive a retention bonus in the amount of \$200,000, payable 50% in the next payroll the cut-off date for which follows June 30, 2023, with the remainder payable on or shortly after December 31, 2023. If Dr. Peluso's employment ends because he is terminated other than for either cause (as defined in the Infinity Retention Agreement) or disability before June 30, 2023, he will receive the first 50% of his retention bonus in the same payroll in which he receives his severance benefits under the Infinity Severance Plan, and the remaining portion of his retention bonus will be forfeited. If his employment ends because he is terminated other than for either cause or disability on or after June 30, 2023 and provided that the Closing has occurred prior to such termination, he will receive the remaining 50% of his retention bonus (and the initial 50% if not yet paid) in the same payroll in which he receives his severance benefits. Any portion of the retention bonus payable to Dr. Peluso in connection with his termination of employment is subject to his execution and nonrevocation of a release of claims in favor of Infinity and its affiliates. If Dr. Peluso resigns from employment with Infinity or MEI (including for good reason) or if Infinity or MEI terminates his employment for cause or due to disability, no portion of the retention bonus will be paid to Dr. Peluso. In addition to the retention bonus, Dr. Peluso will remain eligible to receive severance benefits if Infinity or MEI terminates his employment for any reason other than for either cause or disability or he resigns for good reason, in each case no later than one (1) year following the Closing Date or such longer period as the Infinity Severance Plan applies to Dr. Peluso. If, after the Closing Date, Infinity or MEI adopts a plan providing severance benefits that are more generous than those now in effect, Dr. Peluso will be eligible for the additional benefits in accordance with their terms.

## [Table of Contents](#)

Pursuant to the terms of the Infinity Retention Agreement with Dr. Ilaria, as an incentive for Dr. Ilaria to remain employed through the Closing and through December 31, 2023, Dr. Ilaria is eligible to receive a retention bonus in the amount of \$250,000, payable 50% in the next payroll the cut-off date for which follows June 30, 2023, with the remainder payable on or shortly after December 31, 2023. If Dr. Ilaria's employment ends because he is terminated other than for either cause (as defined in the Infinity Retention Agreement) or disability before June 30, 2023, he will receive the first 50% of his retention bonus in the same payroll in which he receives his severance benefits under the Infinity Severance Plan, and the remaining portion of his retention bonus will be forfeited. If his employment ends because he is terminated other than for either cause or disability on or after June 30, 2023 and provided that the Closing has occurred prior to such termination, he will receive the remaining 50% of his retention bonus (and the initial 50% if not yet paid) in the same payroll in which he receives his severance benefits. Any portion of the retention bonus payable to Dr. Ilaria in connection with his termination of employment is subject to his execution and nonrevocation of a release of claims in favor of Infinity and its affiliates. If Dr. Ilaria resigns from employment with Infinity or MEI (including for good reason) or if Infinity or MEI terminates his employment for cause or due to disability, no portion of the retention bonus will be paid to Dr. Ilaria. In addition to the retention bonus, Dr. Ilaria will remain eligible to receive severance benefits if Infinity terminates his employment for any reason other than for either cause or disability or he resigns for good reason, in each case no later than one (1) year following the Closing Date or such longer period as the Infinity Severance Plan applies to Dr. Ilaria. If, after the Closing Date, Infinity or MEI adopts a plan providing severance benefits that are more generous than those now in effect, Dr. Ilaria will be eligible for the additional benefits in accordance with their terms.

Pursuant to the terms of the terms of the Infinity Retention Agreement with Mr. Tasker, Mr. Tasker agreed to remain in the employ of Infinity through June 30, 2023, the Closing, and for a transition period thereafter. The Infinity Retention Agreement provides that Mr. Tasker's employment will end on a termination without cause (as defined in the Infinity Retention Agreement) after the transition period that Infinity requests on or before the Closing and to which Mr. Tasker agrees. As an incentive for Mr. Tasker to remain employed with Infinity through June 30, 2023, Mr. Tasker is eligible to receive a retention bonus in the amount of \$225,000, payable in the next payroll the cut-off date for which follows June 30, 2023. If Mr. Tasker's employment ends because he is terminated other than for either cause or disability before June 30, 2023, he will receive the retention bonus in the same payroll in which he receives his severance benefits, subject to his execution and nonrevocation of a release of claims in favor of Infinity and its affiliates. If Mr. Tasker resigns from employment with Infinity (including for good reason) prior to June 30, 2023 or if Infinity terminates his employment for cause or due to disability prior to June 30, 2023, no portion of the retention bonus will be paid to Mr. Tasker. In addition to the retention bonus, Mr. Tasker is eligible to receive severance benefits under the Infinity Severance Plan when Infinity terminates Mr. Tasker's employment without cause before, on or following the Closing.

For an estimate of the amounts of severance that would be payable upon an Infinity Covered Termination to Infinity's named executive officers, please see the section titled "*The Merger—Compensation Payable to Infinity Named Executive Officers*" beginning on page 172 of this joint proxy statement/prospectus. The cash severance paid to Dr. Bloch in connection with his termination of employment was \$502,654, which was paid as a lump sum on April 7, 2023. He is also entitled to receive up to \$46,365 in outplacement and health continuation benefits. The cash severance that will be payable to Mr. Tasker upon his Infinity Covered Termination is estimated to be \$428,131, which will be paid in a lump sum following his termination. He will also be entitled to receive an estimated amount of up to \$46,365 in outplacement and health continuation benefits.

### ***Board Member Affiliations***

Sujay R. Kango serves on the boards of directors of each of MEI and Infinity. The Infinity board of directors considered, among other things, that Mr. Kango holds stock options exercisable for shares of MEI Common Stock and Infinity Common Stock.



### ***Management Following the Merger***

As described in the section titled “*Management Following the Merger*” beginning on page 299 of this joint proxy statement/prospectus, the board of directors of the combined company will include certain current directors and executive officers of MEI and Infinity. Following the Closing, the board of directors of the combined company is expected to be composed of eight members, consisting of Norman C. Selby (currently Infinity’s Lead Independent Director), who is expected to chair the combined company board, David Urso (currently MEI’s Chief Operating Officer and General Counsel), Daniel P. Gold, Ph.D. (currently MEI’s Chief Executive Officer and chair of the MEI board of directors), Adelene Perkins (currently Infinity’s Chief Executive Officer and chair of the Infinity board of directors), Richard Gaynor, M.D. (currently a director of Infinity), Charles V. Baltic III (currently the Chair of the MEI board of directors), Thomas C. Reynolds, M.D., Ph.D. (currently a director of MEI) and Sujay R. Kango (currently a director of MEI and Infinity). The non-employee directors of the combined company will be eligible to be compensated pursuant to the MEI non-employee director compensation policy that is expected to remain in place following the Effective Time.

In addition, following the Closing, Dr. Ilaria is expected to serve as Chief Medical Officer of the combined company and Dr. Peluso is expected to serve as Chief Scientific Officer of the combined company.

### ***Directors’ and Officers’ Insurance and Indemnification***

Pursuant to the terms of the Merger Agreement, certain directors and officers of Infinity and its subsidiaries will be entitled to certain ongoing indemnification and coverage under directors’ and officers’ liability and fiduciary liability insurance policies following the Merger. Such indemnification and insurance coverage is further described in the section titled “*The Merger Agreement—Directors’ and Officers’ Insurance and Indemnification*” beginning on page 183 of this joint proxy statement/prospectus.

### **Compensation Payable to Infinity Named Executive Officers**

The following information, tables and the related footnotes present information about the compensation payable to Infinity’s named executive officers in connection with the Merger. The following tables set forth the information required by Item 402(t) of Regulation S-K regarding the compensation that will or may be payable to Infinity’s named executive officers, which is based on or otherwise relates to the Merger, assuming the following:

- the relevant price per share of Infinity Common Stock is \$0.24, which equals the average closing price of a share of Infinity Common Stock over the first five business day period following the first public announcement of the Merger (i.e., the five business day period beginning February 23, 2023);
- the completion of the Merger occurs on June 30, 2023 and constitutes a “change in control” or term of similar meaning for purposes of Infinity’s compensation and benefits plans;
- each such named executive officer experiences a severance-qualifying termination immediately following the completion of the Merger;
- each such named executive officer will not receive any pro-rated minimum bonus for the year of termination;
- each such named executive officer will receive six months of outplacement benefits with an estimated aggregate value of \$10,000;
- each such named executive officer will receive 12 months of benefits continuation determined based upon the benefits elections and premiums in effect as of June 30, 2023; and
- the Infinity Stock Options and Infinity RSUs outstanding and unvested on June 30, 2023 will fully vest.

The amounts below are based on multiple assumptions that may or may not actually occur or be accurate on the relevant date, including assumptions described in footnotes to the tables. The amounts below do not reflect certain compensation actions that may occur before the actual effective time of the Merger. The actual amounts

## Table of Contents

payable to Infinity's named executive officers, if any, will depend on whether the named executive officer incurs a qualifying termination, the date of termination of the named executive officer's employment (if applicable), the Closing Date, the value of Infinity Common Stock on the termination date, the manner of termination, and the terms of the plans or agreements in effect at such time. More detail on the included payments and benefits are set forth above in this section titled "*Interests of Infinity's Directors and Executive Officers in the Merger*" beginning on page 18 of this joint proxy statement/prospectus.

### All Golden Parachute Compensation

The following table sets forth all golden parachute compensation that will or may be payable to Infinity's named executive officers.

Name	Cash \$(1)	Equity \$(2)	Perquisites / Benefits \$(3)	Other \$(4)	Total (\$)
Adelene Q. Perkins	717,168	184,352	35,006	250,000	1,186,526
Robert Ilaria, Jr.	475,150	85,619	45,653	250,000	856,422
Stéphane Peluso	436,800	65,824	45,653	200,000	748,277

- (1) The amounts in this column represent the cash amounts to which Infinity's named executive officers would be entitled as severance payments under the Infinity Severance Plan, which consist of the following:

Name	Cash Severance Payments (\$)
Adelene Q. Perkins	717,168
Robert Ilaria, Jr.	475,150
Stéphane Peluso	436,800

The cash severance payments are "double trigger" benefits payable upon an Infinity Covered Termination; however, cash severance payments under the Infinity Severance Plan would also be payable on an Infinity Covered Termination that occurred prior to or following the one-year period following the occurrence of a change in control.

- (2) The amounts in this column represent the value of unvested Infinity Stock Options prior to the application of the Exchange Ratio and unvested Infinity RSUs, in each case as of June 30, 2023, and includes, in the case of Infinity RSUs, the number of Infinity RSUs to be sold to satisfy tax withholding obligations upon the accelerated vesting of such Infinity RSUs. The vesting in full of each outstanding Infinity Stock Option and Infinity RSU are "single trigger" benefits in connection with the Closing.

Name	Number of Infinity Stock Options Subject to Acceleration	Value of Infinity Stock Options Subject to Acceleration (\$ (1))	Number of Infinity RSUs Subject to Acceleration	Value of Infinity RSUs Subject to Acceleration (\$)
Adelene Q. Perkins	607,615	0	768,133	184,352
Robert Ilaria, Jr.	223,420	0	356,747	85,619
Stéphane Peluso	189,809	0	274,267	65,824

- (1) The value of the Infinity Stock Options subject to acceleration is \$0, as none of the accelerated Infinity Stock Options described in this table are in-the-money.
- (3) The amounts in this column represent the estimated value of continued health benefits under COBRA for up to 12 months and the estimated value of certain outplacement benefits for up to 6 months, each of which are "double trigger" benefits payable following an Infinity Covered Termination. However, the same amounts would also be payable on an Infinity Covered Termination that occurred prior to or following the one-year period following the occurrence of a change in control.

## [Table of Contents](#)

Name	Continued Health Benefits (\$)	Outplacement Benefits (\$)
Adelene Q. Perkins	25,006	10,000
Robert Ilaria, Jr.	35,653	10,000
Stéphane Peluso	35,653	10,000

- (4) The amounts in this column represent cash retention payments that are “single trigger” benefits in connection with the Closing. The cash retention payment to Ms. Perkins is contingent upon Ms. Perkins remaining employed with Infinity until the Closing, and is payable in the next payroll the cutoff date for which follows the Closing Date. The cash retention payments to each of Dr. Ilaria and Dr. Peluso are contingent upon Dr. Ilaria and Dr. Peluso respectively remaining employed with Infinity until the Closing and with the combined company through December 31, 2023, and in each case are payable 50% in the next payroll the cutoff date for which follows June 30, 2023, with the remainder payable on or shortly after December 31, 2023.

### ***New Golden Parachute Compensation***

The following table sets forth only the golden parachute compensation that will or may be payable to Infinity’s named executive officers subject to new arrangements in connection with the Merger. It does not include compensation that will or may be payable to Infinity’s named executive officers that was previously disclosed and the subject of a shareholder advisory vote.

Name	Other (\$)(1)	Total (\$)
Adelene Q. Perkins	250,000	250,000
Robert Ilaria, Jr.	250,000	250,000
Stéphane Peluso	200,000	200,000

- (1) The amounts in this column represent cash retention payments that are “single trigger” benefits in connection with the Closing. The cash retention payment to Ms. Perkins is contingent upon Ms. Perkins remaining employed with Infinity until the Closing, and is payable in the next payroll the cutoff date for which follows the Closing Date. The cash retention payments to each of Dr. Ilaria and Dr. Peluso are contingent upon Dr. Ilaria and Dr. Peluso respectively remaining employed with Infinity until the Closing and with the combined company through December 31, 2023, and in each case are payable 50% in the next payroll the cutoff date for which follows June 30, 2023, with the remainder payable on or shortly after December 31, 2023.

Pursuant to the terms of the Infinity Retention Agreements, with respect to each of Infinity’s named executive officers, clause (i) of the definition of “Cause” in the Infinity Severance Plan will be replaced by “a good faith finding by Infinity’s board of directors or its public parent corporation of a knowing and willful failure by the employee to perform the employee’s material duties to Infinity in a manner reasonably acceptable to Infinity, which failure continues for a period of more than 30 days after notice thereof has been provided to the employee in writing by Infinity, setting forth in reasonable detail the nature of such failure” and (ii) any severance payment under the Infinity Severance Plan will be made as a lump sum rather than in installments. These changes to the definition of cause and the form of the severance payment do not impact the amounts of compensation payable to Infinity’s named executive officers as disclosed under “–All Golden Parachute Compensation” above.

### **Delisting and Deregistration of Infinity Common Stock**

If the Merger is completed, Infinity Common Stock will be delisted from the Nasdaq Global Select Market and deregistered under the Exchange Act, and Infinity will no longer be required to file periodic reports with the SEC with respect to Infinity Common Stock.

## Table of Contents

Each of the parties has agreed to cooperate with the other party to take, or cause to be taken, all actions necessary to enable the delisting of the Infinity Common Stock from the Nasdaq Global Select Market and the deregistration of the shares of Infinity Common Stock under the Exchange Act after the Effective Time.

### **Regulatory Approvals**

MEI and Infinity are not currently aware of any other material governmental consents, approvals or filings that are required prior to the parties' completion of the Merger. If the parties become aware of any notices, reports and other documents required to be filed with respect to the Merger, MEI and Infinity have agreed to use reasonable best efforts to file, as soon as practicable, such notices, reports and other documents, and to submit promptly any information reasonably requested by any governmental entity in connection therewith.

### **Anticipated Accounting Treatment**

The Merger is expected to be accounted for as an asset acquisition pursuant to Accounting Standards Codification Topic 805 –*Business Combinations* (“ASC 805”). MEI is the accounting acquirer and will record assets acquired and liabilities assumed from Infinity primarily by allocating the cost of the acquisition, including transaction costs, on a fair value basis without the recognition of goodwill.

The final allocation of the purchase price will be determined after the Merger is completed and after completion of an analysis to determine the estimated net fair value of Infinity's assets and liabilities. Accordingly, the final acquisition accounting adjustments may be materially different from the unaudited pro forma adjustments.

The financial condition and results of operations of MEI after completion of the Merger will reflect Infinity's balances and results after completion of the Merger but will not be restated retroactively to reflect the historical financial condition or results of operations of Infinity. The earnings of MEI following completion of the Merger will reflect acquisition accounting adjustments, including the effect of changes in the carrying value of assets and liabilities.

### **No Appraisal Rights**

Appraisal rights are statutory rights that, if applicable under law, enable stockholders to dissent from an extraordinary transaction, such as a merger, and to demand that the corporation pay the fair value for their shares as determined by a court in a judicial proceeding instead of receiving the consideration offered to the stockholders in connection with the transaction. Under the DGCL, stockholders do not have appraisal rights if the shares of stock they hold are either listed on a national securities exchange or held of record by more than 2,000 holders. Notwithstanding the foregoing, appraisal rights are available if stockholders are required by the terms of the merger agreement to accept for their shares anything other than (a) shares of stock of the surviving corporation, (b) shares of stock of another corporation that will either be listed on a national securities exchange or held of record by more than 2,000 holders, (c) cash in lieu of fractional shares or (d) any combination of the foregoing. Because the Merger is of Merger Sub with and into Infinity and holders of MEI Common Stock will continue to hold their shares following completion of the Merger, holders of MEI Common Stock are not entitled to appraisal rights. Because Infinity stockholders will hold shares listed on a national securities exchange immediately prior to the completion of the Merger and are not required by the terms of the Merger Agreement to accept for their shares anything other than shares of MEI Common Stock (which are listed on a national securities exchange) and cash in lieu of fractional shares, holders of Infinity Common Stock will not be entitled to appraisal rights in the Merger.

## MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES OF THE MERGER

The following is a general discussion of material U.S. federal income tax consequences of the Merger to U.S. Holders (as defined below) that exchange their Infinity Common Stock for MEI Common Stock in the Merger. This discussion is based on the Code, U.S. Treasury regulations promulgated thereunder, judicial decisions and published rulings and administrative pronouncements of the IRS, in each case as in effect as of the date hereof. These authorities may change or be subject to differing interpretations. Any such change or differing interpretation may be applied retroactively in a manner that could adversely affect a U.S. Holder. Infinity has not sought and will not seek any rulings from the IRS regarding the matters discussed below. There can be no assurance the IRS or a court will not take a contrary position to that discussed below regarding the tax consequences of the Merger. This discussion assumes that the Merger will be consummated in accordance with the Merger Agreement and as further described in this joint proxy statement/prospectus. This discussion is not a complete description of all of the tax consequences of the Merger and, in particular, does not address any tax consequences arising under the Medicare contribution tax on net investment income or the alternative minimum tax (including the corporate alternative minimum tax on financial statement income), nor does it address any tax consequences arising under the laws of any state, local or non-U.S. jurisdiction, or under any U.S. federal laws other than those pertaining to the income tax.

This discussion applies only to U.S. Holders who hold shares of Infinity Common Stock as a capital asset within the meaning of Section 1221 of the Code (generally, property held for investment). Further, this discussion does not purport to address all aspects of U.S. federal income taxation that may be relevant to U.S. Holders in light of their particular circumstances and does not apply to U.S. Holders subject to special treatment under the U.S. federal income tax laws including, without limitation:

- banks, insurance companies and other financial institutions;
- tax-exempt and governmental organizations;
- partnerships, S corporations and other pass-through entities (and investors therein);
- regulated investment companies and real estate investment trusts;
- controlled foreign corporations and passive foreign investment companies;
- brokers and dealers in stocks, securities, commodities, or currencies;
- traders in securities that elect to apply a mark-to-market method of accounting;
- persons who acquired Infinity Common Stock pursuant to the exercise of employee stock options, through a tax qualified retirement plan or otherwise as compensation;
- persons who purchased or sold their shares of Infinity Common Stock as part of a wash sale;
- persons whose functional currency is not the U.S. dollar;
- persons who hold Infinity Common Stock as part of a hedge, straddle, constructive sale, conversion, or other integrated transaction;
- persons subject to certain rules of Section 451(b) of the Code by reason of filing an applicable financial statement;
- U.S. expatriates; and
- persons holding Infinity Common Stock who exercise dissenters' rights.

For purposes of this discussion, the term "U.S. Holder" means a beneficial owner of Infinity Common Stock that is, for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States;
- a corporation organized under the laws of the United States, any state thereof or the District of Columbia;

## Table of Contents

- a trust if (i) a court within the United States is able to exercise primary supervision over the administration of the trust and one or more United States persons (as defined in Section 7701(a)(30) of the Code) has authority to control all substantial decisions of the trust or (ii) the trust has made a valid election to be treated as a United States person for U.S. federal income tax purposes; or
- an estate, the income of which is subject to U.S. federal income tax regardless of its source.

If an entity or arrangement treated as a partnership for U.S. federal income tax purposes holds Infinity Common Stock, the tax treatment of a partner in such partnership generally will depend on the status of the partner and the activities of the partnership. Any entity treated as a partnership for U.S. federal income tax purposes that holds Infinity Common Stock and any partners in such partnership should consult their tax advisors regarding the tax consequences of the Merger to them.

**THE FOLLOWING DISCUSSION DOES NOT PURPORT TO BE A COMPLETE ANALYSIS OR DISCUSSION OF ALL OF THE POTENTIAL TAX CONSEQUENCES OF THE MERGER. ALL HOLDERS OF INFINITY COMMON STOCK SHOULD CONSULT THEIR TAX ADVISORS AS TO THE PARTICULAR TAX CONSEQUENCES TO THEM OF THE MERGER, INCLUDING THE APPLICABILITY AND EFFECT OF ANY U.S. FEDERAL, STATE, LOCAL, NON-U.S., AND OTHER TAX LAWS.**

### **U.S. Federal Income Tax Consequences of the Merger to U.S. Holders**

The Merger is intended to qualify as a “reorganization” within the meaning of Section 368(a) of the Code and the Treasury Regulations promulgated thereunder. The completion of the Merger is, however, not conditioned on the Merger qualifying as such a “reorganization” or upon the receipt of an opinion of counsel to that effect. No assurance can be given that the Merger will qualify as a “reorganization” within the meaning of Section 368(a) of the Code and the Treasury regulations promulgated thereunder. Neither MEI nor Infinity intends to obtain a ruling from the IRS or an opinion of counsel with respect to the tax consequences of the Merger. If the IRS were to successfully challenge the qualification of the Merger as a “reorganization,” the tax consequences would differ materially from those described in this joint proxy statement/prospectus as discussed below under “— *Tax Consequences if the Merger Fails to Qualify as a Reorganization.*”

Assuming that the Merger qualifies as a “reorganization” within the meaning of Section 368(a) of the Code and the Treasury regulations promulgated thereunder, generally, a U.S. Holder that exchanges Infinity Common Stock for MEI Common Stock in the Merger:

- will not recognize any gain or loss upon the exchange of Infinity Common Stock for MEI Common Stock in the Merger, except with respect to cash received in lieu of a fractional share of MEI Common Stock (as discussed below);
- will have a tax basis in the MEI Common Stock received in the Merger (including any fractional share of MEI Common Stock deemed received and redeemed for cash as described below) equal to the tax basis of the Infinity Common Stock surrendered in exchange therefor;
- will have a holding period for the MEI Common Stock received in the Merger (including any fractional share of MEI Common Stock deemed received and redeemed for cash as described below) that includes its holding period for its Infinity Common Stock surrendered in exchange therefor.

U.S. Holders that acquired different blocks of Infinity Common Stock at different times or at different prices should consult their tax advisors regarding the allocation of the tax basis and holding period of such shares.

### **Cash in Lieu of Fractional Shares**

A U.S. Holder that receives cash in lieu of a fractional share of MEI Common Stock in the Merger will generally be treated as having received the fractional share pursuant to the Merger and then as if MEI redeemed such

## [Table of Contents](#)

fractional share for cash, and will generally recognize capital gain or loss measured by the difference between the cash received for such fractional share of MEI Common Stock and the U.S. Holder's tax basis in the fractional share of MEI Common Stock (calculated as described above). Such capital gain or loss will generally be long-term capital gain or loss if the holding period for such fractional share of MEI Common Stock (calculated as described above) is more than one year. Long-term capital gains of certain non-corporate holders of MEI common stock, including individuals, are generally taxed at preferential rates. The deductibility of capital losses is subject to limitations.

### **Tax Consequences if the Merger Fails to Qualify as a Reorganization**

If the Merger does not qualify as a "reorganization" within the meaning of Section 368(a) of the Code, a U.S. Holder generally would recognize gain or loss for U.S. federal income tax purposes in an amount equal to the difference between the fair market value, at the Effective Time, of the MEI Common Stock received in the Merger (including any cash received in lieu of a fractional share of MEI Common Stock) in exchange for the U.S. Holder's shares of Infinity Common Stock surrendered in the Merger and such U.S. Holder's tax basis in the shares of Infinity Common Stock surrendered in the Merger. Gain or loss must be calculated separately for each block of Infinity Common Stock exchanged by such U.S. Holder if such blocks were acquired at different times or for different prices. Any gain or loss recognized generally would be capital gain or loss, and generally would be long-term capital gain or loss if the U.S. Holder's holding period in the relevant block of Infinity Common Stock is more than one year at the Effective Time. Long-term capital gain of certain non-corporate taxpayers, including individuals, generally is taxed at reduced U.S. federal income tax rates. The deductibility of capital losses is subject to limitations. A U.S. Holder's tax basis in MEI Common Stock received in the Merger would be equal to the fair market value thereof as of the Effective Time, and such U.S. Holder's holding period in such MEI Common Stock would begin on the day following the Merger.

### **Reporting Requirements**

Each U.S. Holder that receives shares of MEI Common Stock in the Merger is required to retain permanent records pertaining to the Merger and make such records available to any authorized IRS officers and employees. Such records should specifically include information regarding the amount, basis, and fair market value of the Infinity Common Stock exchanged and the amount of MEI Common Stock and cash received in exchange therefor. U.S. Holders who owned immediately before the Merger at least five percent (by vote or value) of the total outstanding stock of Infinity are required to attach a statement to their tax returns for the year in which the Merger is consummated that contains the information listed in Treasury Regulation Section 1.368-3(b). Such statement must include the U.S. Holder's tax basis in such holder's Infinity Common Stock surrendered in the Merger, the fair market value of such stock, the date of the Merger and the name and employer identification number of each of Infinity and MEI. U.S. Holders are urged to consult with their tax advisors to comply with these rules.

### **Information Reporting and Backup Withholding**

U.S. Holders may be subject to information reporting and backup withholding of U.S. federal income tax with respect to any cash received in the Merger, including any cash received in lieu of fractional shares of MEI Common Stock. Backup withholding will not apply, however, to a U.S. Holder that furnishes a correct taxpayer identification number and certifies that it is not subject to backup withholding on IRS Form W-9 or is otherwise exempt from backup withholding and provides proof of the applicable exemption. Backup withholding is not an additional tax and any amounts withheld will be allowed as a refund or credit against the U.S. Holder's U.S. federal income tax liability, if any, provided that such U.S. Holder timely furnishes the required information to the IRS.

**THE ABOVE DISCUSSION OF MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES OF THE MERGER IS NOT INTENDED TO BE, AND SHOULD NOT BE CONSTRUED AS, LEGAL OR TAX ADVICE AND IS NOT INTENDED TO BE A COMPLETE ANALYSIS OR DESCRIPTION OF ALL POTENTIAL U.S. FEDERAL INCOME TAX CONSEQUENCES OF THE MERGER. IN ADDITION, THE DISCUSSION DOES NOT ADDRESS TAX CONSEQUENCES THAT MAY VARY**



**WITH, OR ARE CONTINGENT ON, INDIVIDUAL CIRCUMSTANCES. MOREOVER, THE DISCUSSION DOES NOT ADDRESS ANY U.S. FEDERAL NON-INCOME TAX OR ANY FOREIGN, STATE OR LOCAL TAX CONSEQUENCES OF THE MERGER, NOR ANY TAX CONSEQUENCES OF ANY TRANSACTION OTHER THAN THE MERGER. ALL HOLDERS OF INFINITY COMMON STOCK SHOULD CONSULT THEIR TAX ADVISORS WITH RESPECT TO THE APPLICATION OF U.S. FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATIONS AS WELL AS ANY TAX CONSEQUENCES ARISING UNDER THE U.S. FEDERAL ESTATE OR GIFT TAX RULES, OR UNDER THE LAWS OF ANY STATE, LOCAL, NON-U.S., OR OTHER TAXING JURISDICTION OR UNDER ANY APPLICABLE TAX TREATY.**

## THE MERGER AGREEMENT

The following is a summary of the material terms of the Merger Agreement. A copy of the Merger Agreement is attached to this joint proxy statement/prospectus as Annex A and is incorporated by reference into this joint proxy statement/prospectus. The Merger Agreement has been attached to this joint proxy statement/prospectus to provide you with information regarding its terms. It is not intended to provide any other factual information about Infinity, MEI or Merger Sub. The following description does not purport to be complete and is qualified in its entirety by reference to the Merger Agreement. You should refer to the full text of the Merger Agreement for details of the Merger and the terms and conditions of the Merger Agreement.

The Merger Agreement contains representations and warranties that MEI and Merger Sub, on the one hand, and Infinity, on the other hand, have made to one another as of specific dates. These representations and warranties have been made for the benefit of the other parties to the Merger Agreement and may be intended not as statements of fact but rather as a way of allocating the risk to one of the parties if those statements prove to be incorrect. In addition, the assertions embodied in the representations and warranties are qualified by information in confidential disclosure schedules exchanged by the parties in connection with signing the Merger Agreement. While Infinity and MEI do not believe that these disclosure schedules contain information required to be publicly disclosed under the applicable securities laws, other than information that has already been so disclosed, the disclosure schedules do contain information that modifies, qualifies and creates exceptions to the representations and warranties set forth in the attached Merger Agreement. Accordingly, you should not rely on the representations and warranties as current characterizations of factual information about MEI or Infinity, because they were made as of specific dates, may be intended merely as a risk allocation mechanism between MEI and Merger Sub, and Infinity, and are modified by the disclosure schedules.

For purposes of this summary, each of MEI and Infinity are referred to as “a party” and collectively as “the parties.”

### General

Under the Merger Agreement, Merger Sub, a wholly owned subsidiary of MEI formed by MEI in connection with the Merger under the laws of the state of Delaware, will merge with and into Infinity, with Infinity surviving as a wholly owned subsidiary of MEI (the “Surviving Company”).

### Merger Consideration

At the Effective Time:

- each share of Infinity Common Stock issued and outstanding as of immediately prior to the Effective Time (excluding shares of Infinity Common Stock held in treasury, if any) shall by virtue of the Merger and without any action on the part of the holder thereof, be automatically converted into the right to receive 0.052245 (the “Exchange Ratio”) shares of MEI Common Stock, and shall thereafter cease to be outstanding, be cancelled and cease to exist;
- each share of common stock, par value \$0.001 per share, of Merger Sub issued and outstanding immediately prior to the Effective Time shall be automatically and without further action converted into and become one validly issued, fully paid and non-assessable share of common stock, par value \$0.001 per share, of the Surviving Company;
- each Infinity Stock Option will become fully vested in accordance with the terms of the underlying stock option agreement. Each Infinity Stock Option will be assumed by MEI at the Effective Time and converted into a stock option to purchase shares of MEI Common Stock. The number of shares of MEI Common Stock underlying each such assumed Infinity Stock Option will be equal to the product of (i) the number of shares of Infinity Common Stock underlying the applicable Infinity Stock Option immediately prior to the Effective Time multiplied by (ii) the Exchange Ratio, with the resulting number of shares of MEI Common Stock rounded down to the nearest whole share, and the exercise price per share of each such assumed Infinity Stock Option will be equal to (a) the per share exercise

## Table of Contents

price applicable to such Infinity Stock Option immediately prior to the Effective Time divided by (b) the Exchange Ratio, with the resulting exercise price per share rounded up to the nearest whole cent. Except as noted above, each assumed and converted Infinity Stock Option will continue to be governed by substantially the same terms and conditions (after giving effect to the full acceleration of vesting of such Infinity Stock Option in connection with the Merger) as were applicable to such Infinity Stock Option immediately prior to the Effective Time.

- Before the Effective Time, each outstanding Infinity RSU will become fully vested and the shares of Infinity Common Stock subject to such Infinity RSU will be distributed in accordance with the terms of the applicable restricted stock unit agreement. The shares of Infinity Common Stock issued upon the vesting of Infinity RSUs will be treated as shares of Infinity Common Stock issued and outstanding immediately prior to the Effective Time and in accordance with the terms and conditions of the Merger Agreement. No Infinity RSUs will be outstanding from and after the Effective Time.
- Infinity and the Infinity board of directors shall take such actions as may be necessary, including providing advance written notice to each holder of options (the “Infinity ESPP Options”) pursuant to the Infinity ESPP prior to the Effective Time such that: (i) the Purchase Periods and Offering Periods (each, as defined in the Infinity ESPP) then in effect under the Infinity ESPP shall be terminated by the Infinity board of directors in accordance with the terms of the Infinity ESPP and (ii) all outstanding Infinity ESPP Options shall be exercised to the extent of accumulated payroll deductions as of a date specified by the Infinity board of directors in such notice, which date shall not be less than ten (10) days preceding the Effective Time. No Infinity ESPP Options shall be outstanding from and after the Effective Time.
- The Exchange Ratio is subject to customary equitable adjustment in the event that the outstanding shares of MEI Common Stock and/or capital stock of Infinity, as applicable, have been changed into, or exchanged for, a different number of shares or a different class or series of shares during the period from the date of the Merger Agreement until the Effective Time.

No fractional shares of MEI Common Stock will be issuable pursuant to the Merger, and no certificates or scrip representing any such fractional shares shall be issued. The Exchange Agent (as defined below), acting as agent for the holders of the shares of Infinity Common Stock otherwise entitled to receive fractional shares of MEI Common Stock, will aggregate all fractional shares of MEI Common Stock that would otherwise have been required to be distributed and cause them to be sold in the open market for the accounts of such holders. Each holder of shares of Infinity Common Stock who would otherwise have been entitled to receive a fraction of a share of MEI Common Stock shall receive, in lieu thereof, cash, rounded to the nearest whole cent and without interest, in an amount equal to the proceeds from such sale by the Exchange Agent, if any, less any reasonable brokerage commissions or other fees, transfer taxes or other out-of-pocket transaction costs, as well as a proportional amount of any expenses of the Exchange Agent incurred from the sale of such fractional shares of MEI Common Stock.

The Merger Agreement provides that, at the Closing, MEI will issue and cause to be deposited with Computershare Trust Company, N.A. (the “Exchange Agent”) evidence of book entry shares representing the non-certificated shares of MEI Common Stock issuable in connection with the Merger.

The Merger Agreement provides that, promptly (and in any event within five business days) after the Effective Time, the Exchange Agent shall mail to each record holder of (i) shares of Infinity Common Stock (other than any shares held in treasury) represented by a certificate (a “Certificate”) or (ii) each book-entry account representing any uncertificated shares of Infinity Common Stock (“Uncertificated Shares”) a letter of transmittal and instructions for surrendering such Certificates (or affidavit of loss, if applicable) or Uncertificated Shares to the Exchange Agent. Upon surrender of a Certificate (or affidavit of loss, if applicable) to the Exchange Agent or, with respect to Uncertificated Shares, receipt of an “agent’s message” in customary form (or such other

## Table of Contents

evidence, if any, as the Exchange Agent may reasonably request) by the Exchange Agent, the holder will be entitled to receive in exchange (in each case less any required tax withholdings):

- the non-certificated shares of MEI Common Stock in book-entry form that such holder has the right to receive pursuant to the provisions of the Merger Agreement;
- cash in lieu of any fractional shares of MEI Common Stock that such holder has the right to receive pursuant to the provisions of the Merger Agreement; and
- dividends or other distributions, if any, declared or made with respect to MEI Common Stock with a record date after the Effective Time.

At the Effective Time, all holders of shares of Infinity Common Stock (other than any shares held in treasury) that were issued and outstanding immediately prior to the Effective Time will cease to have any rights as stockholders of Infinity. In addition, no transfer of shares of Infinity Common Stock after the Effective Time will be registered on the stock transfer books of Infinity.

If any Certificate has been lost, stolen or destroyed, in order for the person claiming such Certificate to be lost, stolen or destroyed to receive the shares of MEI Common Stock, cash in lieu of fractional shares and/or dividends or other distributions to which such person would otherwise be entitled pursuant to the terms of the Merger Agreement, such person will have to (i) make an affidavit of that fact, and (ii) if required by the Exchange Agent's customary practices, enter into an indemnification agreement in customary form providing an indemnity against any claim that may be made against the Exchange Agent with respect to such Certificate.

From and after the Effective Time, until it is surrendered, each Certificate or Uncertificated Share will represent only the right to receive shares of MEI Common Stock and cash in lieu of fractional shares. MEI will not pay dividends or other distributions on any shares of MEI Common Stock to be issued in exchange for any unsurrendered Certificate or Uncertificated Share until such Certificate (or affidavit of loss in lieu thereof) or Uncertificated Share is surrendered as provided in the Merger Agreement.

### **Treatment of Infinity Stock Options**

In connection with the Merger, each Infinity Stock Option will become fully vested in accordance with the terms of the underlying stock option agreement. Each Infinity Stock Option will be assumed by MEI at the Effective Time and converted into a stock option to purchase shares of MEI Common Stock. The number of shares of MEI Common Stock underlying each such assumed Infinity Stock Option will be equal to the product of (i) the number of shares of Infinity Common Stock underlying the applicable Infinity Stock Option immediately prior to the Effective Time multiplied by (ii) the Exchange Ratio, with the resulting number of shares of MEI Common Stock rounded down to the nearest whole share, and the exercise price per share of each such assumed Infinity Stock Option will be equal to (a) the per share exercise price applicable to such Infinity Stock Option immediately prior to the Effective Time divided by (b) the Exchange Ratio, with the resulting exercise price per share rounded up to the nearest whole cent. Except as noted above, each assumed and converted Infinity Stock Option will continue to be governed by substantially the same terms and conditions (after giving effect to the full acceleration of vesting of such Infinity Stock Option in connection with the Merger) as were applicable to such Infinity Stock Option immediately prior to the Effective Time.

### **Treatment of Infinity RSUs**

Before the Effective Time, each outstanding Infinity RSU will become fully vested and the shares of Infinity Common Stock subject to such Infinity RSU will be distributed in accordance with the terms of the applicable restricted stock unit agreement. The shares of Infinity Common Stock issued upon the vesting of Infinity RSUs will be treated as shares of Infinity Common Stock issued and outstanding immediately prior to the Effective Time in accordance with the terms and conditions of the Merger Agreement. No Infinity RSUs will be outstanding from and after the Effective Time.

## [Table of Contents](#)

### **Treatment of Infinity ESPP Options**

Infinity and the Infinity board of directors shall take such actions as may be necessary, including providing advance written notice to each holder of Infinity ESPP Options pursuant to the Infinity ESPP prior to the Effective Time such that: (i) the Purchase Periods and Offering Periods (each, as defined in the Infinity ESPP) then in effect under the Infinity ESPP shall be terminated by the Infinity board of directors in accordance with the terms of the Infinity ESPP and (ii) all outstanding Infinity ESPP Options shall be exercised to the extent of accumulated payroll deductions as of a date specified by the Infinity board of directors in such notice, which date shall not be less than ten (10) days preceding the Effective Time. No Infinity ESPP Options shall be outstanding from and after the Effective Time.

### **Directors, Officers and Committee Chairs of MEI Following the Merger**

Effective immediately following the Effective Time, the MEI board of directors will consist of four designees selected by MEI, three designees selected by Infinity, and one designee jointly selected by MEI and Infinity. The composition of the MEI board of directors following the Effective Time in the aggregate is expected to satisfy the requisite independence requirements and SEC rules, as well as the sophistication and independence requirements for the required committees, pursuant to Nasdaq listing requirements. It is anticipated that after the Effective Time, the MEI board of directors will consist of the following members, each as a member of the class of director with a term expiring at the applicable annual meeting of the stockholders of MEI (each, a "MEI Annual Meeting") set forth across from such member's name:

<u>Name</u>	<u>Class</u>
Dr. Daniel P. Gold Dr. Richard Gaynor Sujay R. Kango	Class with term expiring at the 2023 MEI Annual Meeting
Charles V. Baltic, III Adelene Q. Perkins	Class with term expiring at the 2024 MEI Annual Meeting
Dr. Thomas C. Reynolds David M. Urso Norman Selby	Class with term expiring at the 2025 MEI Annual Meeting

It is anticipated that the executive officers of MEI upon the consummation of the Merger will be:

<u>Name</u>	<u>Title</u>
David M. Urso	Chief Executive Officer
Dr. Robert Ilaria, Jr.	Chief Medical Officer
Dr. Stéphane Peluso	Chief Scientific Officer
Brian G. Drazba	Chief Financial Officer

It is anticipated that the chairs of the committees of the MEI board of directors upon the consummation of the Merger will be:

<u>Name</u>	<u>Committee Chair</u>
Adelene Q. Perkins	Chair of Audit Committee
Dr. Thomas C. Reynolds	Chair of Compensation Committee
Charles V. Baltic, III	Chair of Nominating and Corporate Governance Committee

### Conditions to the Completion of the Merger

Each party's obligation to complete the Merger is subject to the satisfaction or waiver (to the extent permitted by applicable legal requirements) by each of the parties, at or prior to the Merger, of various conditions, which include the following:

- the issuance of shares of MEI Common Stock pursuant to the Merger Agreement (the "MEI Share Issuance") shall have been approved by the affirmative vote of the majority of votes cast thereon at the MEI Special Meeting (as defined below) (the "MEI Stockholder Approval");
- the Merger Agreement shall have been adopted by the affirmative vote of the holders of a majority of the outstanding shares of Infinity Common Stock entitled to vote thereon at the Infinity Special Meeting (as defined below) (the "Infinity Stockholder Approval");
- no governmental entity of competent jurisdiction shall have enacted, issued, promulgated, enforced or entered any law or judgment (whether temporary, preliminary or permanent) that is in effect and restrains, enjoins or otherwise prohibits the consummation of the Merger;
- the registration statement on Form S-4 of which this joint proxy statement/prospectus forms a part, which is being filed by MEI with the SEC to register the MEI Common Stock to be issued to the holders of the shares of Infinity Common Stock in connection with the Merger, must have become effective in accordance with the provisions of the Securities Act of 1933 (as amended, the "Securities Act") and no stop order suspending the effectiveness of such registration statement has been issued and no proceedings for that purpose have been initiated or threatened; and
- the existing shares of MEI Common Stock shall have been continually listed on Nasdaq as of and from the date of the Merger Agreement through the Closing Date, and the shares of MEI Common Stock issuable in connection with the Merger shall have been approved for listing on The Nasdaq Capital Market, subject to official notice of issuance.

In addition, each party's obligation to complete the Merger is further subject to the satisfaction or waiver by that party of the following additional conditions:

- (i) each of the representations and warranties of the other party other than the MEI Fundamental Representations and the Infinity Fundamental Representations (as such terms are defined below), as applicable, shall be true and correct (without giving effect to any limitation as to "materiality" or "material adverse effect" set forth in the Merger Agreement) as of the Closing Date as though made on and as of the Closing Date (except to the extent in either case expressly made as of an earlier date, in which case as of such date), except where the failure of such representations and warranties to be true and correct (without giving effect to any limitation as to "materiality" or "material adverse effect" set forth in the Merger Agreement), would not have a material adverse effect on the other party, (ii) the representations and warranties of the other party related to, due organization, capitalization, authority to enter into the Merger Agreement and brokers/finders (other than the portions of the capitalization representation related to authorized capital stock and the existence of undisclosed outstanding equity securities) shall be true and correct in all material respects as of the date of the closing of the Merger as though made on and as of the Closing Date (except to the extent in either case expressly made as of an earlier date, in which case as of such date), and (iii) the portions of the capitalization representation related to authorized capital stock and the existence of undisclosed outstanding equity securities (such representations and warranties referenced in clauses (ii) and (iii) by MEI, the "MEI Fundamental Representations" and such representations and warranties referenced in clauses (ii) and (iii) by Infinity, the "Infinity Fundamental Representations") shall be true and correct in all respects except for de minimis inaccuracies as of the date of the closing of the Merger as though made on and as of the Closing Date (except to the extent in either case).
- the other party must have performed in all material respects all obligations in the Merger Agreement required to be performed by it at or prior to the Closing; and
- there shall not have occurred any material adverse effect on the other party that is continuing; and

## Table of Contents

- the other party to the Merger Agreement must have delivered a customary closing certificate to such party certifying that the closing conditions related to the accuracy of representations and warranties, lack of material adverse effect and performance of obligations have been satisfied.

In addition, MEI's obligation to complete the Merger is further subject to the satisfaction or waiver by MEI of the following additional conditions:

- Infinity's amount of net cash, as finally determined in accordance with the provisions of the Merger Agreement, shall be greater than or equal to: (a) if the Closing occurs on or before June 30, 2023, \$4,000,000, (b) if the Closing occurs after June 30, 2023 but on or before July 31, 2023, \$3,000,000 and (c) if the Closing occurs after July 31, 2023 but on or before August 31, 2023, \$2,000,000.
- Infinity must have delivered a complete and duly executed certificate to MEI satisfying the requirements of Treasury Regulation section 1.1445-2(c)(3).

In addition, Infinity's obligation to complete the Merger is further subject to the satisfaction or waiver by Infinity of the following additional condition:

- MEI's amount of net cash, as finally determined in accordance with the provisions of the Merger Agreement, shall be greater than or equal to: (a) if the Closing occurs on or before June 30, 2023, \$80,000,000, (b) if the Closing occurs after June 30, 2023 but on or before July 31, 2023, \$78,000,000 and (c) if the Closing occurs after July 31, 2023 but on or before August 31, 2023, \$76,000,000.

The Merger Agreement provides that the following events shall not be considered a material adverse effect to MEI or Infinity, as applicable:

- general business or economic conditions generally affecting the industry in which such party and its subsidiaries operate;
- political conditions, acts of war, the outbreak or escalation of armed hostilities, acts of terrorism, earthquakes, wildfires, hurricanes, tsunamis, folds, mudslides, weather conditions, other natural disasters, man-made disasters, health and other emergencies, calamities, epidemics, pandemics (including COVID-19 and any evolutions or mutations thereof), disease outbreaks, other acts of God or force majeure events;
- changes in financial, banking or securities markets, including changes in interest rates in the United States or any other country or region in the world and changes in exchange rates for the currencies of any countries and any suspension of trading in securities (whether equity, debt, derivative or hybrid securities) generally on any securities exchange or over-the-counter market operating in the United States or any other country or region in the world;
- any applicable law, directive or guideline from any governmental entity arising out of, or otherwise related to, the COVID-19 pandemic (including any response to COVID-19);
- any change in, or any compliance with or action taken for the purpose of complying with, any law or generally accepted accounting principles (or interpretations thereof);
- any change in the stock price or trading volume of such party's Common Stock;
- any failure by such party to meet internal or analysts' expectations or projections or the results of operations of such party;
- the announcement of the Merger Agreement or the pendency of the transactions contemplated by the Merger Agreement (the "Contemplated Transactions"), including (A) the identity of the other party, (B) the loss or departure of officers or other employees of such party or any of its subsidiaries directly or indirectly resulting from, arising out of, attributable to, or related to the Contemplated Transactions and (C) any other negative development (or potential negative development) in the relationships of such party or any of its subsidiaries with business partners, whether as a direct or indirect result of the loss or departure of officers or employees of such party or any of its subsidiaries or otherwise, directly or indirectly resulting from, arising out of, attributable to, or related to the Contemplated Transactions;



## Table of Contents

- any actions taken or failure to take action, in each case, to which such party has provided its prior written consent; or compliance with the terms of, or the taking of any action required or contemplated by, the Merger Agreement; or the failure to take any action prohibited by the Merger Agreement;
- any product candidate of such party or any of its subsidiaries, including any change, event, circumstance or development relating to the use or sale of any such product candidate, the suspension, rejection, refusal of, request to refile or any delay in obtaining or making any regulatory application or filing relating to any such product candidate, any other negative actions, requests, recommendations or decisions of the FDA or any other governmental entity relating to any such product candidate, any other regulatory development affecting any such product candidate, or the failure to conduct successful clinical trials on a timely basis for any such product candidate;
- any product or product candidate of any person (other than such party and its subsidiaries), including the entry into the market of any product competitive with any product or product candidate of such party or any of its subsidiaries;
- any clinical trials or studies undertaken by any person, and any negative publicity or unfavorable media attention resulting therefrom;
- any fees or expenses incurred in connection with the Contemplated Transactions; or
- any legal proceedings made or brought by any of the current or former stockholders of such party (on their own behalf or on behalf of such party) against MEI, Merger Sub, Infinity or any of their directors or officers, including legal proceedings arising out of the Merger or in connection with any other Contemplated Transactions.

provided, that (i) any effect causing or contributing to the events described in the sixth and seventh bullets above may be taken into account in determining whether there has been, or would reasonably be expected to be, a material adverse effect to such party (unless such effects are otherwise included in the events listed above), and (ii) any event referred to in the first, second, third, fourth and fifth bullets above may be considered a material adverse effect to such party to the extent disproportionately affecting such party and its subsidiaries, taken as a whole, relative to other similarly situated companies in the industries in which such party and its subsidiaries operate.

### **Representations and Warranties**

The Merger Agreement contains customary representations and warranties of MEI, Merger Sub and Infinity for a transaction of this type relating to, among other things:

- organizational documents
- due organization; subsidiaries
- capitalization
- authority; binding nature of the Merger Agreement
- non-contravention; consents
- SEC filings; financial statements
- absence of changes
- absence of undisclosed liabilities
- title to assets
- legal proceedings; orders
- contracts
- employee and labor matters; benefit plans
- environmental matters

## Table of Contents

- taxes
- intellectual property
- regulatory matters
- insurance; real estate
- registration statement and joint proxy statement/prospectus
- transactions with affiliates
- brokers and finders
- opinion of financial advisor
- anti-bribery
- ownership of common stock
- ownership and operations of Merger Sub (with respect to MEI and Merger Sub only)

The representations and warranties are, in many respects, qualified by materiality and knowledge, and will not survive the Merger, but their accuracy forms the basis of certain of the conditions to the obligations of MEI and Infinity to complete the Merger.

### **No Solicitation**

The Merger Agreement provides that, except as described below, each of MEI and Infinity will not, and it will cause it and its subsidiaries' officers, directors, employees, investment bankers, attorneys, accountants and other advisors, agents or representatives not to, directly or indirectly:

- solicit, initiate, induce, encourage or facilitate any inquiries or the making of any proposal or offer that constitutes, or could reasonably be expected to lead to, an Acquisition Proposal (as defined below);
- participate in any discussions or negotiations or cooperate in any way with any person regarding any Acquisition Proposal or any inquiry, proposal or offer that could reasonably be expected to lead to an Acquisition Proposal;
- provide any non-public information or data concerning it or any of its subsidiaries to any person in connection with any Acquisition Proposal or any inquiry, proposal or offer that could reasonably be expected to lead to an Acquisition Proposal, or for the purpose of soliciting, initiating, inducing, encouraging or facilitating an Acquisition Proposal;
- enter into any binding or nonbinding letter of intent, term sheet, memorandum of understanding, merger agreement, acquisition agreement, agreement in principle, option agreement, joint venture agreement, partnership agreement, lease agreement or other similar agreement with respect to an Acquisition Proposal;
- adopt, approve or recommend or make any public statement approving or recommending any inquiry, proposal or offer that constitutes, or could reasonably be expected to lead to, an Acquisition Proposal (including by approving any transaction, or approving any person becoming an "interested stockholder," for purposes of Section 203 of the DGCL);
- take any action or exempt any person (other than the other party and its subsidiaries) from the restriction on "business combinations" or any similar provision contained in applicable takeover laws or its organizational or other governing documents; or
- publicly propose, resolve or agree to do any of the foregoing actions.

Each of MEI and Infinity also agreed that it shall, and shall cause its subsidiaries and representatives to, immediately cease and cause to be terminated any solicitation, encouragement, discussions and negotiations with any person conducted prior to the date of the Merger Agreement with respect to any Acquisition Proposal, or

## Table of Contents

inquiry, proposal, or offer that could reasonably be expected to lead to an Acquisition Proposal, and shall promptly terminate access by any such person to any physical or electronic data rooms relating to any such Acquisition Proposal. Each of MEI and Infinity also agreed to deliver a notice to any person it entered into a confidentiality agreement with, end any discussions and require the return or destruction of any confidential information. Each of MEI and Infinity also agreed to enforce any standstill agreement entered into with any other person, unless such party's board of directors determined, in good faith after consultation with outside legal counsel, that such actions would reasonably be expected to be inconsistent with the directors' fiduciary duties under applicable law.

An "Acquisition Proposal" means, with respect to MEI or Infinity, any proposal (other than a proposal or offer by the other party or any of its Affiliates) for:

- any merger, consolidation, share exchange, business combination, issuance of securities, direct or indirect acquisition of securities, recapitalization, tender offer, exchange offer or other similar transaction in which a person or "group" (as defined in the Securities Exchange Act of 1934, as amended, and the rules promulgated thereunder) of persons directly or indirectly acquires, or if consummated in accordance with its terms would acquire, beneficial or record ownership of securities representing more than 15% of the outstanding shares of any class of voting securities of such party;
- issuance or acquisition of securities representing more than 15% of the outstanding shares of any class of voting securities of such party;
- any direct or indirect sale, lease, exchange, transfer, acquisition or disposition of any assets of such party and of its subsidiaries that constitute or account for (x) more than 15% of the consolidated net revenues of such party, consolidated net income of such party or consolidated book value of such party; or (y) more than 15% of the fair market value of the consolidated assets of such party; or
- any liquidation or dissolution of such party.

However, prior to the time the Stockholder Approval of MEI or Infinity, as applicable, is obtained, such party may (i) subject to certain conditions, provide access to nonpublic information regarding such party or any of its subsidiaries to, and (ii) may engage or participate in discussions or negotiations with, any third party in response to an unsolicited, written bona fide Acquisition Proposal first received after the date of the Merger Agreement (and which has not been withdrawn), if:

- such Acquisition Proposal did not result from a breach of the non-solicitation provisions of the Merger Agreement described above with respect to such Acquisition Proposal;
- such party has, at least three (3) Business Days prior, provided prior written notice to the other party of the identity of the person or group making such Acquisition Proposal, the material terms and conditions of such Acquisition Proposal (including, if applicable, copies of any material written communications), and its intention to engage or participate in any discussions or negotiations with any such person; and
- such party's board of directors determines in good faith, after consultation with its outside legal counsel and outside financial advisors, that such Acquisition Proposal either (x) constitutes or would reasonably be expected to result in a "Superior Proposal" (as defined below) and (y) the failure to take such action would reasonably be expected to be inconsistent with the directors' fiduciary duties under applicable laws.

Each of MEI and Infinity agreed to promptly (and in any event within 24 hours), notify the other party (orally and in writing) if (i) such party receives any proposals, offers or inquiries with respect to an Acquisition Proposal or that could reasonably be expected to lead to an Acquisition Proposal, (ii) any person requests non-public information is requested from such party in connection with any Acquisition Proposal (provided that such party shall only be required to provide notice once per person under this clause (ii)), or (iii) any discussions or negotiations with respect to or that could reasonably be expected to lead to an Acquisition Proposal are sought to

## Table of Contents

be initiated with such party (which notification shall include certain required information and ongoing notice obligations as further specified in the Merger Agreement).

Each party agreed that it and its subsidiaries would not enter into a confidentiality agreement with any person that would prohibit it from providing confidential information to the other party pursuant to the terms of, or otherwise complying with its obligations under the non-solicitation provision of, the Merger Agreement; and that it would not provide any information to any other person pursuant to any confidentiality agreement entered into prior to the date of the Merger Agreement unless such person agreed to waive any provision that would prohibit such party from providing confidential information to the other party pursuant to the terms of the Merger Agreement.

A “Superior Proposal” means, with respect to MEI or Infinity, any bona fide, binding, written Acquisition Proposal on terms which the board of MEI or Infinity, as applicable, determines in its good faith judgment, after consultation with outside financial advisors and outside legal counsel, would reasonably be expected to be consummated in accordance with its terms, taking into account all legal, financial and regulatory aspects of the proposal and the person or group of persons making the proposal, and, if consummated, would result in a transaction more favorable to such party’s stockholders from a financial point of view than the Merger (after taking into account any revisions to the terms of the Contemplated Transactions and the time likely to be required to consummate such Acquisition Proposal); provided that for purposes of the definition of “Superior Proposal”, the references to “15%” in the definition of Acquisition Proposal shall be deemed to be references to “50%.”

### **No Change in Recommendation or Alternative Acquisition Agreement**

Except as provided below, the board of directors of MEI or Infinity, as applicable, and each committee thereof may not (i) withhold, withdraw, qualify or modify (or publicly propose or resolve to withhold, withdraw, qualify or modify), in a manner adverse to the other party, its recommendation to such party’s stockholders to, (a) in the case of MEI, approve the MEI Share Issuance (the “MEI Board Recommendation”) and (b) in the case of Infinity, adopt the Merger Agreement (the “Infinity Board Recommendation”) or approve, recommend or otherwise declare advisable (or publicly propose or resolve to approve, recommend or otherwise declare advisable) any Acquisition Proposal or make or authorize the making of any public statement (oral or written) that has the substantive effect of such a withdrawal, qualification or modification, or remove such party’s Board Recommendation from or fail to include such party’s Board Recommendation in this joint proxy statement/prospectus (each, a “Change in Recommendation”) or (ii) cause or permit such party or any of its subsidiaries to enter into any letter of intent, term sheet, memorandum of understanding, agreement in principle, acquisition agreement, merger agreement, option agreement, joint venture agreement, partnership agreement, lease agreement or other similar agreement (other than a confidentiality agreement as permitted by the Merger Agreement) relating to or that could reasonably be expected to lead to any Acquisition Proposal or requiring such party (or that would require or could reasonably be expected to require such party) to abandon, terminate, or fail to consummate the Merger or any other transaction contemplated by the Merger Agreement or that would otherwise materially impede, interfere with or be inconsistent with, the Contemplated Transactions (an “Alternative Acquisition Agreement”).

### **Exceptions to No Change in Recommendation and Alternative Acquisition Agreement**

Notwithstanding the foregoing, upon receipt of an unsolicited written Acquisition Proposal in compliance with the terms of the Merger Agreement, the board of directors of MEI or Infinity, as applicable may make a Change in Recommendation and enter into an Alternative Acquisition Agreement prior to the receipt of such party’s Stockholder Approval if:

- the board of directors of such party determined in good faith, in consultation with outside financial advisors and outside legal counsel, that such Acquisition Proposal constitutes a Superior Proposal;
- such party provided the other party with four business days’ written notice, which notice shall contain certain required information as further specified in the Merger Agreement;

## Table of Contents

- prior to making such Change in Recommendation, such party engaged in good faith negotiations with the other party, during such notice period to consider adjustments to the terms and conditions of the Merger Agreement that may have been proposed in writing by the other party such that the Alternative Acquisition Agreement would cease to constitute a Superior Proposal; and
- the board of directors of such party determined in good faith, in consultation with outside financial advisors and outside legal counsel, that, in light of such Superior Proposal and taking into account any revised terms proposed in writing by the other party, such Superior Proposal continues to constitute a Superior Proposal and, after consultation with outside legal counsel, that the failure to make such Change in Recommendation would reasonably be expected to be inconsistent with the directors' fiduciary duties under applicable law.

Notwithstanding the foregoing, the board of directors of such party may make a Change in Recommendation upon the occurrence of an Intervening Event (as defined below) prior to receipt of the such party's Stockholder Approval if:

- such party provided the other party with four Business Days' written notice, which notice shall contain certain required information as further specified in the Merger Agreement;
- such party engaged in good faith negotiations with the other party, and took into account any changes to the terms of the Merger Agreement proposed in writing by the other party; and
- the board of directors of such party determined in good faith, in consultation with outside financial advisors and outside legal counsel, that, in light of such Intervening Event and taking into account any revised terms proposed in writing by the other party, that the failure of the board of directors of such party to make a Change in Recommendation would reasonably be expected to be inconsistent with the directors' fiduciary duties under applicable law.

"Intervening Event" means any effect that is material to MEI or Infinity, as applicable and in each case their subsidiaries taken as a whole, occurring or arising after the date of the Merger Agreement that (i) was not known to, or reasonably foreseeable by, the board of directors of such party (or, if known, the effect of which was not known to, or reasonably foreseeable) prior to the execution of the Merger Agreement, which effect becomes known to, or reasonably foreseeable by, the board of directors of such party prior to the receipt of such party's Stockholder Approval and (ii) does not relate to (A) an Acquisition Proposal made to such party or (B) (1) any changes in the market price or trading volume of either party, (2) either party meeting or failing to meet or exceeding published or unpublished revenue or earnings projections, in each case in and of itself, (3) any events or developments relating to the other party or any of its affiliates, (4) any event or development generally affecting the industries in which MEI or Infinity operate or in the economy generally or other general business, financial, market or political conditions, including changes in interest rates in the United States or any other country or region in the world and changes in exchange rates for the currencies of any countries and any suspension of trading in securities (whether equity, debt, derivative or hybrid securities) generally on any securities exchange or over-the-counter market operating in the United States or any other country or region in the world, (5) any change in any applicable law or other legal or regulatory conditions or changes in GAAP or other accounting standards, (6) any event or development to the extent directly resulting from the announcement or pendency of, or any actions required to be taken by MEI or Infinity (or refrained to be taken by MEI or Infinity) pursuant to the Merger Agreement or the consummation of the Contemplated Transactions, (7) earthquakes, hurricanes, tsunamis, tornadoes, floods, mudslides, wild fires or other natural disasters, weather conditions and other force majeure events or (8) any legal proceedings made or brought by any of the current or former stockholders of MEI or Infinity (on their own behalf or on behalf of MEI or Infinity) against MEI or Infinity, including legal Proceedings arising out of the Contemplated Transactions.

### **Meetings of Stockholders**

Unless the Merger Agreement is terminated in accordance with the terms of the Merger Agreement, MEI is obligated under the Merger Agreement to establish the record date for, duly call, give notice of and use its

## Table of Contents

reasonable best efforts to convene and hold a meeting of holders of shares of MEI Common Stock to consider and vote upon the MEI Share Issuance, which meeting shall in any event take place within 45 days after the declaration of the effectiveness of the Registration Statement (the “MEI Special Meeting”).

Notwithstanding any MEI Change in Recommendation, MEI shall seek the MEI Stockholder Approval at the MEI Special Meeting unless the Merger Agreement is terminated in accordance with its terms prior to the MEI Special Meeting.

Unless the Merger Agreement is terminated in accordance with the terms of the Merger Agreement, Infinity is obligated under the Merger Agreement to establish the record date for, duly call, give notice of and use its reasonable best efforts to convene and hold a meeting of holders of shares of Infinity Common Stock to consider and vote upon the adoption of the Merger Agreement, which meeting shall in any event take place within 45 days after the declaration of the effectiveness of the Registration Statement (the “Infinity Special Meeting”).

Notwithstanding any Infinity Change in Recommendation, Infinity shall submit the Merger Agreement to the holders of shares of Infinity Common Stock for adoption at the Infinity Special Meeting unless the Merger Agreement is terminated in accordance with its terms prior to the Infinity Special Meeting.

### **Covenants; Conduct of Business Pending the Merger**

Each of MEI and Infinity agreed that during the period from the date of the Merger Agreement to the earlier of the termination of the Merger Agreement in accordance with its terms and the Effective Time (the “Interim Period”), it will, and cause each of its subsidiaries to, use its commercially reasonable efforts to conduct its business in the ordinary course of its normal operations and consistent in all material respects with past practices (the “Ordinary Course of Business”), except as (i) set forth in the disclosure schedules delivered by MEI or Infinity, as applicable pursuant to the Merger Agreement (with respect to MEI, the “MEI Disclosure Schedules” and with respect to Infinity, the “Infinity Disclosure Schedules”), (ii) expressly contemplated or permitted by the Merger Agreement, (iii) as required by applicable laws, (iv) for any applicable law, directive or guideline from any governmental entity arising out of, or otherwise related to, the COVID-19 pandemic (including any response to COVID-19), or (v) as consented to in writing by the other party, which consent shall not be unreasonably withheld, delayed or conditioned. Each of MEI and Infinity also agreed that, subject to certain limited exceptions, without the consent of the other party, it will not, and will not cause or permit any of its subsidiaries to, during the Interim Period (except as set forth in such party’s Disclosure Schedules, expressly permitted by or required in accordance with the Merger Agreement or as required by applicable laws):

- declare, accrue, set aside or pay any dividend or make any other distribution in respect of any shares of its capital stock or repurchase, redeem or otherwise reacquire any shares of its capital stock or other securities (except repurchases from terminated employees, directors or consultants of such party or in connection with the payment of the exercise price and/or withholding taxes incurred upon the exercise, settlement or vesting of any award or purchase rights granted under such party’s equity compensation plans (and with respect to Infinity, inducement grants) in accordance with the terms of such award in effect on the date of this Agreement);
- sell, issue, grant, modify, reprice, pledge or otherwise dispose of or encumber or authorize: (A) any capital stock or other security of such party (and with respect to MEI, Merger Sub) (except for shares of such party’s Common Stock issued upon the valid exercise or conversion of outstanding options or warrants); (B) any option, warrant or right to acquire any capital stock or any other security; or (C) any instrument convertible into or exchangeable for any capital stock or other security of such party or any of its subsidiaries (and, with respect to MEI, Merger Sub);
- except as required to give effect to anything in contemplation of the Closing, amend any of such party’s or its subsidiaries’ organizational documents, or effect or be a party to any merger, consolidation, share exchange, business combination, recapitalization, reclassification of shares, stock split, reverse stock split or similar transaction except for the Contemplated Transactions;

## Table of Contents

- form any subsidiary or acquire any equity interest or other interest in any other entity or enter into a joint venture with any other entity (other than, with respect to MEI, Merger Sub);
- (A) lend money to any person (except for the advancement of expenses to employees, directors and consultants in the Ordinary Course of Business, (B) incur or guarantee any indebtedness for borrowed money, (C) guarantee any debt securities of others, or (D) other than the incurrence or payment of transaction expenses, make any capital expenditure in excess of 110% of the budgeted capital expenditure amounts set forth in such party's operating budget delivered to the other party concurrently with the execution of the Merger Agreement;
- other than as required by the terms of any employee benefit plan as in effect on the date of the Merger Agreement: (A) adopt, terminate, establish or enter into any employee benefit plan, other than in the Ordinary Course of Business; (B) cause or permit any employee benefit plan to be amended in any material respect other than in the Ordinary Course of Business (other than, with respect to Infinity, discretionary accelerated vesting of some or all of the Infinity RSUs to facilitate pre-closing tax withholding); (C) increase or modify the amount or form of the wages, salary, commissions, or bonus compensation payable to any of its directors, officers or employees (including, with respect to Infinity, the 2022 annual bonuses paid pursuant to the Infinity Contingent Cash Compensation program), other than increases in base salary and annual cash bonus opportunities and payments made in the Ordinary Course of Business or (D) hire any officer or employee (other than ordinary course replacement of departed employees or officers in the positions set forth on the Disclosure Schedules of MEI or Infinity, as applicable, during the Interim Period);
- recognize any labor union or labor organization, except as otherwise required by applicable laws;
- acquire any material asset or sell, lease or otherwise irrevocably dispose of any of its material assets or properties, or grant any lien with respect to such assets or properties, other than in the Ordinary Course of Business;
- sell, assign, transfer, license, sublicense or otherwise dispose of, with respect to Infinity, any material intellectual property (other than pursuant to non-exclusive licenses in the Ordinary Course of Business), and with respect to MEI, any material intellectual property rights that are owned or purported to be owned by such party or its subsidiaries, or exclusively licensed or purported to be exclusively licensed to such party or its subsidiaries;
- make, change or revoke any material tax election, fail to pay any income or other material tax as such tax becomes due and payable, file any amendment making any material change to any tax return, settle or compromise any income tax or other material tax liability or submit any voluntary disclosure application, enter into any tax allocation, sharing, indemnification or other similar agreement or arrangement (other than customary commercial contracts entered into in the Ordinary Course of Business the principal subject matter of which is not the allocation of taxes), request or consent to any extension or waiver of any limitation period with respect to any claim or assessment for any income tax or other material taxes (other than pursuant to an extension of time to file any tax return granted in the Ordinary Course of Business of not more than seven months), or adopt or change any material accounting method in respect of taxes;
- enter into, materially amend or terminate any material contract, or enter into any contract that would be considered a material contract if in effect on the date hereof;
- other than as required by law or GAAP, take any action to change accounting policies or procedures;
- initiate or settle any legal proceeding;
- enter into or amend a contract for the purpose of preventing or materially impeding, interfering with, hindering or delaying the consummation of the Contemplated Transactions; or
- agree, resolve or commit to do any of the foregoing.



## **Regulatory Approvals and Related Matters**

Each of MEI and Infinity agreed:

- that each party shall give the other party prompt notice of the commencement or known threat of commencement of any legal proceeding by or before any governmental entity with respect to the Merger or any of the Contemplated Transactions, keep the other party reasonably informed as to the status of any such legal proceeding or threat, and in connection with any such legal proceeding, permit authorized representatives of the other party to be present at each meeting or conference relating to any such legal proceeding and to have access to and be consulted in connection with any document, opinion or proposal made or submitted to any governmental entity in connection with any such legal proceeding;
- that each party shall use reasonable best efforts to take, or cause to be taken, all actions necessary to consummate the Merger and make effective the Contemplated Transactions. Without limiting the generality of the foregoing, each party: (i) shall make all filings (if any) and give all notices (if any) required to be made and given by such party in connection with the Merger and the Contemplated Transactions; (ii) shall use reasonable best efforts to obtain each consent (if any) required to be obtained (pursuant to any applicable law or contract, or otherwise) by such party in connection with the Merger or any of the Contemplated Transactions; and (iii) shall use reasonable best efforts to lift any restraint, injunction or other legal bar to the Merger;
- each party shall, upon request by the other, promptly furnish the other with all information concerning itself, its subsidiaries, directors, officers and shareholders and such other matters as may be reasonably necessary or advisable in connection with the Registration Statement, of which this joint proxy statement/prospectus is a part, this joint proxy statement/prospectus and any other statement, filing, notice or application made by or on behalf of MEI, Infinity or any of their respective subsidiaries to any third party and/or any governmental entity in connection with the Contemplated Transactions; and
- that each party shall promptly furnish the other with copies of notices or other communications received by MEI or Infinity, as the case may be, or any of their respective subsidiaries from any third party and/or any governmental entity with respect to the Contemplated Transactions, other than immaterial communications.

## **Indemnification; Directors' and Officers' Insurance**

The Merger Agreement provides that, from and after the Effective Time, each of MEI and the Surviving Company shall, jointly and severally, indemnify each current and former director or officer of Infinity or any of its subsidiaries against all expenses and liabilities incurred in connection with any legal proceeding arising out of or pertaining to such person's status as a director or officer of Infinity, or is or was serving, or has agreed to serve, at the request of Infinity, as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise (including any employee benefit plan), whether asserted or claimed prior to, at or after the Effective Time, to the fullest extent permitted by Delaware law and Infinity's organizational documents.

The Merger Agreement provides that, from and after the Effective Time, MEI shall maintain directors' and officers' liability insurance on commercially available terms and conditions with coverage limits customary for other similarly situated public companies, and that that Infinity will purchase, prior to the Effective Time, a six year "tail policy" for the existing policy of directors' and officers' liability insurance maintained by Infinity as of the date of the Merger Agreement, at an annualized premium not to exceed 300% of the annual premiums currently paid by Infinity for such insurance. The Merger Agreement further provides that all rights to indemnification by Infinity in favor of the directors and officers of Infinity as of the date of the Merger Agreement with respect to acts or omissions occurring prior to the Effective Time, as provided in Infinity's organizational documents and in any indemnification agreements between Infinity and such persons, shall survive the Merger and be observed by the Surviving Company for a period of six years following the Effective Time, in each case to the fullest extent permitted by Delaware law.

## Other Agreements

Each of MEI and Infinity has agreed to:

- during the Interim Period, promptly notify the other party in writing upon becoming aware of any event, condition, fact or circumstance that would reasonably be expected to make the timely satisfaction of any condition to closing of the Merger impossible or unlikely;
- during the Interim Period, promptly advise the other party in writing upon becoming aware of (i) any claim asserted or legal proceeding commenced, or, to the party's knowledge, either: (A) with respect to a governmental entity, overtly threatened; or (B) with respect to any other person, threatened in writing, in each case against, relating to, involving or otherwise affecting any of the Contemplated Transactions; (ii) any knowledge of any notice from any person alleging that the consent of such person is or may be required in connection with the Merger or any of the Contemplated Transactions; and (iii) any other material legal proceeding or material claim threatened, commenced or asserted against or with respect to any party or its respective subsidiaries;
- subject to certain conditions, afford the other party's representatives reasonable access (at the requesting party's cost) under the supervision of appropriate personnel of the other party, during normal business hours during the period prior to the Effective Time, to the other party's, and each of its subsidiaries' employees, properties, assets, books, records and contracts and, during such period, each of MEI and Infinity shall, and shall cause each of its subsidiaries to, furnish promptly to the other all information concerning its or any of its subsidiaries' capital stock, business and personnel as may reasonably be requested by the other;
- use its reasonable best efforts to, and cause its subsidiaries to, cause the Merger to qualify as a "reorganization" within the meaning of Section 368(a) of the Code, as amended, and, if requested by the SEC, use their respective reasonable best efforts to cause its respective counsel to deliver a tax opinion; and
- during the Interim Period following the initial joint press release with respect to the Merger and the Contemplated Transactions, consult with each other prior to making any press releases or other public announcements concerning the Merger and any filings with any governmental entity, subject to certain exceptions.

MEI has agreed to:

- during the Interim Period, use its reasonable best efforts to cause the shares of MEI Common Stock issues in the MEI Share Issuance to be approved for listed on The Nasdaq Capital Market; and
- For the twelve (12) months following the Closing Date, subject to certain requirements, maintain (and cause the Surviving Company to maintain) for each individual employed by Infinity or any of its subsidiaries at the Effective Time, to the extent they continue to be employed by MEI or the Surviving Company: (i) base salary or wage and cash incentive compensation opportunities at least as favorable, as to each element, as that provided to similarly situated employees of MEI and (ii) benefits, including severance benefits, that are at least as favorable, in the aggregate, to those benefits maintained for and/or provided to similarly situated employees of MEI.

Infinity has agreed to:

- during the Interim Period, take all actions necessary to permit its shares of capital stock and any other security issued by Infinity and listed on The Nasdaq Global Market to be de-listed and de-registered under the Exchange Act as soon as possible following the Effective Time; and
- comply with certain covenants related to the development of its product candidate, eganelisib (the "Clinical Milestones") by a certain deadline (the "Clinical Milestones Deadline").

## Termination

The Merger Agreement may be terminated at any time before the Effective Time, whether before or after the MEI Stockholder Approval and the Infinity Stockholder Approval have been obtained, as set forth below:

- by mutual written consent of MEI and Infinity; or
- by either MEI or Infinity, if (a) the Merger shall not have been consummated by 11:59 p.m. (eastern standard time) on August 31, 2023, (b) if a governmental authority shall have issued a final and non-appealable permanent restraining order, permanent injunction or other similar permanent order which has the effect of permanently restraining, enjoining or otherwise prohibiting consummation of the Contemplated Transactions, (c) the MEI Stockholder Approval was not obtained at the MEI Special Meeting duly convened therefor or at any adjournment or postponement thereof at which a vote upon the adoption of the Merger Agreement was taken, (d) the Infinity Stockholder Approval was not obtained at the Infinity Special Meeting duly convened therefor or at any adjournment or postponement thereof at which a vote upon the adoption of the Merger Agreement was taken, in each of (a), (b), (c) and (d) where the terminating party's material breach of the Merger Agreement is not the cause of, or has resulted in, the failure of such condition;
- by MEI, if:
  - prior to the Effective Time, Infinity breaches any of its representations, warranties, covenants or agreements contained in the Merger Agreement, or any such representation and warranty shall have become untrue after the date of the Merger Agreement, such that any of Infinity's conditions to closing the Merger would not be satisfied, and such breach or failure, to be true is not curable, or, if curable, is not cured in accordance with the terms of the Merger Agreement; provided, that MEI shall not have the right to terminate the Merger Agreement pursuant to this provision if MEI is then in material breach of any of its representations, warranties, covenants or agreements under the Merger Agreement;
  - prior to obtaining the Infinity Stockholder Approval, (i) the Infinity board of directors makes an Infinity Change in Recommendation, (ii) Infinity fails to include the Infinity Board Recommendation in this joint proxy statement/prospectus or (iii) Infinity materially breaches or fails to perform in any material respect its non-solicitation covenant; or
  - Either of the Clinical Milestones has not been completed by the Clinical Milestones Deadline.
- by Infinity, if:
  - prior to the Effective Time, MEI breaches or fails to perform any of its representations, warranties or covenants contained in the Merger Agreement, or any such representation and warranty shall have become untrue after the date of the Merger Agreement, such that any of MEI's conditions to closing the Merger would not be satisfied, and such breach or failure to be true is not curable, or, if curable, is not cured in accordance with the terms of the Merger Agreement; provided, that Infinity shall not have the right to terminate the Merger Agreement pursuant to this provision if Infinity is then in material breach of any of its representations, warranties, covenants or agreements under the Merger Agreement; or
  - prior to obtaining the MEI Stockholder Approval, (i) the MEI board of directors makes an MEI Change in Recommendation, (ii) MEI fails to include the MEI Board Recommendation in this joint proxy statement/prospectus or (iii) MEI materially breaches or fails to perform in any material respect its non-solicitation covenant.

## Termination Fee and Expense Reimbursement

The Merger Agreement provides that the payment of a termination fee in the amount of \$4,000,000, if payable by MEI, and in the amount of \$2,900,000, if payable by Infinity (in each case, the "Termination Fee"), will be payable by the terminating party to the non-terminating party under the following circumstances:

## Table of Contents

In the event that (i) (A) after the date of the Merger Agreement, an Acquisition Proposal shall have been made to MEI or Infinity, as applicable (the “Paying Party”), and such Acquisition Proposal becomes publicly known prior to the Paying Party’s Stockholders’ Meeting and, in either case, such Acquisition Proposal shall not have been withdrawn at the time of the Paying Party’s Stockholders Meeting, (B) the Merger Agreement is terminated (I) by either party due to such party’s Stockholder Approval not being obtained at such party’s Stockholder Meeting, or (II) by the other party (the “Non-Paying Party”) due to the Paying Party breaching any of its representations, warranties, covenants or agreements contained in the Merger Agreement, or any such representation and warranty having become untrue after the date of the Merger Agreement, such that any of the Paying Party’s conditions to closing the Merger would not be satisfied, and such breach or failure, if curable, is not cured in accordance with the terms of the Merger Agreement (provided, that Non-Paying shall not have the right to terminate the Merger Agreement pursuant to this provision if the Non-Paying is then in material breach of any of its representations, warranties, covenants or agreements contained in the Merger Agreement or agreements under the Merger Agreement), and (C) within 12 months after such termination, the Paying Party enters into an Alternative Acquisition Agreement with respect to an Acquisition Proposal or consummates an Acquisition Proposal (solely for purposes of this provision, the references to “15%” in the definition of Acquisition Proposal shall be deemed to be references to “50%”); or (ii) the Merger Agreement is terminated by the Non-Paying Party if, prior to obtaining its Stockholder Approval, (a) the Paying Party Board makes a Change in Recommendation, (b) the Paying Party fails to include its Board Recommendation in this joint proxy statement/prospectus or (c) the Paying Party materially breaches or fails to perform its non-solicitation covenant; then, in each case, the Paying Party shall, subject to certain conditions pay the Non-Paying Party the Termination Fee. In no event shall either party be required to pay the Termination Fee more than once.

The Merger Agreement provides that each party will reimburse the other party for all reasonable out of pocket fees and expenses incurred by such party in connection with the Merger Agreement and the Contemplated Transactions, up to a maximum of \$1,000,000, if the Merger Agreement is terminated by MEI or Infinity, as applicable, due to (i) the other party’s Stockholder Approval not being obtained at such party’s Stockholder Meeting; (ii) prior to obtaining its Stockholder Approval, (a) the other party’s board of directors making a Change in Recommendation, (b) such other party failing to include the its Board Recommendation in this joint proxy statement/prospectus or (c) such other party materially breaching or failing to perform in any material respect its non-solicitation covenant; or (iii) prior to the Effective Time, such other party breaching any of its representations, warranties, covenants or agreements contained in the Merger Agreement, or any such representation and warranty having become untrue after the date of the Merger Agreement, such that any of its conditions to closing the Merger would not be satisfied, and such breach or failure to be true is not curable or, if curable, is not cured in accordance with the terms of the Merger Agreement (provided, that the terminating party shall not have the right to terminate the Merger Agreement pursuant to this subsection (iii) if the terminating party is then in material breach of any of its representations, warranties, covenants or agreements under the Merger Agreement).

### **Specific Performance**

The parties to the Merger Agreement acknowledged and agreed that irreparable damage would occur and that the parties would not have any adequate remedy at law if any provision of the Merger agreement were not performed in accordance with its specific terms or were otherwise breached, and that monetary damages, even if available, would not be an adequate remedy therefor. The parties accordingly agreed that each party shall be entitled to an injunction or injunctions, specific performance and other equitable relief to prevent breaches of the Merger Agreement and to enforce specifically the performance of the terms and provisions hereof, without proof of actual damages (and each party waived any requirement for the security or posting of any bond in connection with such remedy), in addition to any other remedy to which they are entitled at law or in equity. The parties further agreed not to assert that a remedy of specific enforcement is unenforceable, invalid, contrary to applicable law or inequitable for any reason, and not to assert that a remedy of monetary damages would provide an adequate remedy for any such breach or that MEI or Infinity otherwise have an adequate remedy at law. The parties acknowledged that the agreements described in this paragraph are an integral part of the Contemplated Transactions, and that, without these agreements, the parties would not have entered into the Merger Agreement.

---

[Table of Contents](#)

**Expenses**

Except as described under the headings of the Merger Agreement titled “*Iris Termination Fee and Expenses Reimbursement*” and “*Meadow Termination Fee and Expenses Reimbursement*,” whether or not the Merger is consummated, all costs and expenses incurred in connection with the Merger Agreement and the Contemplated Transactions will be paid by the party incurring such expense.

**Amendment**

The Merger Agreement may be amended by an instrument in writing signed by the parties at any time, except that after the Merger Agreement has been adopted and approved by the stockholders of a party, no amendment which by law requires further approval by the stockholders of such party shall be made without such further approval.

**Governing Law**

The Merger Agreement is governed by the laws of the State of Delaware.

## MEI EXECUTIVE COMPENSATION

### Executive Compensation

The Compensation Committee of the MEI Board has responsibility for establishing, implementing and continually monitoring adherence with MEI's compensation philosophy. The Compensation Committee seeks to ensure that the total compensation paid to the executives is fair, reasonable and competitive. MEI's named executive officers for the fiscal year 2022 were Daniel P. Gold, Brian G. Drazba, David M. Urso and Richard G. Ghalie.

### Summary Compensation Table

The table below sets forth for the fiscal years ended June 30, 2022, 2021 and 2020, the compensation of MEI's named executive officers.

Name and Principal Position	Year	Salary (\$)	Stock Awards (\$) <sup>(1)</sup>	Option Awards (\$) <sup>(2)</sup>	Non-Equity Incentive Plan Compensation (\$) <sup>(3)(4)(5)(6)</sup>	Bonus (\$) <sup>(3)(4)(5)(6)</sup>	All Other Compensation (\$)	Total (\$) <sup>(7)</sup>
<i>Daniel P. Gold</i>	2022	716,625	—	1,536,800	275,184	—	—	2,528,609
<i>President, Chief Executive Officer and Director</i>	2021	682,500	279,200	1,638,800	348,075	—	—	2,948,575
	2020	650,000	—	1,120,037	292,500	195,000	—	2,257,537
<i>Brian G. Drazba</i> <i>Chief Financial Officer</i>	2022	414,140	—	359,500	106,020	—	—	879,660
	2021	406,020	—	554,300	138,047	—	—	1,098,367
	2020	402,000	—	378,836	120,600	80,400	—	981,836
<i>David M. Urso</i> <i>Chief Operating Officer and General Counsel</i>	2022	516,810	—	1,078,500	148,842	—	—	1,744,152
	2021	492,200	174,500	1,265,250	188,267	—	—	2,120,217
	2020	460,000	—	576,490	155,250	103,500	—	1,295,240
<i>Richard G. Ghalie</i> <i>Chief Medical Officer</i>	2022	463,000	—	575,200	118,528	—	—	1,156,728
	2021	432,481	69,800	522,750	118,065	—	—	1,143,096

- (1) Represents the aggregate grant date fair value of restricted stock unit awards (RSUs) granted in accordance with Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, Topic 718, "Stock Compensation", calculated based on the closing market price of MEI common stock on the date of grant. The RSUs, which were granted in July 2020, are reported as fiscal year 2021 compensation because the grant date occurred after the end of fiscal year 2020. These RSUs were viewed as separate from the regular option program in fiscal year 2021 because they were a reward for fiscal year 2020.
- (2) Represents the aggregate grant date fair value of options granted in accordance with ASC Topic 718. For the relevant assumptions used in determining these amounts, refer to Note 9 to MEI's audited financial statements contained in its Annual Report on Form 10-K.
- (3) Dr. Gold received a bonus of 38% of his base salary for the fiscal year ended June 30, 2022, based upon the Compensation Committee's determination to award bonuses at 64% of target levels. Dr. Gold received a bonus of 51% of his base salary for the fiscal year ended June 30, 2021, based upon the Compensation Committee's determination to award bonuses at 85% of target levels. Dr. Gold received a bonus of 75% of his base salary for the fiscal year ended June 30, 2020 based upon the Compensation Committee's determination to award bonuses at 125% of target levels.
- (4) Mr. Drazba received a bonus of 26% of his base salary for the fiscal year ended June 30, 2022 based upon the Compensation Committee's determination to award bonuses at 64% of target levels. Mr. Drazba received a bonus of 34% of his base salary for the fiscal year ended June 30, 2021 based upon the Compensation Committee's determination to award bonuses at 85% of target levels. Mr. Drazba received a

## Table of Contents

bonus of 50% of his base salary for the fiscal year ended June 30, 2020 based upon the Compensation Committee's determination to award bonuses at 125% of target levels.

- (5) Mr. Urso received a bonus of 29% of his base salary for the fiscal year ended June 30, 2022, based upon the Compensation Committee's determination to award bonuses at 64% of target levels. Mr. Urso received a bonus of 38% of his base salary for the fiscal year ended June 30, 2021, based upon the Compensation Committee's determination to award bonuses at 85% of target levels. Mr. Urso received a bonus of 56.3% of his base salary for the fiscal year ended June 30, 2020 based upon the Compensation Committee's determination to award bonuses at 125% of target levels.
- (6) Dr. Ghalie received a bonus of 26% for the fiscal year ended June 30, 2022, based on the compensation committee's determination to award bonuses at 64% of target levels. Dr. Ghalie received a bonus of 26% for the fiscal year ended June 30, 2021, based on the compensation committee's determination to award bonuses at 85% of target levels.
- (7) In accordance with SEC rules, the compensation described in this table does not include various health and welfare or other benefits received by MEI's named executive officers that were generally available to all of its regular, full-time employees, as well as certain perquisites and other benefits received by its named executive officers that, in the aggregate, were less than \$10,000 for any officer.

### **Employment Agreements**

MEI has entered into written employment agreements with each of the named executive officers, which set forth the terms of their respective employments.

#### *Employment Agreement between Daniel P. Gold and MEI Pharma*

In connection with Dr. Gold's appointment as President and Chief Executive Officer, MEI entered into an Employment Letter Agreement, dated April 23, 2010 with Dr. Gold (the "Gold Employment Letter"). The Gold Employment Letter provided for an annual base salary of \$400,000, subject to upward adjustment at the discretion of the Compensation Committee of the Board of Directors. Pursuant to the terms of the Gold Employment Letter, Dr. Gold was eligible to earn an annual cash bonus in an amount up to a maximum of 40% of the base salary, based on his achievement of milestones established by the Compensation Committee of the Board of Directors. Beginning in fiscal year 2015, the Compensation Committee established the target amount of Dr. Gold's annual cash bonus as 50% of his base salary. Beginning in fiscal year 2020, the Compensation Committee established the target amount of Dr. Gold's annual cash bonus as 60% of his base salary.

Dr. Gold may terminate his employment at any time and for any reason, upon providing three (3) months advance notice to MEI. Dr. Gold may terminate his employment with Good Reason (as defined in the Gold Employment Letter) by providing MEI with notice within sixty (60) days of the event giving rise to the Good Reason (and MEI does not cure the Good Reason event within thirty (30) days after receiving notice). MEI has the right to terminate the Gold Employment Letter with or without Cause (as defined in the Gold Employment Letter) at any time. If Dr. Gold's employment is terminated by MEI without Cause or by Dr. Gold for Good Reason, Dr. Gold will be entitled to (i) a lump sum payment in an amount equal to twelve (12) months of his base salary and (ii) accelerated vesting of his options such that Dr. Gold will be vested in the same number of options as if he had continued to be employed by MEI for an additional twelve (12) months, subject to his execution and nonrevocation of a release of claims. The Gold Employment Letter contains confidentiality provisions.

#### *Employment Agreement between Brian G. Drazba and MEI Pharma*

In connection with Mr. Drazba's appointment as Chief Financial Officer, MEI entered into an Employment Letter, dated February 1, 2017, with Mr. Drazba (the "Drazba Employment Letter"). The Drazba Employment Letter provided for an annual base salary of \$350,000, which has been increased periodically by the Compensation Committee. Pursuant to the terms of the Drazba Employment Letter, Mr. Drazba is eligible to earn an annual cash bonus, beginning for the fiscal year starting on July 1, 2017, in an amount up to a maximum of



## Table of Contents

40% of the base salary, based on his achievement of milestones established by the Compensation Committee of the Board of Directors.

Mr. Drazba may terminate his employment at any time other than for Good Reason (as defined in the Drazba Employment Letter), upon providing two (2) months advance notice to MEI. Mr. Drazba may terminate his employment with Good Reason by providing MEI with notice within sixty (60) days of the event giving rise to the Good Reason (and MEI does not cure the Good Reason event within thirty (30) days after receiving notice). MEI has the right to terminate the Drazba Employment Letter with or without Cause (as defined in the Drazba Employment Letter) at any time. If Mr. Drazba's employment is terminated by MEI without Cause or by Mr. Drazba for Good Reason, Mr. Drazba will be entitled to (i) a lump sum payment in an amount equal to twelve (12) months of his base salary and (ii) accelerated vesting of his options such that Mr. Drazba will be vested in the same number of options as if he had continued to be employed by MEI for an additional twelve (12) months, subject to his execution and nonrevocation of a release of claims. The Drazba Employment Letter contains confidentiality provisions.

On August 2, 2021, Mr. Drazba and MEI signed a Transition and Retirement Agreement, where Mr. Drazba's employment with MEI would have terminated on December 31, 2021. On December 21, 2021, the Transition and Retirement Agreement was extended to June 30, 2022. On June 30, 2022, the Transition and Retirement Agreement was terminated by Mr. Drazba and MEI. Mr. Drazba continues to be the Chief Financial Officer of MEI. In consideration of the Transition and Retirement Agreement, Mr. Drazba was entitled to receive a payment of \$414,140 and 216,666 shares subject to his outstanding options would have vested.

### *Employment Agreement between David M. Urso and MEI Pharma*

In connection with Mr. Urso's appointment as Senior Vice President, Corporate Development and General Counsel, MEI entered into an Employment Letter dated March 6, 2014, with Mr. Urso, which was amended in connection with his promotion to Chief Operating Officer, effective July 12, 2018 (the "Urso Employment Letter"). The Urso Employment Letter provided for an annual base salary of \$426,000, which has been increased periodically by the Compensation Committee. Beginning in fiscal year 2015, the Compensation Committee set the target amount of Mr. Urso's annual cash bonus as 35% of his base salary based on his achievement of milestones established by the Compensation Committee of the Board of Directors. Beginning in fiscal year 2017, the Compensation Committee established the target amount of Mr. Urso's annual cash bonus as 40% of his base salary. Beginning in fiscal year 2020, the Compensation Committee established the target amount of Mr. Urso's annual cash bonus as 45% of his base salary.

Mr. Urso may terminate his employment at any time other than for Good Reason (as defined in the Urso Employment Letter), upon providing one month advance notice to MEI. Mr. Urso may terminate his employment with Good Reason by providing MEI with notice within sixty (60) days of the event giving rise to the Good Reason (and MEI does not cure the Good Reason event within thirty (30) days after receiving notice). MEI has the right to terminate the Urso Employment Letter with or without Cause (as defined in the Urso Employment Letter) at any time. If Mr. Urso's employment is terminated by MEI without Cause or by Mr. Urso for Good Reason, Mr. Urso will be entitled to (i) a lump sum payment in an amount equal to twelve (12) months of his base salary and (ii) accelerated vesting of his options such that Mr. Urso will be vested in the same number of options as if he had continued to be employed by MEI for an additional twelve (12) months, subject to his execution and nonrevocation of a release of claims. The Urso Employment Letter contains confidentiality provisions.

### *Employment Agreement between Richard G. Ghalie and MEI Pharma*

In connection with Dr. Ghalie's appointment as Chief Medical Officer, effective May 3, 2021, MEI entered into an amendment to his Employment Letter, dated February 17, 2016 (as amended, the "Ghalie Employment Letter"). The Ghalie Employment Letter provides for an annual base salary of \$463,000, and a stock option award to purchase 75,000 shares of MEI common stock. Effective July 1, 2021, pursuant to the terms of the

## [Table of Contents](#)

Ghalie Employment Letter, Dr. Ghalie is eligible to earn an annual cash bonus in an amount up to a maximum of 40% of the base salary based on his achievement of milestones established by the Compensation Committee of the Board of Directors.

Dr. Ghalie may terminate his employment at any time other than for Good Reason (as defined in the Ghalie Employment Letter), upon providing one (1) month advance notice to MEI. Dr. Ghalie may terminate his employment with Good Reason by providing MEI with notice within sixty (60) days of the event giving rise to the Good Reason (and MEI does not cure the Good Reason event within thirty (30) days after receiving notice). MEI has the right to terminate the Ghalie Employment Letter with or without Cause (as defined in the Ghalie Employment Letter) at any time. If Dr. Ghalie's employment is terminated by MEI without Cause or by Dr. Ghalie for Good Reason, Dr. Ghalie will be entitled to (i) a lump sum payment in an amount equal to twelve (12) months of his base salary and (ii) accelerated vesting of his options such that Dr. Ghalie will be vested in the same number of options as if he had continued to be employed by MEI for an additional twelve (12) months, subject to his execution and nonrevocation of a release of claims. The Ghalie Employment Letter contains confidentiality provisions.

### Grants of Plan-Based Awards For Fiscal Year Ended June 30, 2022

Name	Grant Date	Estimated Possible Payouts Under Non-Equity Incentive Plan Awards (1)		All Other Stock Awards Number of Shares of Stocks or Units	All Other Option Awards Number of Securities Underlying Options	Exercise or Base Price of Option Awards	Grant Date Fair Value of Stock and Option Awards
		Target	Maximum				
Daniel P. Gold	July 1, 2021	\$ 275,184	N/A	—	42,750	\$ 59.00	\$ 1,536,800
Brian G. Drazba	July 1, 2021	\$ 106,020	N/A	—	10,000	\$ 59.00	\$ 359,500
David M. Urso	July 1, 2021	\$ 148,842	N/A	—	30,000	\$ 59.00	\$ 1,078,500
Richard G. Ghalie	July 1, 2021	\$ 118,528	N/A	—	16,000	\$ 59.00	\$ 575,200

- (1) The Board established single bonus targets and, as disclosed in the Summary Compensation Table, determined to pay out bonuses at 64% of the target levels.

### Outstanding Equity Awards at Fiscal Year-End

The following table provides information on all stock options and RSUs held by MEI's named executive officers on June 30, 2022:

Name	Option Awards				Stock Awards		
	Number of Securities Underlying Unexercised Options (Exercisable) (#)	Number of Securities Underlying Unexercised Options (Unexercisable) (#)	Option Exercise Price (\$/share)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested (\$)	
Daniel P. Gold	—	42,750	(1)	\$ 59.00	7/1/2031	—	—
	16,292	17,708	(2)	\$ 69.80	7/2/2030	—	—
	24,542	9,208	(3)	\$ 50.40	7/1/2029	—	—
	14,688	313	(4)	\$ 85.60	7/12/2028	—	—
	19,000	—	(5)	\$ 86.60	6/22/2028	—	—
	19,000	—	(6)	\$ 56.60	7/6/2027	—	—
	19,000	—	(7)	\$ 27.20	7/28/2026	—	—
	13,775	—	(9)	\$ 31.40	7/28/2025	—	—

[Table of Contents](#)

Name	Option Awards				Stock Awards		
	Number of Securities Underlying Unexercised Options (Exercisable) (#)	Number of Securities Underlying Unexercised Options (Unexercisable) (#)	Option Exercise Price (\$/share)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested (\$)	
Brian G. Drazba	—	10,000	(1)	\$ 59.00	7/1/2031	—	—
	5,510	5,990	(2)	\$ 69.80	7/2/2030	—	—
	8,360	3,115	(3)	\$ 50.40	7/1/2029	—	—
	4,896	104	(4)	\$ 85.60	7/12/2028	—	—
	6,500	—	(5)	\$ 86.60	6/22/2028	—	—
	2,500	—	(6)	\$ 56.60	7/6/2027	—	—
	7,500	—	(8)	\$ 31.40	4/3/2027	—	—
David M. Urso	—	30,000	(1)	\$ 59.00	7/1/2031	—	—
	12,578	13,672	(2)	\$ 69.80	7/2/2030	—	—
	12,760	4,740	(3)	\$ 50.40	7/1/2029	—	—
	10,771	229	(4)	\$ 85.60	7/12/2028	—	—
	6,500	—	(5)	\$ 86.60	6/22/2028	—	—
	6,500	—	(6)	\$ 56.60	7/6/2027	—	—
	6,500	—	(7)	\$ 27.20	7/29/2026	—	—
Richard G. Ghalie	6,375	—	(9)	\$ 31.40	7/28/2025	—	—
	—	16,000	(1)	\$ 59.00	7/1/2031	—	—
	1,016	2,734	(12)	\$ 71.00	5/3/2031	—	—
	3,594	3,906	(2)	\$ 69.80	7/2/2030	—	—
	5,469	2,031	(3)	\$ 50.40	7/1/2029	—	—
	6,365	135	(4)	\$ 85.60	7/12/2028	—	—
	3,250	—	(13)	\$ 57.60	7/7/2027	—	—
	1,250	—	(11)	\$ 27.60	7/14/2026	—	—
6,500	—	(10)	\$ 24.20	3/7/2026	—	—	
—	—	—	—	—	1,000 (14)	\$ 12,100	

- (1) Twenty-five percent of the options vest on July 5, 2022; the remaining seventy-five percent of the option will vest in equal monthly installments over the following 36 months.
- (2) Twenty-five percent of the options vested on July 2, 2021; the remaining seventy-five percent of the options will vest in equal monthly installments over the following 36 months.
- (3) Twenty-five percent of the options vested on July 1, 2020; the remaining seventy-five percent of the options will vest in equal monthly installments over the following 36 months.
- (4) Twenty-five percent of the options vested on July 12, 2019; the remaining seventy-five percent of the options will vest in equal monthly installments over the following 36 months.
- (5) Twenty-five percent of the options vested on June 22, 2019; the remaining seventy-five percent of the options will vest in equal monthly installments over the following 36 months.
- (6) Twenty-five percent of the options vested on July 6, 2018; the remaining seventy-five percent of the options will vest in equal monthly installments over the following 36 months.
- (7) The options vested in equal installments over 36 months from the grant date of July 29, 2016.
- (8) The options vested in equal monthly installments over 36 months from the date of grant of April 3, 2017.
- (9) The options vested in equal installments over 36 months from the grant date of July 28, 2015.
- (10) The options vested in equal installments over 36 months from the grant date of March 7, 2016.
- (11) The options vested in equal installments over 36 months from the grant date of July 14, 2016.
- (12) Twenty-five percent of the options vested on May 3, 2022; the remaining seventy-five percent of the option vest in equal monthly installments over the following 36 months.

## [Table of Contents](#)

- (13) Twenty-five percent of the options vested on July 7, 2018; the remaining seventy-five percent of the option vested in equal monthly installments over the following 36 months.
- (14) The RSUs were granted on July 2, 2020 and vest two years from the date of grant.

### **Option Exercises and Stock Vested**

Dr. Gold, Mr. Drazba, Dr. Mass, Mr. Urso and Dr. Ghalie did not exercise any stock options during the fiscal year ended June 30, 2022. 4,000 RSUs and 2,500 RSUs vested for Dr. Gold and Mr. Urso, respectively, during the fiscal year ended June 30, 2022.

### **Indemnification Agreements**

MEI has entered into an indemnification agreement with each of MEI's directors and executive officers. Subject to certain exceptions, the indemnification agreements provide that an indemnitee will be indemnified for all expenses incurred or paid by the indemnitee in connection with a proceeding to which the indemnitee was or is a party, or is threatened to be made a party, by reason of the indemnitee's status with or service to MEI or to another entity at MEI's request. In connection with proceedings other than those by or in the right of MEI's company and to which the indemnitee was or is a party, or is threatened to be made a party, by reason of the indemnitee's status with or service to MEI or to another entity at MEI's request, the indemnification agreements provide that an indemnitee will also be indemnified for all liabilities incurred or paid by the indemnitee. The indemnification agreements also provide for advancement of expenses incurred by an indemnitee in connection with an indemnifiable claim, subject to reimbursement in certain circumstances.

The rights of each indemnitee are in addition to any other rights provided for under the MEI COI, and the MEI Bylaws, as may be amended from time to time, and under Delaware law.

**INFINITY EXECUTIVE COMPENSATION**

The following discussion provides details of the compensation and other benefits paid by Infinity to Adelene Q. Perkins, Infinity’s Chief Executive Officer, and Robert Ilaria, Jr., M.D., Infinity’s Chief Medical Officer, each of whom was a named executive officer of Infinity for 2022 and who is expected to serve as a director or an executive officer of the combined company following the consummation of the Merger.

**Summary Compensation Table for Named Executive Officers**

<b>Name and Principal Position</b>	<b>Year</b>	<b>Salary (\$)</b>	<b>Bonus (\$)</b>	<b>Stock Awards (\$)<sup>(1)</sup></b>	<b>Option Awards (\$)<sup>(2)</sup></b>	<b>Non-Equity Incentive Plan Compensation (\$)<sup>(3)</sup></b>	<b>All Other Compensation (\$)<sup>(4)</sup></b>	<b>Total (\$)</b>
Adelene Q. Perkins, Chief Executive Officer <sup>(5)</sup>	2022	689,585	—	—	721,047	—	11,922	1,422,554
	2021	689,585	—	—	—	448,230	11,472	1,149,287
Robert Ilaria, Jr., M.D. Chief Medical Officer	2022	456,875	185,000	—	109,480	—	11,922	763,277
	2021	143,846	150,000	—	878,520	55,577	9,590	1,237,533

- In 2022, Infinity issued a one-time grant of Infinity RSUs, where each Infinity RSU represents a contingent right to receive one share of Infinity Common Stock. As of each grant date, it was deemed to be not probable that the pre-specified performance-based vesting conditions related to each award would be achieved and, therefore, no value is included for these Infinity RSUs in the Stock Awards or Total columns. See the information in Note 3, “Stock-Based Compensation,” to Infinity’s consolidated financial statements and related notes included elsewhere in this joint proxy statement/prospectus, for assumptions made in determining these values. Assuming all performance conditions are achieved, the aggregate grant date value of the restricted stock units based on the closing price of the Infinity Common Stock on grant date as reported by Nasdaq for Ms. Perkins and Dr. Ilaria are \$829,584 and \$385,287, respectively, as computed in accordance with FASB ASC Topic 718. Each Infinity RSU will vest in full upon the achievement of certain performance metrics prior to June 30, 2024, or earlier upon Infinity’s termination without cause of the employment of the award recipient.
- The amounts in this column reflect the aggregate grant date fair value of option awards as computed in accordance with FASB ASC Topic 718 and granted during the applicable fiscal year. See the information in Note 3, “Stock-Based Compensation,” to Infinity’s consolidated financial statements and related notes included elsewhere in this joint proxy statement/prospectus, for assumptions made in determining these values.
- For 2022, the amounts in this column reflect amounts paid to Ms. Perkins under the contingent cash compensation program described under the subsection entitled “Narrative Disclosure to Executive Summary Compensation Table and Outstanding Equity at Fiscal Year-End Table” below. For 2021, the amounts in this column reflect amounts paid to the named executive officers under the contingent cash compensation program described in “Compensation Discussion and Analysis” in the annual proxy statement filed by Infinity with the SEC on April 25, 2022.
- Amounts in this column represent the sum of (i) any life insurance premiums paid on behalf of the officer and (ii) the amount contributed to the officer’s 401(k) account as a matching contribution.
- Ms. Perkins received the amounts listed above for service as Infinity’s Chief Executive Officer for 2022 and 2021 and received no compensation for service as a director for all years reported.

**Outstanding Equity Awards at Fiscal Year-End Table**

Name	Option Awards				Stock Awards	
	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$)	Option Expiration Date	Equity incentive plan awards: Number of unearned shares, units or other rights that have not vested (#)(5)	Equity incentive plan awards: Market or payout value of unearned shares, units or other rights that have not vested \$(6)
	<b>Stock Options</b>				<b>Restricted Stock</b>	
Adelene Q. Perkins	153,835	—	36.85	1/4/2023	768,133	426,314
	85,500	—	12.91	1/10/2024	—	—
	250,000	—	15.74	1/14/2025	—	—
	185,000	—	6.71	1/6/2026	—	—
	1,000,000	—	1.46	1/6/2027	—	—
	180,000	—	2.23	1/2/2028	—	—
	500,000	—	1.99	1/8/2028	—	—
	243,000	—	1.24	1/4/2029	—	—
	242,000	—	1.24	1/4/2029	—	—
	454,688	151,562(1)	1.25	1/10/2030	—	—
	252,604	232,396(2)	2.14	12/22/2030	—	—
	144,025	432,075(3)	1.53	1/11/2032	—	—
Robert Ilaria, Jr., M.D.	93,750	206,250(4)	3.59	9/1/2031	356,747	197,995
	21,868	65,604(3)	1.53	1/11/2032	—	—

1. Vests in equal monthly installments on the last day of each month through January 31, 2024.
2. Vests in equal monthly installments on the last day of each month through December 31, 2024.
3. Vests in equal monthly installments on the last day of each month through January 31, 2026.
4. Vested as to one quarter of the shares on September 1, 2022 and thereafter vests as to the remaining shares in equal monthly installments through September 1, 2025.
5. Totals in this column represent the unvested portion of a performance-based restricted stock award granted on August 11, 2022, which vests upon the achievement of certain performance metrics, as determined by Infinity’s Compensation Committee, prior to June 30, 2024, or earlier upon Infinity’s termination without cause of the employment of the award recipient.
6. Market value is based on the closing price of \$0.555 per share of Infinity Common Stock on December 30, 2022 (the last day of trading in 2022) as reported on the Nasdaq Global Select Market.

**Narrative Disclosures to Executive Summary Compensation Table and Outstanding Equity At Fiscal Year-End Table**

Infinity reviews compensation for its executive officers annually. The material terms of the elements of Infinity’s executive compensation program for 2022 are described below.

The objectives of Infinity’s compensation program are to attract, retain and motivate high caliber clinical, scientific and business professionals to develop and execute Infinity’s business plan and achieve Infinity’s mission; ensure that compensation aligns Infinity’s citizen-owners with Infinity’s corporate strategy and business objectives; promote the achievement of important and measurable scientific, business, organizational and operational goals by linking annual cash bonus and long-term equity incentives to the achievement of these goals; and, to align incentives with the creation of stockholder value.

## Table of Contents

The key elements of Infinity's compensation program discussed in further detail below include an annual base salary, annual performance-based cash bonus awards, and equity awards, typically in the form of stock options or restricted stock units. Additionally, Infinity offers an employee stock purchase plan, a severance benefits plan and employee benefits, such as health and life insurance, and a 401(k) retirement savings plan with partial matching of employee contributions in the form of cash.

Infinity's Compensation Committee is responsible for reviewing and approving the compensation of Infinity's executive officers. In determining the compensation of Infinity's executive officers, the Compensation Committee considers Infinity's performance against annual goals approved by the board of directors, the individual performance of executive officers, the alignment of executive compensation with the compensation objectives described above, compensation for comparable positions at other companies in Infinity's industry that compete with Infinity for talent. Additionally, the allocation of compensation between long-term and short-term compensation, between cash and non-cash compensation, or among the different forms of non-cash compensation is determined by the Compensation Committee after reviewing relevant information of other companies with whom Infinity competes for talent and other relevant data, including industry compensation survey data, as well as what it believes to be the appropriately competitive level and mix of the various compensation components.

Near the end of each year, Infinity's executive leadership team conducts a qualitative and quantitative assessment of Infinity's overall company performance against goals and recommends a company performance rating to the Compensation Committee for consideration within a range between 0.7x of target bonus opportunity where the overall company performance rating was "Met Some Goals" and 1.5x of target bonus opportunity where the overall company performance rating was "Exceeded All Goals". There is no guaranteed minimum bonus for named executive officers where the weighted-average assessment of overall company performance is determined to be less than a rating of "Met Some Goals." The Compensation Committee makes the final determination as to what level of performance was achieved as measured against the company goals. The Compensation Committee may review, and historically has reviewed, its assessment with Infinity's board of directors, although the Compensation Committee is not required to do so.

As part of Infinity's annual individual performance evaluation process for Ms. Perkins, the Chair of the Compensation Committee solicits and organizes feedback from Infinity's board of directors and Infinity's human resources function solicits and organizes feedback from company management. The Chair of the Compensation Committee meets with her to summarize her annual performance assessment and to provide development feedback. Additionally, Ms. Perkins prepares written performance reviews of her direct reports, including Dr. Ilaria, and discusses these reviews with the Compensation Committee.

### ***Base Salary***

Each of Infinity's named executive officers receives a base salary that is intended to provide a fair and competitive base level of compensation for day-to-day performance. Base salaries are originally established at the time such executive is hired in consideration of the intended responsibilities of the executive officer, their individual experience and skills, internal equity, external peer company data, and negotiations during the recruiting process. The base salaries of Infinity's executive officers are reviewed annually and may be adjusted to reflect market conditions and their performance during the prior year as well as Infinity's financial position, or if there is a change in the scope of the officer's responsibilities or a promotion to a more senior level. Infinity does not provide for any formulaic or guaranteed increases for any of its executive officers.

For the fiscal year ended December 31, 2022, the annual base salary for Ms. Perkins was \$698,585 and the annual base salary for Dr. Ilaria was \$456,875.

### ***Annual Contingent Cash Bonus***

Under Infinity's contingent cash compensation program, the Compensation Committee establishes a pool of cash available for potential award, as a percentage of aggregate base salary for all citizen-owners at specified levels of



## [Table of Contents](#)

seniority, based on the Compensation Committee's assessment of overall company performance. Infinity's Compensation Committee establishes annual contingent cash bonus targets for each of Infinity's named executive officers. For the fiscal year ended December 31, 2022, annual target contingent cash bonus opportunities as a percent of base salary for Ms. Perkins and Dr. Ilaria were 65% and 40%, respectively.

Decisions by the Compensation Committee regarding individual annual cash bonuses are driven by an assessment of company and individual performance against predetermined goals related to the development of egnelisib and corporate development. Ms. Perkins' annual cash bonus is entirely based on company performance relative to goals. In the case of Dr. Ilaria, contingent cash bonus is a factor of both company and individual performance. Dr. Ilaria's performance assessment is based 80% on company performance and 20% on individual performance.

Following a review of 2022 company performance, Infinity's Compensation Committee determined that the overall company performance rating was less than "Met Some Goals" and determined not to make annual cash bonus payments to any of Infinity's named executive officers. Payments under the contingent cash compensation program for 2021 are shown in the Summary Compensation Table under the caption "Non-Equity Incentive Plan Compensation."

### ***Equity Incentive Awards***

Infinity's equity award program is the primary vehicle for offering long-term incentives to its named executive officers. Infinity believes that equity grants are fundamental to providing its named executive officers with a strong link to Infinity's long-term performance and aligning the interests of Infinity's named executive officers with that of its non-employee stockholders by allowing named executive officers to participate in Infinity's long-term success as reflected in stock price appreciation. In addition, the vesting feature of Infinity's equity grants is intended to further Infinity's goal of retention because it provides an incentive for named executive officers to remain in Infinity's employ during the vesting period. All equity-based awards made to Infinity's named executive officers are approved by the Compensation Committee.

Infinity's equity awards have generally taken the form of stock options or, less frequently, performance-based or time-based restricted stock units. Stock options are typically granted to new executive officers upon their hire and typically vest as to one-quarter of the shares on the first anniversary of the date of hire, and in equal monthly installments over the following three years. All stock options granted under Infinity's equity incentive plans have a maximum term of ten years and substantially all awards have vesting rights that terminate upon termination of service to Infinity and exercise rights that cease shortly after termination of service to Infinity. Prior to the exercise of an option, the holder has no rights as a stockholder with respect to the shares underlying such option, including no voting rights and no right to receive dividends or dividend equivalents. The exercise price per share for each stock option granted by Infinity is equal to the closing price of a share of Infinity Common Stock on the date of grant. In the event of a change of control of the company, under the terms of the equity awards made under Infinity's 2010 Stock Incentive Plan and Infinity's 2019 Equity Incentive Plan (the "Infinity 2019 Plan"), vesting fully accelerates in the case of restricted stock units.

Infinity does not seek to coordinate the timing of equity grants to its named executive officers with its release of material non-public information, and Infinity's named executive officers are prohibited from pledging or engaging in short sales or derivative transactions of Infinity's securities. Infinity has not adopted stock ownership guidelines for its named executive officers; however, Infinity encourages its named executive officers to maintain an equity position in the company.

Infinity's named executive officers are eligible to receive stock option grants in connection with the annual performance review process. For stock option grants made in January 2022, the Compensation Committee determined target award sizes and vesting schedules that were informed by an assessment of executive compensation by the Compensation Committee's consultant Radford, an Aon Hewitt company, which Infinity

## [Table of Contents](#)

refers to as Radford. The Compensation Committee additionally considered 2021 overall company performance assessment and 2021 individual performance assessment for each named executive officer to determine actual sizes of grants made in January 2022.

On January 11, 2022, Infinity granted Ms. Perkins and Dr. Ilaria options to purchase 576,100 and 87,472 shares, respectively, under the Infinity 2019 Plan. Each of these options is exercisable at a price per share of \$1.53 and vests as to 1/48th of the shares on January 31, 2022 and as to 1/48th of the shares at the end of each calendar month thereafter, in each case subject to continued services provided by the award recipient through the vesting date.

On August 11, 2022, Infinity granted Ms. Perkins and Dr. Ilaria restricted stock units of 768,133 and 356,747, respectively, under the Infinity 2019 Plan. Each of these restricted stock unit awards vests in full upon the achievement of certain performance metrics prior to June 30, 2024, or earlier upon Infinity's termination without cause of the employment of the award recipient. If the Merger is successfully consummated, the performance condition will be satisfied and Ms. Perkins' and Dr. Ilaria's RSUs will vest in full.

### ***Executive Retention Agreements***

On February 22, 2023, Infinity entered into a Retention and Severance Protection Agreement with each of Ms. Perkins, Dr. Peluso, Dr. Ilaria and Mr. Tasker (each, an "Infinity Retention Agreement" and together, the "Infinity Retention Agreements"). The Infinity Retention Agreements are described in greater detail in the section titled "*Interests of Infinity Directors and Executive Officers in the Merger - Infinity Change in Control Severance Payments in Connection with the Merger - Infinity Retention and Severance Protection Agreements*" beginning on page 170 of this joint proxy statement/prospectus.

### ***Severance Benefits***

Infinity's executive officers are eligible to receive severance benefits under Infinity's Executive Severance Benefits Plan, as amended. Infinity's Executive Severance Benefits Plan is described in greater detail in the section titled "*Interests of Infinity Directors and Executive Officers in the Merger - Infinity Change in Control Severance Payments in Connection with the Merger - Infinity Executive Severance Benefits Plan*" beginning on page 169 of this joint proxy statement/prospectus.

### ***Employee Stock Purchase Plan***

The Infinity ESPP permits citizen-owners, including Infinity's named executive officers, to purchase shares of Infinity Common Stock at a discount and consists of consecutive, overlapping 24-month offering periods, each consisting of four six-month purchase periods. On the first day of each offering period, each citizen-owner who is enrolled in the Infinity ESPP will automatically receive an option to purchase shares of Infinity Common Stock in accordance with the terms of the Infinity ESPP. The purchase price of each of the shares purchased in a given purchase period will be 85% of the closing price of a share of Infinity Common Stock on the first day of the offering period or the last day of the purchase period, whichever is lower.

### ***Benefits and Other Compensation***

Infinity provides a broad-based benefits program for all of Infinity's citizen-owners, including health, dental and vision insurance, life and disability insurance, group insurance discounts, first-time homebuyer's assistance, educational assistance, paid vacation time, paid sabbatical leave following each five-year period of service, subsidized parking, and a 401(k) savings plan. Infinity's named executive officers are eligible to participate in all of Infinity's benefit plans, in each case on the same basis as other citizen-owners. Under the company-matching feature under Infinity's 401(k) savings plan, Infinity matches in cash 100% of each citizen-owner's contributions, up to a maximum of 6% of such citizen-owner's base salary and subject to applicable IRS limitations.

---

## [Table of Contents](#)

In particular circumstances, Infinity sometimes awards cash signing bonuses when executive officers first join Infinity. Such cash signing bonuses typically are subject to repayment in full or on a pro-rated basis if the executive officer voluntarily terminates employment with Infinity during a prescribed period of time following their date of hire. Whether a signing bonus is paid and the amount of the bonus is determined on a case-by-case basis under the hiring circumstances specific to each candidate. For instance, Infinity may consider paying signing bonuses to compensate for amounts forfeited by an executive candidate upon terminating prior employment or to create additional incentive for an executive to join Infinity in a position where there is high market demand.

Given Infinity's objective of attracting the highest caliber talent, Infinity may recruit talented individuals from outside of the Boston area to fill open positions. Infinity generally provides reasonable relocation assistance to those individuals.

**MEI DIRECTOR COMPENSATION**

For the fiscal year ended June 30, 2022, each of MEI's non-executive directors received an annual cash retainer of \$45,600. In addition to the annual cash retainer, the Chair of the MEI board of directors received additional annual compensation of \$35,000, and each MEI Board Committee chair received additional compensation as follows: Audit Committee: \$20,000; Compensation Committee: \$15,000; and Nominating and Governance Committee: \$10,000. Committee members not receiving compensation as a committee chairperson received additional compensation as follows: Audit Committee: \$10,000; Compensation Committee: \$7,500; and Nominating and Governance Committee: \$5,000. Such amounts are pro-rated for periods of service less than the full fiscal year.

The following table sets forth information regarding the compensation earned for service on MEI's board of directors for fiscal year 2022 by MEI directors who were also not its employees. Dr. Gold, President and Chief Executive Officer of MEI, does not receive any compensation for performing his duties as a director of MEI. The compensation for Mr. Gold as an executive officer is set forth above under "MEI Executive Compensation—Summary Compensation Table."

**Compensation of Directors**

<u>Name</u>	<u>Fees Earned or Paid in Cash (\$)</u>	<u>Option Awards (\$)</u> <u>(1)</u>	<u>Total (\$)</u>
Christine A. White, M.D. (2)	85,600	86,500	172,100
Charles V. Baltic III (3)	65,600	86,500	152,100
Kevan E. Clemens, Ph.D. (4)	23,903	86,500	110,403
Cheryl L. Cohen (5)	55,600	86,500	142,100
Frederick W. Driscoll (6)	65,600	86,500	152,100
Tamar D. Howson (7)	58,100	86,500	144,600
Nicholas R. Glover, Ph.D. (8)	67,662	86,500	154,162
Sujay R. Kango (9)	31,651	93,200	124,851
Thomas C. Reynolds, M.D., Ph.D. (10)	58,100	86,500	144,600

- (1) Represents the aggregate grant date fair value of options granted in accordance with FASB ASC Topic 718. For the relevant assumptions used in determining these amounts, refer to Note 9 to MEI's audited financial statements contained herein. All stock options granted to non-employee directors in the fiscal year ended June 30, 2022, were granted under MEI's 2008 Equity Plan, and are ten-year options with an exercise price equal to the closing market price of MEI Common Stock on the date of grant. The stock options granted vest ratably each month over 12 months, subject to continued service on the MEI board of directors. During the fiscal year ended June 30, 2022, Dr. White, Mr. Baltic, Dr. Clemens, Mr. Driscoll, Ms. Howson, Dr. Glover, Dr. Reynolds, and Ms. Cohen each received an annual grant of 2,500 options at an exercise price of \$59.00 per share. Upon joining the MEI board of directors in the fiscal year ended June 30, 2022, Mr. Kango received a grant of 1,250 options at an exercise price of \$53.80 and a grant of 1,667 options at an exercise price of \$53.80.
- (2) Dr. White received cash compensation of \$35,000 in connection with her service as Chair of the Board, and \$5,000 in connection with her service on the Nominating and Governance Committee.
- (3) Mr. Baltic received cash compensation of \$10,000 in connection with his service on the Audit Committee and \$10,000 in connection with his service as Chair of the Nominating and Governance Committee.
- (4) Dr. Clemens received cash compensation of \$5,917 in connection with his service as Chair of the Compensation Committee, prior to his retirement from the board on November 22, 2021.
- (5) Ms. Cohen received cash compensation of \$10,000 in connection with her service on the Audit Committee.
- (6) Mr. Driscoll received cash compensation of \$20,000 in connection with his service as Chair of the Audit Committee.
- (7) Ms. Howson received cash compensation of \$7,500 in connection with her service on the Compensation Committee and \$5,000 in connection with her service on the Nominating and Governance Committee.

---

[Table of Contents](#)

- (8) Dr. Glover received cash compensation of \$10,000 in connection with his service on the Audit Committee and \$12,062 in connection with his service on the Compensation Committee.
- (9) Mr. Kango received cash compensation of \$3,911 in connection with his service on the Compensation Committee.
- (10) Dr. Reynolds received cash compensation of \$7,500 in connection with his service on the Compensation Committee and \$5,000 in connection with his service on the Nominating and Governance Committee.

Dr. Gold, President and Chief Executive Officer of MEI, does not receive any compensation for performing his duties as a director of MEI.

## INFINITY DIRECTOR COMPENSATION

None of Infinity's employee directors receive compensation for his or her service as a director. The following table details the total compensation earned by Infinity's non-employee directors who are expected to serve as directors of the combined company, during Infinity's 2022 fiscal year.

**Director Summary Compensation Table**

<u>Name</u>	<u>Fees Earned or Paid in Cash (\$)<sup>(1)</sup></u>	<u>Option Awards (\$)<sup>(2)</sup></u>	<u>Total (\$)</u>
Richard Gaynor, M.D. (3)	59,500	23,576	83,076
Sujay R. Kango (4)	60,012	78,192	138,204
Norman C. Selby (5)	97,000	28,815	125,815

- (1) In addition to his 2022 cash retainer for annual board service, Mr. Kango also received a prorated portion of the 2021 cash retainer for board services rendered in 2021 and 2022 totaling \$10,512.10 and paid in 2022.
- (2) The amounts in this column reflect the aggregate grant date fair value of option awards made to such individual, as computed in accordance with FASB ASB Topic 718.
- (3) On June 16, 2022, Dr. Gaynor was granted an option award that had a grant-date fair value of \$23,576. As of December 31, 2022, Dr. Gaynor held options to purchase 135,000 shares of Infinity Common Stock.
- (4) Upon joining Infinity's board, Mr. Kango was granted an option award on March 30, 2022 that had a grant-date fair value of \$78,192. As of December 31, 2022, Mr. Kango held options to purchase 90,000 shares of Infinity Common Stock.
- (5) On June 10, 2021, Mr. Selby was granted an option award that had a grant-date fair value of \$28,815. As of December 31, 2022, Mr. Selby held options to purchase 387,000 shares of Infinity Common Stock.

The following is a description of the cash compensation of Infinity's non-employee directors as of December 31, 2022:

- a \$42,000 annual retainer for service as a non-executive chair of Infinity's board of directors;
- a \$42,000 annual retainer for service as a director;
- a \$30,000 annual retainer for service as lead independent director;
- a \$20,000 annual retainer for service as chair of the Audit Committee;
- a \$15,000 annual retainer for service as chair of the Compensation Committee;
- a \$10,000 annual retainer for service as chair of the Nominating and Corporate Governance Committee;
- a \$10,000 annual retainer for service as chair of the Research and Development Committee;
- a \$10,000 annual retainer for service as a non-chairing member of the Audit Committee;
- a \$7,500 annual retainer for service as a non-chairing member of a committee of the board other than the Audit Committee.

Directors may elect to receive some or all of their annual cash retainer for service on Infinity's board, but not for committee service, in shares of Infinity Common Stock.

Each non-employee director is also reimbursed for reasonable out-of-pocket expenses incurred in attending meetings of Infinity's board of directors or any committee of Infinity's board of directors.

In addition to the cash compensation discussed above, each non-employee director automatically receives nonstatutory stock options under the Infinity 2019 Equity Incentive Plan. In the first quarter of 2022, Infinity's

## [Table of Contents](#)

Compensation Committee engaged Radford to conduct an assessment of overall board compensation, including a review of the appropriate mix of cash and equity compensation to determine market alignment. In March 2022, after taking into consideration the recommendations of Radford, Infinity's Compensation Committee approved the changes to equity compensation for Infinity's board of directors, as follows:

- upon commencement of service on the board, each new non-employee director receives a nonstatutory stock option to purchase 90,000 shares of Infinity Common Stock; and
- on the date of each annual meeting of stockholders, each then-continuing non-employee director receives a nonstatutory stock option to purchase 45,000 shares of Infinity Common Stock, provided that such director was serving as a director of Infinity on the last day of the immediately preceding calendar year.

In addition to the awards listed above, each non-employee director who serves in the following positions receives a nonstatutory stock option to purchase shares of Infinity Common Stock in the amount indicated below upon the date of commencement of service in such position and upon the date of each annual stockholder meeting thereafter:

<u>Position</u>	<u>Stock Option Grant</u>
Non-Executive Chair of the Board of Directors	12,000 shares
Lead Independent Director	10,000 shares

Each of these stock options has an exercise price per share equal to the closing price on the date of grant, which Infinity's board of directors determined to be the fair market value per share of Infinity Common Stock on the grant date and has a ten-year term, subject to earlier termination following cessation of board service by the holder of the option. Grants made to board members vest in equal quarterly installments beginning at the end of the first calendar quarter after the grant date, provided that the board member continues to serve as director and in the position for which the grant was made. Grants made in connection with the commencement of services vest over a period of two years (one-eighth each quarter), while grants made in connection with the annual meeting of stockholders vest over a period of one year (one-fourth each quarter). These options immediately vest in full upon certain changes in control or ownership or upon death or disability of the option holder while serving as a director.



**MEI'S BUSINESS**

**Overview**

MEI Pharma, Inc. (Nasdaq: MEIP) is a clinical stage pharmaceutical company focused on developing potential new therapies for cancer. MEI Pharma's portfolio of drug candidates includes clinical-stage candidates with differentiated or novel mechanisms of action intended to address unmet medical needs and deliver improved benefit to patients, either as standalone treatments or in combination with other therapeutic options. MEI's common stock is listed on the Nasdaq Capital Market under the symbol "MEIP."

In November 2022, MEI announced plans to realign its clinical development efforts after jointly deciding with its development partner, Kyowa Kirin Co., Ltd. ("Kyowa Kirin"), to discontinue development of MEI's lead drug candidate, zandelisib, outside of Japan. In connection with the realignment, MEI is focusing its development efforts on its two earlier stage clinical assets, voruciclib and ME-334. Additionally, MEI initiated a staggered workforce reduction, affecting 28 employees in December 2022 (representing approximately 27% of its workforce) and an additional nine employees as of April 21, 2023. Following completion of the close of the zandelisib development program, workforce reductions completed to date and any further workforce reductions necessary to fully align resources going forward, MEI expects that its existing cash, cash equivalents and short-term investments will be sufficient to fund operations for approximately two years.

**Clinical Development Programs**

MEI's business strategy is to build its pipeline by licensing or acquiring promising cancer agents and creating value in programs through development, strategic partnerships and commercialization, as appropriate. MEI's objective is to leverage the mechanisms and properties of its pipeline drug candidates to optimize the balance between efficacy and tolerability to meet the needs of patients with cancer. MEI's drug candidate pipeline includes voruciclib, an oral cyclin-dependent kinase 9 ("CDK9") inhibitor and ME-344, an intravenous small molecule targeting the oxidative phosphorylation pathway in the mitochondria.

INVESTIGATIONAL AGENTS	THERAPEUTIC AREA	COMBINATION	PHASE 1/1B	PHASE 2	PHASE 3
<b>Voruciclib</b> Oral CDK9 Inhibitor	B-Cell Malignancies & AML Relapsed/refractory (2L+)	Monotherapy Venclexta®	■		
<b>ME-344</b> Mitochondrial Inhibitor	Colorectal Cancer <sup>1</sup> Relapsed	Avastin®	■		

1. Study pending initiation

*Voruciclib: Potent Orally Administered CDK9 Inhibitor in Phase 1 Studies*

Voruciclib is a potent orally administered CDK9 inhibitor. Voruciclib is being evaluated in a Phase 1b trial evaluating dose and schedule in patients with acute myeloid leukemia ("AML") and B-cell malignancies. Voruciclib is also being evaluated in pre-clinical studies to explore the potential synergistic activity in various solid tumor cancers of voruciclib in combination with drug-candidates that targets in the RAS signaling pathway, including KRAS.

*Voruciclib Scientific Overview: Cell Cycle Signaling*

CDK9 has important functions in cell cycle regulation, including the modulation of two therapeutic targets in cancer:

- CDK9 is a transcriptional regulator of the myeloid leukemia cell differentiation protein ("MCL1"), a member of the family of anti-apoptotic proteins which, when elevated, may prevent the cell from undergoing cell death. Inhibition of CDK9 blocks the production of MCL1, which is an established resistance mechanism to the B-cell lymphoma ("BCL2") inhibitor venetoclax (marketed as Venclexta®).

## [Table of Contents](#)

- CDK9 is a transcriptional regulator of the MYC proto-oncogene protein (“MYC”) which regulates cell proliferation and growth. Upregulation of MYC is implicated in many human cancers and is frequently associated with poor prognosis and unfavorable patient survival. CDK9, in addition to being a transcription factor for MYC, also decreases phosphorylation of MYC protein that is implicated in stabilizing MYC in KRAS mutant cancers.

Targeting MYC directly has historically been difficult, but CDK9 is a promising approach to target this oncogene.

### *Voruciclib: Inhibition of MCL1*

In pre-clinical studies voruciclib shows dose-dependent suppression of MCL1; in December 2017, a study of voruciclib published in the journal Nature Scientific Reports reported that the combination of voruciclib plus the BCL-2 inhibitor venetoclax was capable of inhibiting two master regulators of cell survival, MCL-1 and BCL-2, and achieved synergistic antitumor effect in an aggressive subset of DLBCL pre-clinical models.

In a peer reviewed manuscript published in 2020 by Luedtke et al, it was reported that the inhibition of CDK9 by voruciclib synergistically enhances cell death induced by the BCL-2 selective inhibitor venetoclax in preclinical models of AML. The data demonstrated that voruciclib synergizes with venetoclax to induce programmed cell death, or apoptosis, in both AML cell lines and primary patient samples. It was also demonstrated that voruciclib downregulates MCL1, which is relevant for the synergy between voruciclib and venetoclax, and further that voruciclib also downregulates MYC, which also contributes to the synergies with venetoclax.

The research presented suggests that voruciclib is an attractive therapeutic target for treating cancers in combination with venetoclax or other BCL-2 inhibitors, and is supportive of MEI’s ongoing clinical evaluation of voruciclib in B-cell malignancies and AML.

### *Voruciclib: Inhibition of MYC*

Many cancers are associated with overexpression of MYC, a transcription factor regulating cell proliferation and growth. CDK9 is a known regulator of MYC transcription and a modulator of MYC protein phosphorylation. Data reported at the American Association for Cancer Research (“AACR”) Annual Meeting 2021 in preclinical models demonstrates that voruciclib:

- Results in a rapid decrease in the phosphorylation of proteins that promote MYC transcription;
- Rapidly decreases phosphorylation of MYC protein on Ser62, a site implicated in stabilizing MYC in KRAS mutant cancers;
- Possesses single agent activity against multiple KRAS mutant cancer cell lines both in vitro and in vivo; and
- Synergistically inhibits KRAS G12C mutant cancer cell lines in combination with KRAS G12C inhibitors, both in vitro and in vivo.

The research presented suggests that voruciclib could be an attractive therapeutic agent for cancers, including solid tumors, dependent on the activity of MYC.

### *Clinical Program*

MEI is evaluating patients with hematological malignancies in a Phase 1b clinical trial evaluating the dose and schedule of voruciclib. The trial started with the evaluation of dose and schedule of voruciclib as a monotherapy in patients with relapsed and refractory B-cell malignancies and AML after failure of prior standard therapies to determine the safety, preliminary efficacy and maximum tolerated dose. MEI is now also evaluating the dose and schedule of voruciclib in combination with venetoclax, a BCL2 inhibitor, initially in patients with AML and subsequently across multiple indications where BCL2 inhibition has been shown to be effective. The primary

goal of the Phase 1b study is to assess the safety, and possible synergies, of voruciclib administered in combination with venetoclax. MEI is planning to report key interim clinical data from this trial around calendar year-end 2023.

As reported at the American Society of Hematology 2021 annual meeting in a poster presentation, data to date from the Phase 1 study evaluating voruciclib as a monotherapy on an optimized schedule of 14 consecutive days in a 28-day cycle was well tolerated. No dose limiting toxicities were observed and no significant myelosuppression was seen in patients with B-cell malignancies, suggesting a lower likelihood of additive toxicities in combination with venetoclax. Disease stabilization was observed in heavily pretreated patients and differentiation syndrome was observed in AML patients, which is indicative of biologic activity.

Voruciclib was also previously evaluated in more than 70 patients with solid tumors in multiple Phase 1 studies. The totality of the clinical data, along with data from pre-clinical studies, suggests voruciclib's ability to inhibit its molecular target at a projected dose as low as 150 mg daily. In one clinical study, voruciclib was evaluated in combination with vemurafenib (marketed as Zelboraf®) in nine patients with BRAF mutated advanced/inoperable malignant melanoma. All three BRAF/MEK naive patients achieved a response: two partial responses and one complete response. In this study voruciclib was dosed at 150 mg daily plus vemurafenib 720 mg or 960 mg twice daily in 28-day cycles. The most common adverse events were fatigue, constipation, diarrhea, arthralgia and headache. One instance of grade 3 fatigue was dose limiting and no serious adverse events related to voruciclib were reported. Other clinical studies evaluated voruciclib at doses up to 850 mg in patients with solid tumors, demonstrating additional evidence of potential biologic activity and an adverse event profile generally consistent with other drugs in its class.

#### *ME-344: Clinical Stage Mitochondrial Inhibitor with Combinatorial Potential*

ME-344 is MEI's novel isoflavone-derived mitochondrial inhibitor drug candidate that demonstrates tumor selective activity in pre-clinical studies. It targets the oxidative phosphorylation pathway involved in adenosine triphosphate ("ATP") production in the mitochondria. ME-344 has been evaluated in clinical studies, including an investigator-initiated, multi-center, randomized, window of opportunity clinical trial in combination with the vascular endothelial growth factor ("VEGF") inhibitor bevacizumab (marketed as Avastin®) that enrolled a total of 42 patients with human epidermal growth factor receptor 2 ("HER2") negative breast cancer.

#### *ME-344 Scientific Overview: Cancer Metabolism*

Tumor cells often display a high metabolic rate to support cell division and growth. This heightened metabolism requires a continual supply of energy in the form of ATP. The two major sources of ATP are the specialized cellular organelles termed mitochondria and through the metabolism of carbohydrates via the glycolysis pathway, which is frequently unregulated in cancer cells in a phenomenon called the Warburg Effect.

ME-344 was identified through a screen of more than 400 new chemical structures originally created based on the central design of naturally occurring plant isoflavones. MEI believes that some of these synthetic compounds, including MEI's drug candidate ME-344, interact with specific mitochondrial enzyme targets, resulting in the inhibition of ATP generation. When these compounds interact with their target, a rapid reduction in ATP occurs, which leads to a cascade of biochemical events within the cell and ultimately to cell death.

#### *Clinical Program*

ME-344 demonstrated evidence of single agent activity against refractory solid tumors in a Phase 1 trial, and in pre-clinical studies tumor cells treated with ME-344 resulted in a rapid loss of ATP and cancer cell death. In addition to single agent activity, ME-344 may also have significant potential in combination with anti-angiogenic therapeutics. In pre-clinical studies, it was shown that one outcome of anti-angiogenics was to reduce the rate of glycolysis in tumors as a mechanism to slow tumor growth. However, tumor metabolism was able to shift to mitochondrial metabolism for energy production to support continued tumor proliferation. In such cases of tumor

## [Table of Contents](#)

plasticity in the presence of treatment with anti-angiogenics, targeting the alternative metabolic source with ME-344 may open an important therapeutic opportunity.

Support for this combinatorial use of ME-344 was first published in the June 2016 edition of Cell Reports; pre-clinical data from a collaboration with the Spanish National Cancer Research Centre in Madrid demonstrated mitochondria-specific effects of ME-344 in cancer cells, including substantially enhanced anti-tumor activity when combined with agents that inhibit the activity of VEGF. These data demonstrating the potential anti-cancer effects of combining ME-344 with a VEGF inhibitor due to an inhibition of both mitochondrial and glycolytic metabolism provided a basis for commencement of an investigator-initiated trial of ME-344 in combination with bevacizumab in HER2 negative breast cancer patients.

Results published in the November 2019 issue of Clinical Cancer Research from a multicenter, investigator-initiated, randomized, open-label, clinical trial that evaluated the combination of ME-344 and bevacizumab in 42 women with early HER2-negative breast cancer further support the combinatorial use of ME-344 with anti-angiogenic therapeutics.

The primary objective of the trial was to show proof of ME-344 biologic activity as measured by Ki67 reductions in the presence of the nuclear protein Ki67 (expression of which is strongly associated with tumor cell proliferation and growth) from days 0 to 28 compared to the control group who received bevacizumab alone. Secondary objectives included determining whether ME-344 biologic activity correlates with vascular normalization. The data demonstrate significant biologic activity in the ME-344 treatment group:

- In ME-344 treated patients, mean absolute Ki67 decreases were 13.3 compared to an increase of 1.1 in the bevacizumab monotherapy group (P=0.01).
- In ME-344 treated patients, mean relative Ki67 decreases were 23% compared to an increase of 186% in the bevacizumab monotherapy group (P < 0.01).
- The mean relative Ki67 reduction in patients experiencing vascular normalization in the ME-344 treated patients was 33%, compared to an increase of 11.8% in normalized patients from the bevacizumab monotherapy group (P=0.09). Approximately one-third of patients in each arm had vascular normalization.

Treatment was generally well tolerated; three grade 3 adverse events of high blood pressure were reported, two in the ME-344 arm and one in the bevacizumab monotherapy arm.

Results from MEI's earlier, first-in-human, single-agent Phase 1 clinical trial of ME-344 in patients with refractory solid tumors were published in the April 1, 2015 edition of Cancer. The results indicated that eight of 21 evaluable patients (38%) treated with ME-344 achieved stable disease or better, including five who experienced progression-free survival that was at least twice the duration of their last prior treatment before entry into the trial. In addition, one of these patients, a heavily pre-treated patient with small cell lung cancer, achieved a confirmed partial response and remained on study for two years. ME-344 was generally well tolerated at doses equal to or less than 10 mg/kg delivered on a weekly schedule for extended durations. Treatment-related adverse events included nausea, dizziness and fatigue. Dose-limiting toxicities were observed at both the 15 mg/kg and 20 mg/kg dose levels, consisting primarily of grade 3 peripheral neuropathy.

MEI is planning to advance ME-344 in combination with the anti-angiogenic antibody bevacizumab in a Phase 1b study evaluating patients with relapsed colorectal cancer in the first half of calendar year 2023. The study will enroll patients with progressive disease after failure of standard therapies with patients treated until disease progression or intolerance. The primary objective is progression free survival. Secondary endpoints include overall response rate, duration of response, overall survival and safety. MEI is planning to report key interim clinical data from this trial around calendar year-end 2023.

Additionally, ME-344 may also have clinical potential against hematological malignancies. At the AACR Annual Meeting 2022, a poster presentation reported results from preclinical studies exploring the ability of ME-344 to

## [Table of Contents](#)

enhance the activity of venetoclax against AML. Data from the in vitro and in vivo preclinical studies evaluating the combination of ME-344 with venetoclax in standard-of-care-resistant AML cell lines and relapsed or refractory AML patient samples suggest that ME-344, both alone and in combination with venetoclax, inhibits purine biosynthesis, suppresses oxidative phosphorylation, induces apoptosis and decreases MCL-1, which together target metabolic vulnerabilities of AML cells. The data demonstrated that ME-344 and venetoclax prolong survival in MV4-11 and MV4-11/AraC-R-derived xenograft AML models. The poster concludes that ME-344 enhances venetoclax activity against AML cells including resistant AML.

### *Zandelisib: PI3Kd Inhibitor Overview*

Zandelisib is an oral, once-daily, selective PI3Kd inhibitor that MEI is jointly developing with Kyowa Kirin under a global license, development and commercialization agreement entered into in April 2020.

In March 2022, MEI and Kyowa Kirin reported the outcome of an end of Phase 2 meeting with the FDA wherein the agency discouraged a filing based on data from a single-arm Phase 2 trial, called TIDAL, evaluating zandelisib in patients with relapsed or refractory follicular lymphoma. At this meeting, the FDA stated that data generated from single arm studies such as the Phase 2 TIDAL trial are insufficient to adequately assess the risk/benefit of PI3K inhibitors evaluating indolent non-Hodgkin lymphoma. At that time the FDA emphasized that the companies continue efforts with the ongoing randomized Phase 3 COASTAL trial evaluating patients with relapsed or refractory follicular or marginal zone lymphomas. Subsequently, at an April 2022 meeting of the FDA Oncology Drugs Advisory Committee, the committee voted that future approvals of PI3K inhibitors for hematologic malignancies should be supported by randomized data.

In November 2022, MEI and Kyowa Kirin met with the FDA in a follow-up meeting to the March 2022 end of Phase 2 meeting. At this meeting, the FDA provided further guidance regarding the design and statistical analysis for the COASTAL trial. Following the November meeting, the companies jointly concluded that a clinical trial consistent with the recent FDA guidance, including modification of the ongoing COASTAL trial, would likely not be feasible to complete within a time period that would support further investment or with sufficient certainty of the regulatory requirements for approval to justify continued global development efforts. As a result, MEI and Kyowa Kirin jointly decided to discontinue global development of zandelisib for indolent forms of non-Hodgkin lymphoma outside of Japan. The discontinuation of zandelisib development outside of Japan was a business decision based on the most recent regulatory guidance from the FDA and is not related to the zandelisib clinical data generated to date.

In March 2023, Kyowa Kirin met with the Pharmaceuticals and Medical Devices Agency, or PMDA, the equivalent to the FDA in Japan, to discuss the continuing development of zandelisib in Japan. Kyowa Kirin is currently evaluating whether to continue developing zandelisib in Japan.

MEI and Kyowa Kirin have begun closing all ongoing zandelisib clinical studies outside of Japan, including the Phase 3 COASTAL trial, the Phase 2 TIDAL trial, and the Phase 2 CORAL trial. Depending on the achievement of certain regulatory and commercial milestones in Japan, MEI may be eligible for additional payments from Kyowa Kirin under the current agreement. MEI may also be entitled to royalties on any sales of zandelisib in Japan.

### *Kyowa Kirin License, Development and Commercialization Agreement*

In April 2020, MEI entered into the Kyowa Kirin Commercialization Agreement under which MEI granted to Kyowa Kirin a co-exclusive, sublicensable, payment-bearing license under certain patents and know-how controlled by MEI to develop and commercialize zandelisib and any pharmaceutical product containing zandelisib for all human indications in the U.S. (the "U.S. License"), and an exclusive (subject to certain retained rights to perform obligations under the Kyowa Kirin Commercialization Agreement), sublicensable, payment-bearing, license under certain patents and know-how controlled by MEI to develop and commercialize zandelisib and any pharmaceutical product containing zandelisib for all human indications in countries outside of the U.S. (the "Ex-U.S." and the "Ex-U.S. License"). Kyowa Kirin granted to MEI a co-exclusive, sublicensable, license

## [Table of Contents](#)

under certain patents and know-how controlled by Kyowa Kirin to develop and commercialize zandelisib for all human indications in the U.S., and a co-exclusive, sublicensable, royalty-free, fully paid license under certain patents and know-how controlled by Kyowa Kirin to perform MEI's obligations in the Ex-U.S. under the Kyowa Kirin Commercialization Agreement. Kyowa Kirin paid MEI an initial payment of \$100.0 million. Additionally, in Japan, the Kyowa Kirin Commercialization Agreement included potential regulatory and commercialization milestone payments plus royalties on net sales of zandelisib in Japan, which are tiered beginning in the teens.

Kyowa Kirin is responsible for the development and commercialization of zandelisib in the Ex-U.S. and, subject to certain exceptions, is solely responsible for all costs related thereto. MEI will also provide to Kyowa Kirin certain drug supplies necessary for the development and commercialization of zandelisib in the Ex-U.S., with the understanding that Kyowa Kirin will assume responsibility for manufacturing for the Ex-U.S. as soon as practicable. MEI and Kyowa Kirin will reevaluate the Kyowa Kirin Commercialization Agreement once Kyowa Kirin makes a decision on its plans to develop zandelisib in Japan.

### **Competition**

The marketplace for MEI's drug candidates is highly competitive. A number of other companies have products or drug candidates in various stages of pre-clinical or clinical development that are intended for the same therapeutic indications for which MEI's drug candidates are being developed. Some of these potential competing drug candidates are further advanced in development than MEI's drug candidates and may be commercialized sooner. Even if MEI is successful in developing products that receive regulatory approval, such products may not compete successfully with products produced by its competitors or with products that may subsequently receive regulatory approval.

MEI's competitors include pharmaceutical companies and biotechnology companies, as well as universities and public and private research institutions. In addition, companies active in different but related fields represent substantial competition for MEI. Many of MEI's competitors developing oncology drugs have significantly greater capital resources, larger research and development staffs and facilities, and greater experience in drug development, regulation, manufacturing, marketing and commercialization than MEI does. They compete with MEI in recruiting sites and eligible patients to participate in clinical studies and in attracting development and/or commercialization partners. They also license technologies that are competitive with MEI's technologies. As a result, MEI's competitors may be able to more easily develop technologies and products that would render MEI's technologies or MEI's drug candidates obsolete or non-competitive.

### **Intellectual Property**

MEI owns, by assignment or exclusive license, worldwide rights to each of its current drug candidates. MEI's intellectual property portfolio includes approximately 36 issued U.S. patents, 209 issued foreign patents, 17 pending U.S. patent applications, and 137 pending foreign applications.

MEI has acquired exclusive worldwide rights to develop, manufacture and commercialize voruciclib from Presage Biosciences, Inc. ("Presage"). The USPTO has issued 18 U.S. patents covering the composition of matter, pharmaceutical compositions, and methods of use to treat cancer which are projected to expire between April 2024 and December 2037, not including any patent term extension. There are approximately 90 allowed or issued foreign patents, seven pending U.S. patent applications, and 34 pending foreign patent applications for voruciclib, related compounds, and related methods of use.

MEI has acquired, by assignment, patents and patent applications from Novogen, MEI's former majority shareholder, relating to a family of isoflavonoid compounds, including ME-344. The USPTO has issued 11 patents covering ME-344 as composition of matter, pharmaceutical compositions, and methods of use to treat cancer. There are approximately 70 foreign patents granted or allowed. The issued U.S. patents with composition of matter claims covering ME-344 are expected to expire in March 2027 and November 2031, not including patent term extension. There are three pending U.S. patent applications, one pending PCT application, and three pending foreign patent applications directed to ME-344 and related compounds or methods of use thereof.

## [Table of Contents](#)

MEI has acquired, by assignment, worldwide rights to zandelisib and other related compounds from Pathway Therapeutics, Inc. The U.S. Patent and Trademark Office (“USPTO”) has issued seven patents covering zandelisib as composition of matter, pharmaceutical compositions, and methods of use to treat cancer. The issued U.S. patents with composition of matter claims covering zandelisib are projected to expire in January 2031 and December 2032, not including any patent term extension. There are approximately 49 foreign patents granted or allowed. There are seven pending U.S. patent applications, one pending international patent application filed under the Patent Cooperation Treaty (“PCT application”), and approximately 98 pending foreign patent applications directed to zandelisib and related compounds or methods of use thereof.

MEI’s success depends in large part on its ability to protect its proprietary technologies, compounds and information, and to operate without infringing the proprietary rights of third parties. MEI relies on a combination of patent, trade secret, copyright, and trademark laws, as well as confidentiality, licensing and other agreements, to establish and protect its proprietary rights. MEI seeks patent protection for its key inventions, including drug candidates it identifies, routes for chemical synthesis and pharmaceutical formulations. There is no assurance that any of MEI’s pending patent applications will issue, or that any of its patents will be enforceable or will cover a drug or other commercially significant product or method. In addition, MEI regularly reviews its patent portfolio to identify patents and patent applications that MEI deems to have relatively low value to its ongoing business operations for potential abandonment. There is also no assurance that MEI will correctly identify which of its patents and patent applications should be maintained and which should be abandoned. The term of most of MEI’s other current patents commenced, and most of its future patents, if any, will commence, on the date of issuance and terminate 20 years from the earliest effective filing date of the patent application. Because any marketing and regulatory approval for a drug often occurs several years after the related patent application is filed, the resulting market exclusivity afforded by any patent on MEI’s drug candidates and technologies will likely be substantially less than 20 years.

As most patent applications in the U.S. are maintained as confidential until published by the USPTO at 18 months from filing for all cases filed after November 29, 2000, or at issue, for cases filed prior to November 29, 2000, MEI cannot be certain that MEI or Presage were the first to make the inventions covered by the patents and applications referred to above. Additionally, publication of discoveries in the scientific or patent literature often lags behind the actual discoveries. Moreover, pursuant to the terms of the Uruguay Round Agreements Act, patents filed on or after June 8, 1995 have a term of twenty years from the date of such filing except for provisional applications, irrespective of the period of time it may take for such patent to ultimately issue. This may shorten the period of patent protection afforded to therapeutic uses of zandelisib, voruciclib or ME-344 as patent applications in the biopharmaceutical sector often take considerable time to issue. However, in some countries the patent term may be extended.

In order to protect the confidentiality of MEI’s technology, including trade secrets and know-how and other proprietary technical and business information, MEI requires all of its consultants, advisors and collaborators to enter into agreements that prohibit the use or disclosure of information that is deemed confidential. These agreements also oblige MEI’s consultants, advisors and collaborators to assign to MEI, or negotiate a license to developments, discoveries and inventions made by such persons in connection with their work relating to MEI’s products. MEI cannot be sure that confidentiality will be maintained by those from whom it has acquired technology or disclosure prevented by these agreements. MEI also cannot be sure that its proprietary information or intellectual property will be protected by these agreements or that others will not independently develop substantially equivalent proprietary information or intellectual property.

The pharmaceutical industry is highly competitive, and patents may have been applied for by, and issued to, other parties relating to products competitive with zandelisib, voruciclib or ME-344. Use of these compounds and any other drug candidates may give rise to claims that they infringe the patents or proprietary rights of other parties, existing now and in the future. An adverse claim could subject MEI to significant liabilities to such other parties and/or require disputed rights to be licensed from such other parties. MEI cannot be sure that any license required under any such patents or proprietary rights would be made available on terms acceptable to MEI, if at



## [Table of Contents](#)

all. If MEI does not obtain such licenses, MEI may encounter delays in product market introductions, or may find that the development, manufacture or sale of products requiring such licenses may be precluded.

### **Research and Development**

The objective of MEI's research and development program is the generation of data sufficient to achieve regulatory approval of MEI's drug candidates in one or more dosage forms in major markets such as the U.S., to meet medical needs and develop a clinical and commercial profile with attractive attributes, and/or to allow MEI to enter into a development and/or commercial relationship with another party. The data are generated by MEI's pre-clinical studies and clinical trial programs.

The key aspects of MEI's research and development program are to provide more complete characterization of the following:

- the relevant molecular targets of action of its drug candidates;
- the relative therapeutic benefits and indications for use of its drug candidates as a monotherapy or as part of combinational therapy with other agents; and
- the most appropriate therapeutic indications and dosage forms for zandelisib, voruciclib and ME-344.

### **Government Regulation**

#### *U.S. Regulatory Requirements*

The FDA, and comparable regulatory agencies in other countries, regulate and impose substantial requirements upon the research, development, pre-clinical and clinical testing, labeling, manufacture, quality control, storage, approval, advertising, promotion, marketing, distribution, import, and export of pharmaceutical products including biologics, as well as significant reporting and record-keeping obligations. State governments may also impose obligations in these and other areas. These requirements are extensive and are frequently changing. For example, there may be changes as a result of the upcoming user fee act reauthorization legislation.

In the U.S., pharmaceutical products are regulated by the FDA under the Federal Food, Drug, and Cosmetic Act ("FDCA") and other laws, including in the case of biologics, the Public Health Service Act. MEI believes, but cannot be certain, that its products will be regulated as drugs by the FDA. The process required by the FDA before drugs may be marketed in the U.S. generally involves the following:

- pre-clinical laboratory evaluations, including formulation and stability testing, and animal tests performed under the FDA's Good Laboratory Practices ("GLP") regulations to assess pharmacological activity and toxicity potential;
- submission and approval of an investigational new drug ("IND") application, including results of pre-clinical tests, manufacturing information, and protocols for clinical tests, which must become effective before clinical trials may begin in the U.S.;
- obtaining approval of IRBs to administer the products to human subjects in clinical trials;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the product for the product's intended use;
- development of manufacturing processes which conform to the FDA's current Good Manufacturing Practices ("cGMP"), as confirmed by FDA inspection or remote regulatory assessments;
- submission of results for pre-clinical, toxicology, and clinical studies, and chemistry, manufacture and control information on the product to the FDA in a non-disclosure agreement ("NDA"); and
- FDA review and approval of an NDA, prior to any commercial sale or shipment of a product.

The testing and approval process requires substantial time, effort, and financial resources, and MEI cannot be certain that it will be able to ultimately submit marketing applications for any of its product candidates, that its



## [Table of Contents](#)

development efforts will prove to be successful, that its studies will have positive outcomes, or that any approval will be granted on a timely basis, if at all.

The results of the pre-clinical studies, together with initial specified manufacturing information, the proposed clinical trial protocol, and information about the participating investigators are submitted to the FDA as part of an IND, which must become effective before MEI may begin human clinical trials in the U.S. Clinical trials must be conducted in accordance with federal regulations and Good Clinical Practice (“GCP”) requirements, and with investigational products that follow cGMP. GCPs include, among other requirements, the requirements related to monitoring, drug accountability, data integrity, and that all research subjects provide their informed consent in writing for their participation in any clinical trial. Additionally, an independent IRB must review and approve each study protocol and oversee conduct of the trial. An IND becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day period, raises concerns or questions about the conduct of the trials as outlined in the IND and imposes a clinical hold. If the FDA imposes a clinical hold, the IND sponsor must resolve the FDA’s concerns before clinical trials can begin. Pre-clinical tests and studies can take several years to complete, and there is no guarantee that an IND that is submitted based on such tests and studies will become effective within any specific time period, if at all.

Sponsors must make certain reports and submissions to FDA and global health authorities, as appropriate, and to clinical investigators who, in turn, make certain reports and submissions to the IRB or ethics committee, including annual reports, and reports of investigator financial interests, serious adverse events and other significant safety information, study amendments, and new study protocols. Information about certain clinical trials, including a description of the study and study results, must also be submitted within specific timeframes to the National Institutes of Health (the “NIH”), for public dissemination on the [clinicaltrials.gov](http://clinicaltrials.gov) website. Sponsors of investigational products for serious diseases must also have a publicly available policy on requests for expanded access.

Investigational drugs and active ingredients imported into the U.S. are also subject to regulation by the FDA. Further, the export of investigational products outside of the U.S. is subject to regulatory requirements of the receiving country as well as U.S. export requirements under the FDCA.

Human clinical trials are typically conducted in three sequential phases that may overlap.

- *Phase 1:* The drug is initially introduced into healthy human subjects or patients and tested for safety and dosage tolerance. Absorption, metabolism, distribution, and excretion testing is generally performed at this stage.
- *Phase 2:* The drug is studied in controlled, exploratory therapeutic trials in a limited number of subjects with the disease or medical condition for which the new drug is intended to be used in order to identify possible adverse effects and safety risks, to determine the preliminary or potential efficacy of the product for specific targeted diseases or medical conditions, and to determine dosage tolerance and the optimal effective dose.
- *Phase 3:* When Phase 2 studies demonstrate that a specific dosage range of the drug may be efficacious and the drug has an acceptable safety profile for further investigation, controlled, large-scale therapeutic Phase 3 trials are undertaken at multiple study sites to demonstrate clinical efficacy and to further test for safety in an expanded patient population. Typically, two Phase 3 trials are required by the FDA for product approval. Under some limited circumstances, however, the FDA may approve an NDA based upon a single Phase 3 clinical study plus confirmatory evidence or a single large multicenter trial without confirmatory evidence.

Concurrent with clinical trials, companies usually complete additional non-clinical and toxicology studies and must also develop additional information about the CMC of the product candidate.

Some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data monitoring committee. This group reviews data and advises the study sponsor

## [Table of Contents](#)

regarding the continuing safety of the trial. This group may also review interim data to assess the continuing validity and scientific merit of the clinical trial. The data monitoring committee may advise the sponsor to halt the clinical trial, modify the clinical trial, or continue the clinical trial depending on safety results and the trial's likelihood of success.

MEI cannot be certain that it will successfully complete clinical testing of its products within any specific time period, if at all. Furthermore, the FDA, the IRB or MEI may suspend or terminate clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable safety risk or noncompliance with applicable regulatory requirements.

Results of pre-clinical and toxicology studies, and clinical trials, as well as detailed information about the manufacturing process, quality control methods, and product composition, among other things, are submitted to the FDA as part of an NDA seeking approval to market and commercially distribute the product on the basis of a determination that the product is safe and effective for its intended use. Once the FDA receives an application, it has 60 days to review the NDA to determine if it is substantially complete to permit a substantive review, before it accepts the application for filing. The FDA may request additional information rather than accept an application for filing. In this event, the application must be resubmitted with the additional information. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. Under the goals agreed to by the FDA under the Prescription Drug User Fee Act ("PDUFA"), the agency currently aims to review 90% of all applications for new molecular entities within ten months of the 60-day filing date for a standard review. The PDUFA date is only a goal, thus, the FDA does not always meet its PDUFA dates. The PDUFA date may also be extended if the FDA requests or the sponsor provides substantial additional information regarding the submission. This timing may also change with the current user fee reauthorization efforts that are being undertaken in Congress.

The FDA may refer certain applications to an advisory committee, which is a panel of experts that make a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA will inspect the facilities at which the product is manufactured and may inspect the sponsor, clinical study vendors, and clinical sites at which the product candidate was studied and will not approve the product unless cGMP and GCP compliance are satisfactory. Inspections may be in-person or conducted remotely. If applicable regulatory criteria are not satisfied, the FDA may issue a complete response letter ("CRL") to the sponsor requiring additional non-clinical or clinical studies or data or additional CMC information. If a CRL is issued, the applicant may either: resubmit the marketing application, addressing all of the deficiencies identified in the letter; withdraw the application; or request an opportunity for a hearing.

Once the FDA determines that the approval requirements are met, it will issue an approval letter that authorizes commercial marketing of the product with specific prescribing information for specific indications. As a condition of approval, the FDA also may require post-marketing commitments and requirements, including studies, and/or surveillance to monitor the product's safety or efficacy. The FDA also may require a Medication Guide and also a risk evaluation and mitigation strategy ("REMS"), or other conditions for a product's approval or following approval to ensure that the benefits of the product candidate outweigh the risks. Moreover, even if the FDA approves a product, it may limit the approved indications or populations for use of the product, require that contraindications, warnings, or precautions be included in the product labeling, including a black box warning, impose other conditions, such as post-approval studies, or may not approve label statements that are necessary for successful commercialization and marketing.

Even after an NDA is approved, the FDA may impose additional obligations or restrictions (such as labeling changes, or clinical post-marketing requirements), or even suspend or withdraw a product approval or require additional testing or label revisions on the basis of data that arise after the product reaches the market, or if compliance with regulatory standards is not maintained. MEI cannot be certain that any NDA MEI submits will

## [Table of Contents](#)

be approved by the FDA for full or accelerated approval on a timely basis, if at all. Also, any such approval may limit the indicated uses for which the product may be marketed. Any refusal to approve, delay in approval, suspension or withdrawal of approval, or restrictions on indicated uses could have a material adverse impact on MEI's business prospects.

Each NDA must be accompanied by a substantial user fee pursuant to the requirements of the PDUFA and its amendments. Fee waivers or reductions are available in certain circumstances. Following product approval, drug products are also subject to annual program fees. The FDA adjusts the PDUFA user fees on an annual basis. A written request can be submitted for a waiver for the application fee for the first human drug application that is filed by a small business, but there are no small business waivers for program fees. Product candidates that are designated as orphan products are not subject to application user fees unless the application includes an indication other than the orphan indication and may be exempt from program fees if certain criteria are met. MEI is not at the stage of development with its products where it is subject to these fees, but they are significant expenditures that may be incurred in the future and must be paid at the time of application submissions to the FDA.

Satisfaction of FDA requirements typically takes many years. The actual time required varies substantially, based upon the type, complexity, and novelty of the pharmaceutical product, among other things. Government regulation imposes costly and time-consuming requirements and restrictions throughout the product life cycle and may delay product marketing for a considerable period of time, limit product marketing, or prevent marketing altogether. Success in pre-clinical or early-stage clinical trials does not ensure success in later stage clinical trials. Data obtained from pre-clinical and clinical activities are not always conclusive and may be susceptible to varying interpretations that could delay, limit, or prevent marketing approval. Even if a product receives marketing approval, the approval is limited to specific clinical indications. Further, even after marketing approval is obtained, the discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market.

After product approval, there are continuing significant regulatory requirements imposed by the FDA, including record-keeping requirements, obligations to report adverse side effects in patients using the products, and restrictions on advertising and promotional activities. Quality control and manufacturing procedures must continue to conform to cGMPs, and the FDA periodically inspects facilities, via in person inspections and remote regulatory assessments, to assess cGMP compliance. Additionally, post-approval changes in ingredient composition, manufacturing processes or facilities, product labeling, or other areas may require submission of an NDA Supplement to the FDA for review and approval. New indications will require additional clinical studies and submission of an NDA Supplement.

Failure to comply with the FDA's regulatory requirements may result in an enforcement action by the FDA, including clinical holds, refusal to approve marketing applications or supplements, Warning Letters, product recalls, suspension or revocation of product approval, seizure of product to prevent distribution, impositions of injunctions prohibiting product manufacture or distribution, and civil and criminal penalties, among other actions. Maintaining compliance is costly and time-consuming. MEI cannot be certain that MEI, or its present or future suppliers or third party manufacturers, will be able to comply with all FDA regulatory requirements, and potential consequences of noncompliance could have a material adverse impact on MEI's business prospects.

The FDA's policies may change, and additional governmental regulations may be enacted that could delay, limit, or prevent regulatory approval of MEI's products, that require that it implements additional compliance steps, or affect MEI's ability to manufacture, market, or distribute its products after approval. For example, in March 2020, the U.S. Congress passed the Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, which includes various provisions regarding FDA drug shortage and manufacturing volume reporting requirements, as well as provisions regarding supply chain security, such as risk management plan requirements, and the promotion of supply chain redundancy and domestic manufacturing. As part of the CARES Act implementation, the FDA issued a guidance on the reporting of the volume of drugs produced, which reporting will require additional administrative efforts by drug manufacturers.

## [Table of Contents](#)

Moreover, increased attention to the containment of healthcare costs in the U.S. and in foreign markets could result in new government regulations that could have a material adverse effect on MEI's business. MEI's ability to commercialize future products will depend in part on the extent to which coverage and reimbursement for the products will be available from government and health administration authorities, private health insurers, and other third party payers. European Union member states and U.S. government and other third party payers increasingly are attempting to contain healthcare costs by consideration of new laws and regulations limiting both coverage and the level of reimbursement for new drugs. MEI's failure to obtain coverage, an adequate level of reimbursement, or acceptable prices for MEI's future products could diminish any revenues it may be able to generate. MEI cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the U.S. or abroad.

MEI's activities also may be subject to state laws and regulations that affect its ability to develop and sell its products. MEI is also subject to numerous federal, state, and local laws relating to such matters as safe working conditions, clinical, laboratory, and manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances. MEI may incur significant costs to comply with such laws and regulations now or in the future, and the failure to comply may have a material adverse impact on its business prospects.

The FDCA includes provisions designed to facilitate the development and expedite the review of drugs and biological products intended for treatment of serious or life-threatening conditions that demonstrate the potential to address unmet medical needs for such conditions or present a significant improvement over existing therapy. These provisions set forth a procedure for designation of a drug as a "fast track product". The fast track designation applies to the combination of the product and specific indication for which it is being studied. A product designated as fast track is ordinarily eligible for additional programs for expediting development and review, such as increased FDA interactions and rolling submission of the application.

Products that are intended to treat serious or life-threatening conditions and that provide a meaningful therapeutic benefit over existing treatments may also be eligible for accelerated approval. Drug approval under the accelerated approval regulations may be based on evidence of clinical effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. A post-marketing clinical study will be required to verify clinical benefit, and other restrictions to assure safe use may be imposed. Failure to conduct required post-approval studies, or confirm a clinical benefit, will allow the FDA to withdraw the drug or biologic from the market on an expedited basis. Moreover, in recent years, the accelerated approval pathway has come under significant FDA and public scrutiny. Accordingly, the FDA may be more conservative in granting accelerated approval or, if granted, may be more apt to withdrawal approval if clinical benefit is not confirmed or the risk benefit assessment changes. There may also be legislative or regulatory changes to the accelerated approval pathway which may impact the ability to obtain or maintain any such approvals, if received.

A third potential designation that may be available is breakthrough therapy designation. A breakthrough therapy is a product that is intended, alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. Products designated as breakthrough therapies are eligible for intensive FDA guidance, a commitment from the FDA to involve senior managers and experienced review staff in a proactive collaborative and cross-disciplinary review, rolling submission of the application, and the facilitation of cross-disciplinary review.

Finally, if a product is intended to treat a serious condition and, if approved, would provide significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of the condition, the product may be eligible for priority review meaning that the FDA's goal for the review of an NDA is shortened to six months (after a two month period during which the FDA decides whether the application is ready for filing) rather than the standard review of ten months from application acceptance. Currently, MEI has fast track designation for one of its clinical programs (zandelisib for patients with relapsed follicular lymphoma who have received at least two prior systemic therapies). If MEI should seek additional designations for any of its

## [Table of Contents](#)

programs, MEI cannot be assured that it will be granted by the FDA. There is also no guarantee that MEI will be able to maintain any designation that it has received or may receive.

Following the FDA's approval of an NDA, sponsors are required to list with the FDA each patent with claims that cover the applicant's drug or a method of using the drug. These patents are published in the FDA's list of Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can be cited by potential competitors as a reference listed drug in support of a 505(b)(2) NDA or an Abbreviated New Drug Application, ("ANDA"). In an effort to clarify which patents must be listed in the Orange Book, in January 2021, Congress passed the Orange Book Transparency Act of 2020, which largely codifies the FDA's existing practices into the FDCA.

A 505(b)(2) NDA is an application that contains full reports of investigations of safety and efficacy but where at least some of the information required for approval comes from investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. This regulatory pathway enables the applicant to rely, in part, on the FDA's prior findings of safety and efficacy for an existing product, or published literature. An ANDA provides for marketing of a generic drug product that has the same active ingredients, dosage form, strength, route of administration, labeling, performance characteristics and intended use as a previously approved product. ANDA applicants generally must only scientifically demonstrate that their product is bioequivalent to, or performs in the same manner as, the innovator drug and can often be substituted by pharmacists under prescriptions written for the reference listed drug.

Generally, the FDA may not approve an ANDA or 505(b)(2) NDA unless the reference listed drug's Orange Book listed patents have expired and/or if the applicant certifies that it is not seeking approval for a patented method of use. The FDA may approve these applications, however, if the 505(b)(2) NDA or ANDA sponsor certifies that the Orange Book listed patents for the reference listed drug are invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. This later certification is called a paragraph IV certification. If the ANDA or 505(b)(2) NDA applicant has made a paragraph IV certification, following notice to the NDA and patent holders, the NDA and patent holders may then initiate a patent infringement lawsuit. If a lawsuit is brought, the FDA may not make an approval effective until the earlier of 30 months from the patent or application owner's receipt of the notice of the paragraph IV certification, the expiration of the patent, when the infringement case concerning each such patent is favorably decided in the applicant's favor or settled, or such shorter or longer period as may be ordered by a court.

Recently, Congress and U.S. federal administrative agencies have taken certain measures to increase drug competition and thus decrease drug prices, including by facilitating 505(b)(2) NDAs and ANDAs, and by introducing additional products into the U.S. market. For example, the FDA finalized a rule and a guidance to facilitate drug importation. Congress also passed a bill requiring sponsors of NDA products to provide sufficient quantities of drug product on commercially reasonable market-based terms to entities developing generic and 505(b)(2) products. This bill also included provisions on shared and individual REMS for generic drug products.

Under the Drug Price Competition and Patent Term Restoration Act of 1984, a sponsor may obtain marketing exclusivity for a specified period of time following FDA approval of certain drug applications. For example, new drugs containing new chemical entities that have not been previously approved by the FDA may obtain five years of exclusivity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the therapeutic activity of the drug substance. During the exclusivity period, the FDA may not accept for review an ANDA or a 505(b)(2) NDA submitted by another company that contains the previously approved active moiety. However, an ANDA or 505(b)(2) NDA may be submitted after four years if it contains a paragraph IV certification. This exclusivity is not absolute. For instance, it will not delay the submission or approval of a full NDA; though, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and efficacy.

## [Table of Contents](#)

Following NDA approval, a patent owner may obtain an extension of a single unexpired patent that has not previously been extended for a period equal to one-half the period of time elapsed between the filing of an IND and the filing of the corresponding NDA plus the period of time between the filing of the NDA and FDA approval, with a five year maximum patent extension. The total patent life of the product with the extension cannot exceed fourteen years from the product's approval date. The period of patent extension may also be reduced for any time that the applicant did not act with due diligence. MEI cannot be certain that it will be able to take advantage of either the patent term extension or marketing exclusivity provisions of these laws or that, if received, they will adequately protect any approved products from competition.

The Best Pharmaceuticals for Children Act ("BPCA") was reauthorized and amended by the FDA Amendments Act of 2007 ("FDAAA"). The reauthorization of BPCA adds an additional six months of marketing exclusivity and patent protection to unexpired exclusivities and unexpired patents listed with the FDA for NDA applicants that conduct acceptable pediatric studies of new and currently marketed drug products for which pediatric information would be beneficial, as identified by the FDA in a Pediatric Written Request. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly address the agreement between the sponsor and the FDA in the Pediatric Written Request, the additional protection is granted.

The Pediatric Research Equity Act ("PREA") also was reauthorized and amended by the FDAAA. The reauthorization of PREA requires that most applications for drugs and biologics include a pediatric assessment (unless waived or deferred) to ensure the drugs' and biologics' safety and effectiveness in children. Such pediatric assessment must contain data, gathered using appropriate formulations for each age group for which the assessment is required, that are adequate to assess the safety and effectiveness of the drug or the biological product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the drug or the biological product is safe and effective. The pediatric assessments can only be deferred provided there is a timeline for the completion of such studies. The FDA may waive (partially or fully) the pediatric assessment requirement for several reasons, including if the applicant can demonstrate that reasonable attempts to produce a pediatric formulation necessary for that age group have failed. Orphan products are also exempt from the PREA requirements. The Food and Drug Administration Safety and Innovation Act signed into law on July 9, 2012, permanently renewed and strengthened BPCA and PREA.

Under the FDA Reauthorization Act of 2017, sponsors submitting original applications on or after August 18, 2020, for product candidates intended for the treatment of adult cancer which are directed at molecular targets that the FDA determines to be substantially relevant to the growth or progression of pediatric cancer must submit, prior to marketing application submission, an initial Pediatric Study Plan for FDA agreement, and with the application, reports from molecularly targeted pediatric cancer clinical investigations designed to yield clinically meaningful pediatric study data, using appropriate pediatric formulations, to inform potential pediatric labeling. While orphan products are not exempt from this requirement, the FDA may grant full or partial waivers, or deferrals, for submission of data.

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a "rare disease or condition," which generally is a disease or condition that affects fewer than 200,000 individuals in the U.S. Additionally, sponsors must present a plausible hypothesis for clinical superiority to obtain orphan drug designation if there is a product already approved by the FDA that is considered by the FDA to be the same as the already approved product and is intended for the same indication. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. Orphan drug designation does, however, entitle a party to financial incentives such as opportunities for grant funding towards clinical study costs, tax advantages, and certain user-fee waivers. The tax advantages, however, were limited in the 2017 Tax Cuts and Jobs Act. If a product which has an orphan drug designation subsequently receives the first FDA approval for the indication for which it has such designation, the product is entitled to orphan exclusivity, i.e., the FDA may not approve any other applications to market the same drug for the same indication for a period of seven years, except in limited circumstances. If there is already a product approved by the FDA

that is the same product for the same indication, the orphan designated product will only receive orphan drug exclusivity if the prior hypothesis of clinical superiority is demonstrated.

#### *Pharmaceutical Coverage, Pricing and Reimbursement & Healthcare Reform*

In addition, future sales of MEI's products, if approved for marketing, will depend, in part, on the availability and extent of coverage and reimbursement by third-party payors, such as government health programs, including Medicare and Medicaid, commercial insurance, and managed healthcare organizations. These third-party payors are increasingly challenging the price and limiting the coverage and reimbursement amounts for medical products and services. There may be significant delays in obtaining coverage and reimbursement for approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA or regulatory authority in other countries. It is time-consuming and expensive to seek reimbursement from third-party payors. Moreover, eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers MEI's costs, including research, development, manufacture, sale and distribution. In the United States, third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies, but they also have their own methods and approval process apart from Medicare coverage and reimbursement determinations.

In addition, the containment of healthcare costs has become a priority for federal and state governments, and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement, and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit MEI's net revenue and results. Decreases in third-party reimbursement for MEI's product candidates or a decision by a third-party payor to not cover MEI's product candidates could reduce physician usage of the product candidate and have a material adverse effect on MEI's sales, results of operations and financial condition. Moreover, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. Individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Most recently, on August 16, 2022, President Biden signed into the law the Inflation Reduction Act of 2022, or the IRA. Among other things, the IRA has multiple provisions that may impact the prices of drug products that are both sold into the Medicare program and throughout the United States.

#### *Foreign Regulatory Requirements*

Outside the U.S., MEI's ability to market its products will also be contingent upon receiving marketing authorizations from the appropriate regulatory authorities and compliance with applicable post-approval regulatory requirements. Although the specific requirements and restrictions vary from country to country, as a general matter, foreign regulatory systems include risks similar to those associated with the FDA's regulations, described above.

Under European Union regulatory systems, marketing authorizations may be submitted either under a centralized or a decentralized procedure ("DCP"). Under the centralized procedure, a single application to the EMA leads to an approval granted by the European Commission which permits the marketing of the product throughout the EU. The centralized procedure is mandatory for certain classes of medicinal products such as new substances for the treatment of oncology. In addition, all medicinal products developed by certain biotechnological means, and those developed for cancer and other specified diseases and disorders, must be authorized via the centralized



procedure. The centralized procedure will apply to any of MEI's products that are developed by means of a biotechnology process or are intended for treatment of cancer. The DCP is used for products that are not eligible or not required to be authorized by the centralized procedure. The centralized procedure is optional for certain other products. Since the exit of the UK from the European Union, the UK has been excluded from the centralized procedure. It will be necessary for applicants to make a separate application to the UK Medicines and Healthcare products Regulatory Agency ("MHRA") for a UK marketing authorization. There is currently no procedure for mutual EU/UK recognition of new medicinal products.

As with FDA approval, MEI may not be able to secure regulatory approvals in the EU in a timely manner, if at all. Additionally, as in the U.S., post-approval regulatory requirements, such as those regarding product manufacture, marketing, or distribution, would apply to any product that is approved in the EU, and failure to comply with such obligations could have a material adverse effect on MEI's ability to successfully commercialize any product.

The conduct of clinical trials in the European Union is governed by the European Clinical Trials Regulation ("CTR"), which was implemented in June 2022. This Regulation governs how regulatory bodies in member states control clinical trials. No clinical trial may be started without a clinical trial authorization granted by the national competent authority and favorable ethics approval. Under the Regulation, clinical trial sponsors were able to use the Clinical Trials Information System ("CTIS") since 31 January 2022, but are not obliged to use it immediately, in line with a three-year transition period. National regulators in the EU Member States and EEA countries could use the CTIS since January 31, 2022. With the exit of the UK from the European Union, the UK did not implement the CTR and the UK provisions implementing the previous law as set out in the previous Clinical Trial Directive (which fundamentally covered the same area as the CTR but was far less detailed and predated the CTIS) will continue to apply until amended by the UK.

Accordingly, there is a marked degree of change and uncertainty both in the regulation of clinical trials and in respect of marketing authorizations which MEI faces for its products in the EU.

### **Manufacturing**

MEI does not have the facilities or capabilities to commercially manufacture any of its drug candidates. MEI is and expects to continue to be dependent on contract manufacturers for supplying its existing and future candidates for clinical trials and commercial scale manufacturing of its candidates in accordance with regulatory requirements, including cGMP. Contract manufacturers may utilize their own technology, technology developed by MEI, or technology acquired or licensed from third parties. FDA approval of the manufacturing procedures and the site will be required prior to commercial distribution.

### **Human Capital Management**

As of March 31, 2022, MEI had 73 employees, 20 of whom hold a Ph.D. or M.D. degree. Other personnel resources are used from time to time as consultants or third party service organizations on an as-needed basis. All members of MEI's senior management team have prior experience with pharmaceutical, biotechnology or medical product companies. MEI believes that it has been successful in attracting skilled and experienced personnel, but there can be no assurance that MEI will be able to attract and retain the individuals needed.

MEI's people are a critical component in its continued success. MEI strives to create a workplace of choice to attract, retain and develop top talent to achieve its strategic goals. MEI strives to maximize the potential of its human capital resources by creating a respectful, rewarding, and inclusive work environment that enables its employees to further its mission. MEI adheres to a philosophy that includes, among other things, commitments to create ongoing job opportunities, pay fair wages, and protect worker health and safety.

MEI invests in its workforce by offering competitive salaries and benefits. MEI endeavors to foster a strong sense of ownership by offering stock options under its equity incentive plan. MEI also offers comprehensive and locally relevant benefits for all eligible employees.



---

## [Table of Contents](#)

MEI focuses on its culture through a combination of regular training for employees at all levels, policies and practices in support of these goals, and a variety of internal and community-based events and actions that reinforce the power of its values and the unique characteristics of each of its employees.

None of MEI's employees are represented by a labor union or covered by collective bargaining agreements. MEI has never experienced a work stoppage and believes MEI's relationship with its employees is good. Management considers its relations with employees to generally be positive.

### **Properties**

MEI occupies 45,100 square feet of office space in San Diego, California under a lease that expires in November 2029. MEI believes its current office space is adequate for its immediate needs and that suitable space will be available as and when needed.

### **Legal Proceedings**

MEI has no material pending legal proceedings.

### **Available Information**

MEI's annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed with or furnished to the Securities and Exchange Commission pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, are available free of charge through its website at [www.meipharma.com](http://www.meipharma.com) as soon as reasonably practicable after they are electronically filed with, or furnished to, the Securities and Exchange Commission. Further, the Securities and Exchange Commission maintains an internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC, and can be found at <http://www.sec.gov>.

## INFINITY'S BUSINESS

Infinity is a clinical-stage innovative biopharmaceutical company dedicated to developing novel medicines for people with cancer. Infinity combines proven scientific expertise with a passion for developing novel small molecule drugs that target disease pathways for potential applications in oncology. Infinity is focused on advancing eganelisib, also known as IPI-549, an orally administered, clinical-stage, immuno-oncology product candidate that reprograms macrophages through selective inhibition of PI3K-gamma. Infinity has retained worldwide development and commercialization rights to eganelisib, subject to certain success-based milestone payment obligations to its licensor, Takeda, which are described in more detail under "Business Overview - Alliances, Collaborations, and Other Arrangements - Takeda."

Selective inhibition of PI3K-gamma by eganelisib has been shown in preclinical studies to reprogram macrophages from a pro-tumor, immunosuppressive function, to an anti-tumor, immune activating function and to enhance the activity of, and overcome resistance to, checkpoint inhibitors. These preclinical findings indicate that eganelisib may have the potential to treat a broad range of solid tumors and represents a potentially additive or synergistic approach to restoring anti-tumor immunity in combination with other immunotherapies such as checkpoint inhibitors. Further, preclinical studies showed that eganelisib significantly inhibits the regrowth of tumors that can occur following treatment with chemotherapy.

On February 22, 2023, MEI, Infinity, and Merger Sub entered into the Merger Agreement, pursuant to which, among other matters, and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into Infinity, with Infinity continuing as a wholly owned subsidiary of MEI and the surviving corporation of the Merger. If the Merger is completed the combined company will combine the expertise and resources of MEI and Infinity to advance a pipeline of three clinical-stage oncology drug candidates.

Infinity expects to devote significant time and resources to the completion of the Merger. However, there can be no assurances that such activities will result in the completion of the Merger. Further, the completion of the Merger may ultimately not deliver the anticipated benefits or enhance shareholder value. If the Merger is not completed, Infinity will consider alternative courses of action. Infinity considers one of the following courses of action to be the most likely alternatives if the Merger is not completed:

- *Pursue another strategic transaction.* Infinity may resume the process of evaluating a potential strategic transaction, including the sale of the company or its assets. Based on Infinity's prior assessment, it does not expect that it would have the necessary time or financial resources to pursue another strategic transaction like the proposed Merger.
- *Wind down the company.* If the Merger does not close and Infinity is unable to enter into another strategic transaction, its board of directors may conclude that it is in the best interest of stockholders to cease normal operations and wind down the company through bankruptcy or dissolution proceedings. In such case, there would be no assurances as to the amount or timing of available cash remaining, if any, to distribute to stockholders after paying its obligations and setting aside funds for reserves.

### Merger Agreement

The Merger is intended to qualify as a reorganization within the meaning of Section 368(a) of the Code. Upon the terms and subject to the conditions set forth in the Merger Agreement, at Effective Time, each share of Infinity Common Stock will be converted into the right to receive 0.052245 (the "Exchange Ratio") shares of MEI Common Stock. Holders of Infinity Common Stock will receive cash in lieu of fractional shares. At the Effective Time, Infinity's common stockholders will own approximately 42%, and MEI's common stockholders will own approximately 58%, of the outstanding shares of common stock of the combined company.

In addition, as of the Effective Time, MEI will assume each Infinity incentive plan and each outstanding option to purchase shares of Infinity Common Stock, excluding options granted under the Infinity 2013 Employee Stock

## [Table of Contents](#)

Purchase Plan, as amended. Each such option so assumed by MEI will continue to have, and be subject to, the same terms and conditions applicable to such option immediately prior to the Effective Time (after giving effect to the full acceleration of vesting of such options applicable to the option in connection with the Merger), except that (A) such option will be exercisable for that number of shares of MEI Common Stock equal to the number of shares of Infinity Common Stock subject to such option immediately prior to the Effective Time multiplied by the Exchange Ratio and rounded down to the nearest whole share, and (B) the exercise price per share will be the exercise price per share in effect for that option immediately prior to the Effective Time divided by the Exchange Ratio and rounded up to the nearest whole cent.

Consummation of the Merger is subject to certain closing conditions, including, among other things, the (1) approval by the stockholders of MEI of the issuance of shares of MEI Common Stock pursuant to the Merger Agreement (the “MEI Stock Issuance”), (2) the adoption by the stockholders of Infinity of the Merger Agreement, (3) authorization for listing on The Nasdaq Capital Market of the shares of MEI Common Stock (including the shares to be issued in the Merger), subject to official notice of issuance, (4) effectiveness of the Registration Statement and (5) the absence of any law, judgment, order, injunction, ruling, writ award or decree by any governmental entity of competent jurisdiction restraining, enjoining or otherwise prohibiting consummation of the Merger. Each party’s obligation to consummate the Merger is also subject to other specified customary conditions, including (1) the representations and warranties of the other party being true and correct as of the date of the Merger Agreement and as of the Closing Date, generally subject to an overall material adverse effect qualification, (2) the performance in all material respects by the other party of its obligations under the Merger Agreement required to be performed on or prior to the date of the closing of the Merger, and (3) the absence of a continuing material adverse effect with respect to the other party. Infinity’s obligation to consummate the Merger is also subject to the condition that MEI’s final net cash is greater than or equal to \$80,000,000 at closing if closing occurs on or before June 30, 2023, \$78,000,000 at closing if closing occurs after June 30, 2023 but on or before July 31, 2023 and \$76,000,000 at closing if closing occurs after July 31, 2023 but on or before August 31, 2023. MEI’s obligation to consummate the Merger is also subject to the condition that Infinity’s final net cash is greater than or equal to \$4,000,000 at closing if closing occurs on or before June 30, 2023, \$3,000,000 at closing if closing occurs after June 30, 2023 but on or before July 31, 2023, and \$2,000,000 at closing if closing occurs after July 31, 2023 but on or before August 31, 2023.

The Merger Agreement contains certain termination rights for both Infinity and MEI. Upon termination of the Merger Agreement by MEI under specified circumstances, MEI may be required to pay Infinity a termination fee of \$4,000,000 and/or reimburse Infinity’s reasonable out of pocket fees and expenses incurred in connection with the Merger Agreement and the transaction contemplated thereby up to a maximum of \$1,000,000. Upon termination of the Merger Agreement by Infinity under specified circumstances, Infinity may be required to pay MEI a termination fee of \$2,900,000 and/or reimburse MEI’s reasonable out of pocket fees and expenses incurred in connection with the Merger Agreement and the transaction contemplated thereby up to a maximum of \$1,000,000.

MEI and Infinity have agreed to use reasonable best efforts and take all necessary action such that, as of the Effective Time, the board of directors of the combined company will consist of eight members, with four such members designated by MEI, three such members designated by Infinity (one of whom shall be designated by Infinity as the chair of the board of directors of the combined company) and one such member designated jointly by MEI and Infinity, with at least one MEI designee and one Infinity designee appointed to each of the three classes of the MEI classified board and MEI’s fourth designee and the jointly designated designee appointed to the class of MEI directors whose terms expire at the next annual meeting of MEI’s stockholders. The parties have also agreed that David M. Urso will be elected as Chief Executive Officer, Robert Ilaria, Jr. will be elected as Chief Medical Officer, and Stéphane Peluso will be elected as Chief Scientific Officer.

## Scientific Overview

### Preclinical Rationale for Development of Eganelisib: Targeting the Immunosuppressive Microenvironment in Solid Tumors

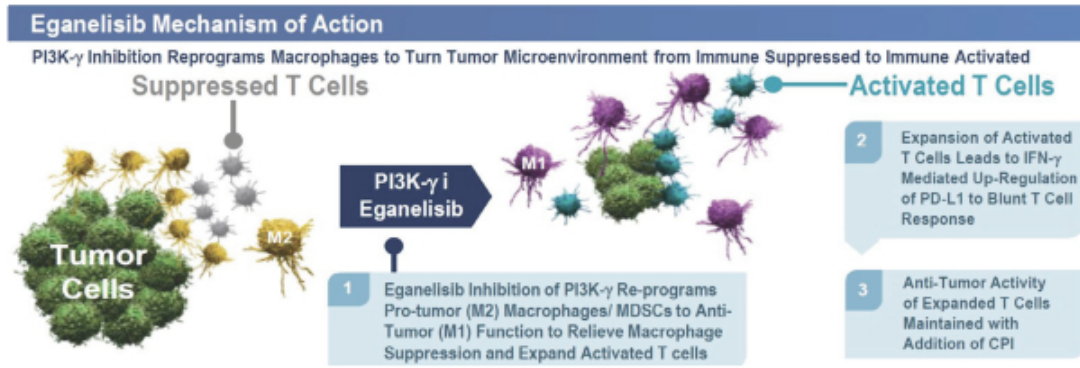
#### *Role of PI3K-gamma in Cancer Growth and Survival*

The body's immune system is responsible for fighting infections and disease, including cancer, and helping the body to heal. The immune system functions by identifying and destroying foreign cells and substances within the body. When confronted by pathogens or disease, an early response of the body's immune system comes in the form of macrophages, a type of white blood cell that produces pro-inflammatory proteins called cytokines. These cytokines activate T cells, another type of immune cell, to attack the threat to the body's health. The macrophages then transition to producing other types of cytokines that dampen T cell activation and promote tissue growth, which, in turn, stimulates repair of the affected tissue.

Cancer cells arise from normal cells that have changed in a way that allows them to grow in an unregulated manner. Cancer cells are not always recognized by the body's immune system as foreign cells that should be destroyed. However, even if cancer cells are recognized by the immune system, both normal homeostatic and cancer cell-induced mechanisms exist to dampen this immune response, including upregulation of "checkpoint proteins," such as programmed death receptor 1 ("PD-1"), on T cells and programmed-death ligand 1 ("PD-L1"), on tumor and immune cells. Additionally, in solid tumors there exists a tumor microenvironment ("TME"), which refers to the non-cancerous cells present in the tumor. Cells within the TME, including macrophages, can suppress the body's immune response and provide signals to cancer cells that facilitate tumor growth. The presence of the pro-tumor, immunosuppressive TME is thought to be one reason why some cancer therapies, including checkpoint inhibitors, have shown limited efficacy and durability to date. PI3K-gamma expression is restricted to the myeloid cell compartment within the TME, including tumor-associated macrophages and myeloid-derived suppressor cells ("MDSCs"), where it plays a key role in maintaining the immunosuppressive function of these cells. Targeting these pro-tumor, immunosuppressive cells represents an emerging approach within the field of cancer immunotherapy, and inhibition of PI3K-gamma by eganelisib represents a novel approach to targeting this immunosuppressive microenvironment that has the potential to be nonredundant and complementary to current approaches such as checkpoint inhibitor therapy.

#### *Anti-Tumor Activity of Eganelisib in Preclinical Models*

Infinity's preclinical research has demonstrated that blockade of PI3K-gamma by treatment with eganelisib leads to a shift in the type of macrophages present in the TME from pro-tumor, immunosuppressive macrophages, known as M2 macrophages, to anti-tumor, immune activating macrophages, known as M1 macrophages. In preclinical studies, treatment with eganelisib in tumor models was shown to increase the ratio of M1 to M2 macrophages, the number of T cells that attack the tumor, and the production of pro-inflammatory, anti-tumor cytokines. The body's natural defense to prevent an over-active immune response involves upregulation of checkpoint proteins, including the upregulation of PD-L1 in response to T cell dependent interferon-gamma signaling. Preclinical data has shown that blocking the PD-1/PD-L1 axis with a checkpoint inhibitor in combination with eganelisib both expanded the number of anti-tumor T cells and enhanced the anti-tumor activity of expanded T cells in preclinical models.



Preclinical studies to investigate the anti-tumor activity of eganelisib have demonstrated dose-dependent, single-agent anti-tumor activity in multiple solid tumor models, including syngeneic models of lung cancer, colon cancer and breast cancer. Additionally, in preclinical models, treatment with eganelisib in combination with a checkpoint inhibitor showed greater tumor growth inhibition and extended survival, including a greater number of complete tumor regressions, compared to treatment with either eganelisib or the checkpoint inhibitor alone. The combination treatment resulted in long-lasting anti-tumor immune memory as evidenced by the lack of tumor growth when animals were re-challenged post-treatment with the same tumor cells in the absence of any treatment.

**Overcoming Resistance to Checkpoint Inhibition**

In recent years, checkpoint inhibitors (“CPIs”), have shown promising results as a treatment for multiple types of cancer, but most patients do not respond, and most who do respond eventually become resistant to and require treatment with an additional therapy. Infinity’s preclinical studies in a number of tumor models demonstrated that resistance to checkpoint inhibition is associated with increased numbers of tumor-associated macrophages (TAMs) and is directly mediated by the immunosuppressive activity of these macrophages on T cells. Furthermore, the data demonstrated that inhibition of PI3K-gamma by eganelisib reprogrammed macrophages to a less immunosuppressive state, enhanced anti-tumor cytotoxic T cell activity, and restored sensitivity to checkpoint inhibitors. These data demonstrated that eganelisib treatment was able to reverse the lack of response to checkpoint inhibitors in models that were refractory to checkpoint inhibitor therapy due to the presence of enhanced numbers of immunosuppressive macrophage.

**Eganelisib Clinical Development Program**

**2023 Eganelisib Development Strategy**

Subject to the successful close of the Merger, the combined company plans to initiate in the third quarter of 2023, subject to FDA review, a global, randomized, controlled Phase 2 clinical trial of eganelisib plus pembrolizumab versus pembrolizumab for the potential treatment of first line relapsed or metastatic head and neck squamous cell carcinoma (“HNSCC”).



The primary endpoint of the Phase 2 study is anticipated to be overall survival, and Infinity plans to have initial safety and progression free survival (“PFS”) data in the second half of 2024. This planned study is intended to address a clear medical need, as patients with recurrent or metastatic HNSCC with a PD-L1 combined positive score (“CPS”) of 1 or greater have relatively short median progression free survival (3.2 months) and overall survival (12.3 months) when treated with pembrolizumab monotherapy. CPS is a scoring system used to determine the proportion of cells (includes tumor and immune cells) that stain positive for PD-L1 relative to all viable tumor cells. Head and neck cancers include cancers of the oral cavity, oropharynx, hypopharynx, and larynx, and it is estimated that squamous cell carcinomas account for more than 90% of these tumors (Tandon P, et al, *Contemp Oncol (Pozn)* 2017). In 2022, it is estimated that there were 66,470 new cases of head and neck cancer, or approximately 3.5% of new cancer cases in the United States, and an estimated 15,050 deaths (Siegel R., et al, *Cancer J Clin, Cancer Statistics* 2022). Worldwide, an estimated 798,577 people were diagnosed with head and neck cancer in 2020 with an estimated 387,117 people dying from the disease (Sung H., et al, *CA Cancer J Clin, Global Cancer Statistics* 2020). The incidence of HNSCC continues to rise, with a 30% anticipated increase by 2030, mostly attributed to the increase in human papillomavirus (“HPV”), associated oropharyngeal squamous cell carcinoma in younger individuals. (Ruffin et al, *Nature Reviews Cancer*, 2022).

This study follows an encouraging signal from Infinity’s MACrophage Reprogramming in Immuno-Oncology-1 study (“MARIO-1”), its Phase 1/1b clinical study designed to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, and activity for eganelisib - both as a monotherapy and in combination with nivolumab - in 224 patients with advanced solid tumors. As of the study’s December 13, 2021 database lock, the median progression free survival (“mPFS”) rate of 3.7 months (1.9, 5.5) was observed in the HNSCC cohort in patients with immediate prior progression on CPI therapy. The mPFS for all patients receiving pembrolizumab monotherapy was 2.3 months in KEYNOTE-048, the benchmark study investigating pembrolizumab monotherapy and pembrolizumab plus chemotherapy or cetuximab plus chemotherapy as a first-line therapy in advanced HNSCC patients. However, Infinity cautions you that the risks in cross-trial comparisons limit its ability to reach definitive conclusions without a prospective, adequately powered, randomized controlled trial. Consequently, the data and results from the HNSCC cohort in MARIO-1 may not be comparable to KEYNOTE-048 for reasons including, but not limited to, differences in clinical trial protocols, patient characteristics, safety management, sample sizes, duration of treatment, median duration of follow up, and other factors. Further, in MARIO-1, a disease control rate (“DCR”) of 36.4% (4 of 11 patients), an overall response rate (“ORR”), of 18.2% (2 of 11 patients), and an mPFS rate of 5.3 months (1.9, 11.1) were observed in the HNSCC cohort in patients with immediate prior progression on CPI therapy and two or fewer prior lines of therapy.

### ***MARIO-3***

MARIO-3 is a multi-arm Phase 2 study designed to evaluate eganelisib in the front-line treatment for metastatic triple negative breast cancer (“mTNBC”), and metastatic renal cell carcinoma (“mRCC”). Infinity has completed enrollment in both cohorts. The mTNBC cohort is evaluating eganelisib in combination with atezolizumab, an anti-PD-L1 monoclonal antibody also known as Tecentriq®, and nab-paclitaxel, an albumin-bound chemotherapy drug also known as Abraxane®, in approximately 60 patients with unresectable locally advanced or mTNBC. The mRCC cohort is evaluating eganelisib in combination with atezolizumab and bevacizumab, also known as Avastin®, in approximately 30 patients with mRCC. Using the same cutoff standard used in the F. Hoffmann-La Roche Ltd. (“Roche”), benchmark IMpassion130 study for PD-L1, Infinity refers to tumors that test below 1% PD-L1 at baseline as “PD-L1(-) tumors” and tumors that test equal to or greater than 1% as “PD-L1(+) tumors.” Infinity entered into clinical supply agreements with Roche, under which Roche has agreed to supply atezolizumab and bevacizumab for its use in MARIO-3.

As of an October 8, 2022, data cut from the mTNBC cohort, 62 patients were enrolled and evaluable for safety, and 57 patients were evaluable for efficacy, with a median duration of follow-up of 10.0 (8.1,14.2) months. Of the 57 evaluable patients:

- 35 patients (61.4%) had PD-L1(-) tumors;

## Table of Contents

- 18 patients (31.6%) had PD-L1(+) tumors; and
- 4 patients (7.0%) had tumors of undetermined PD-L1 status

The October 8, 2022 data snapshot suggests a potential long-term PFS benefit with a one-year PFS rate of 36.0% (23.7, 49.3) in MARIO-3, including in patients with both PD-L1(+) and PD-L1(-) tumors, compared to 23.7% (19.6, 27.9) in the benchmark IMpassion130 study evaluating atezolizumab in combination with nab-paclitaxel compared to placebo with nab-paclitaxel in patients with mTNBC. Infinity designed the MARIO-3 trial to be substantially similar to the IMpassion130 study with respect to inclusion and exclusion criteria, PD-L1 diagnostic, and other factors; however, the risks in cross-trial comparisons limit Infinity's ability to reach definitive conclusions without a prospective, adequately powered, randomized controlled trial. Consequently, the data and results from MARIO-3 may not be comparable to IMpassion130 for reasons including differences in clinical trial protocols, safety management, sample sizes, duration of treatment, median duration of follow up, and other factors.

### MARIO-3 One-Year Progression-Free Survival Rate Compared to IMpassion130 Data

	ITT		PD-L1 (+)		PD-L1 (-)	
	MARIO-3 n=57 <sup>^</sup>	IMpassion130 n=451 <sup>^^</sup>	MARIO-3 n=18	IMpassion130 n=185	MARIO-3 n=35	IMpassion130 n=266
One-Year PFS Rate, % (95% CI)	36.0% (23.7, 49.3)	23.7% (19.6, 27.9)	37.5% (16.8, 60.9)	29.1% (22.2, 36.1)	34.7% (19.6, 51.6)	NR*
One-Year PFS Rate improvement compared to IMpassion130	52% relative improvement		29% relative improvement		(46% relative improvement compared to IMpassion130 ITT)	
Median duration of follow up, months (95% CI)	10.0 (8.1, 14.2)	13.0 (NR*)	9.9 (5.5, NA)	NR*	9.3 (5.9, 14.2)	NR*

Data Snapshot: October 8, 2022, analysis date November 4, 2022

<sup>^</sup> 4 patients of unknown PD-L1 status

<sup>^^</sup> Schmid et al NEJM 2018

\* NR = Not Reported

\*\* NE = Not Evaluable

### Additional MARIO-3 Data by Patient Population Compared to IMpassion130 Data

	PD-L1 (+)		PD-L1 (-)	
	MARIO-3 n=18	IMpassion130 <sup>^</sup> n=185	MARIO-3 n=35	IMpassion130 <sup>^</sup> n=265
CR, % (n) <sup>^^</sup>	16.7 (3)	10.3 (19)	5.7 (2)	4.9 (13)
ORR, % (n) <sup>^^</sup>	66.7 (12)	58.9 (109)	54.3 (19)	54.0 (143)
mDOR (mos) n (95% CI) <sup>^</sup>	11.7 n=12 (1.8, NA)	8.5 n=109 (7.3, 9.7)	7.4 n=19 (3.7, NA)	NR*
mDOR increase compared to IMpassion130	3.2 mos (37.6% increase)		NE**	
mPFS, mos (95% CI)	6.4 (3.6, NA)	7.5 (6.7, 9.2)	7.3 (5.2, 13.3)	5.6 (5.5, 7.3)

Data Snapshot: October 8, 2022, analysis date November 4, 2022

<sup>^</sup> Schmid et al NEJM 2018 with PD-L1(-) data calculated based on ITT and PD-L1(+) data

<sup>^^</sup> Includes unconfirmed and confirmed responses for MARIO-3



**Table of Contents**

\* NR = Not Reported  
 \*\* NE = Not Evaluable

No new safety signals were observed as of the October 8, 2022, data snapshot, and the MARIO-3 safety profile continued to be consistent with expectations for the three component drugs.

**Most Common Treatment-Related TEAEs in ≥ 10% of All Treated Patients<sup>^\*</sup> (n=62)**

<u>Preferred Term/Grouped Term</u>	<u>Treatment-related TEAE (All), n (%)</u>	<u>Treatment-related TEAE (≥ Gr. 3), n (%)</u>
Fatigue	30 (48.4)	4 (6.5)
Skin AEs	29 (46.8)	7 (11.3)
Nausea	28 (45.2)	0 (0.0)
Hepatic AEs <sup>**</sup>	24 (38.7)	15 (24.2)
Peripheral neuropathy	19 (30.6)	7 (11.3)
Diarrhea	18 (29.0)	3 (4.8)
Alopecia	16 (25.8)	0 (0.0)
Neutropenia AEs	16 (25.8)	9 (14.5)
Vomiting	13(21.0)	1 (1.6)
Pyrexia	10 (16.1)	0 (0.0)
Peripheral neuropathy	19 (30.6)	7 (11.3)
Stomatitis	9 (14.5)	0 (0.0)
Decreased appetite	8 (12.9)	0 (0.0)
Headache	8 (12.9)	0 (0.0)
Weight decreased	7 (11.3)	1 (1.6)
Dysgeusia	7 (11.3)	0 (0.0)
Constipation	7 (11.3)	0 (0.0)

Data Snapshot: July 23, 2022

Presented in descending order of all treatment-related treatment-emergent adverse effect (“TEAE”)

<sup>^</sup> Treatment-related is related to any of the study drugs (eganelisib, atezolizumab, nab-paclitaxel)

\* No treatment-related Grade 5 AEs

\*\* One Grade 4 event and no event met Hy’s Law criteria

Hepatic, skin, neutropenia, and peripheral neuropathy represent grouped preferred terms

**Treatment Discontinuation: 74% of MARIO-3 Patients Remained on Triplet Regimen Compared to 81% of Patients with the IMpassion130 Doublet**

	<u>MARIO-3 Egan+ Atezo+Nab-Pac (n=62), n (%)</u>	<u>IMpassion130* Atezo+Nab-Pac (n=460), n (%)</u>
<b>All-causality AEs</b>		
Any grade	61 (98.4)	457 (99.3)
Grade 3 or 4	41 (66.1)	233 (50.7)
Grade 5	5 (8.1)	6 (1.3)
Serious AEs	22 (35.5)	110 (23.9)
AE leading to any drug withdraw	16 (25.8)	88 (19.1)
AE leading to Atezo withdraw	14 (22.6)	37 (8.0)
AE leading to Nab-Pac withdraw	11 (17.7)	85 (18.5)
<b>Treatment-related AEs<sup>**</sup></b>		
Any grade	60 (96.8)	444 (96.5)

	MARIO-3 Egan+ Atezo+Nab-Pac (n=62), n (%)	IMpassion130* Atezo+Nab-Pac (n=460), n (%)
Grade 3 or 4	42 (67.7)	191 (41.5)
Grade 5	0 (0.0)	2 (0.4)
Serious AEs	9 (14.5)	58 (12.6)

Data Snapshot: July 23, 2022

\* Emens et al., Annals of Oncology 2021

\*\* MARIO-3 data listed are for TEAEs related to any study drug

*The Unmet Needs of Patients with Triple Negative Breast Cancer*

There were estimated to be 287,850 new cases of breast cancer in 2022. Compared to other breast cancer subtypes, TNBC, which is so named because the cancer cells lack estrogen and progesterone receptors and do not make much of the protein called human epidermal growth factor receptor 2 (“HER2”) is aggressive and TNBC patients have limited treatment options. TNBC accounts for up to 15% of all breast cancer in women, and the 5-year survival rate of metastatic TNBC patients is only 12%. Available therapies for advanced front-line TNBC offer limited efficacy, particularly in PD-L1(-) patients.

**MARIO-275**

MARIO-275 is Infinity’s global, randomized, placebo-controlled Phase 2 study evaluating the effect of adding eganelisib to nivolumab, also known as Opdivo®, in checkpoint-naïve advanced urothelial cancer (“UC”), patients whose cancer has progressed or recurred following treatment with platinum-based chemotherapy. Nivolumab is an immune checkpoint inhibitor therapy commercialized by BMS, that targets PD-1, a checkpoint protein that helps regulate the body’s immune system. MARIO-275 is complete and all sites have been closed.

Infinity presented MARIO-275 data at the American Society of Clinical Oncology Genitourinary Cancers Symposium (“ASCO GU”) in February 2021, and presented updates on overall survival data in July 2021 and January 2022, as well as a two-year landmark analysis announced in a press release issued on August 9, 2022. The data from the 49 patients enrolled in the trial include the following findings:

- At a two-year landmark survival analysis presented on of July 29, 2022, 45% of patients in the eganelisib plus nivolumab arm are alive compared to 24% of patients in the nivolumab control arm. The data also suggests a potential durable survival benefit in the PD-L1(-) subgroup, with 38% of patients alive at two years in the eganelisib plus nivolumab arm versus 17% in the control group. No new safety signals were observed during the extended period on treatment.
- Median overall survival (mOS) in the intent to treat population as presented in July 2021 was 15.4 months (6.2, NE) on the eganelisib plus nivolumab combination arm as compared to 7.9 months (2.3, NE) on the control arm of nivolumab alone with a hazard ratio (HR) 0.62 (0.28, 1.36), reflecting a 38% lower probability of death.
- The mOS in PD-L1(-) patients, as updated in January 2022, was 15.3 months (4.7, NE) on the eganelisib plus nivolumab arm versus 7.9 months (1.9, NE) on the nivolumab control arm with an HR 0.58 (0.21, 1.66), reflecting a 42% lower probability of death.

The most common TEAEs for the eganelisib plus nivolumab combination arm across all doses, all causality, were pyrexia (33.3%), decreased appetite (30.3%), pruritus (27.3%), asthenia (27.3%), rash (27.3%), and increased alanine aminotransferase (24.2%); and the most common ≥Grade 3 TEAEs across all doses, all causality, were anemia (12.1%), and hepatic AEs including hepatotoxicity (15.2%), increased ALT (12.1%), and increased AST (12.1%) with no Hy’s Law. No Grade 5 Aes were reported.

## [Table of Contents](#)

Data presented at ASCO GU demonstrated the greatest benefit of the combination of eganelisib and nivolumab was observed in the patient population (n=23) with tumors expressing low levels of PD-L1, with improvement over nivolumab monotherapy (n=7) in ORR (26% vs. 14%); DCR (57% vs. 14%); and best responses of complete response (“CR”) (9% vs. 0%) and stable disease (“SD”) (30% vs. 0%). Of patients with PD-L1 low tumors in the combination arm, 58% (11 of 19) achieved a reduction in tumor burden, compared to 17% (1 of 6) in the nivolumab plus placebo arm.

### *The Unmet Needs of Patients with Urothelial Cancer*

Approximately 95% of bladder cancers are urothelial cancer. According to SEER Cancer Statistics Review estimations of 2022 data, bladder cancer was estimated to be the sixth most common form of cancer in the U.S., with 81,180 new cases, or 4.2% of all new cancers, and 17,100 deaths, or 2.8% of all cancer deaths. According to a recent meta-analysis of clinical studies investigating PD-L1 status in metastatic UC, the ORR in PD-L1 high UC patients is approximately 25% in contrast to an ORR of 14% for patients with low levels of PD-L1 expression. The patients with low levels of PD-L1 expression have a poorer PFS and a poorer OS relative to the PD-L1 high patients. (Tan WP et al. *Bladder Cancer*. 2019;5(3):211-223.) Compounding these disparate outcomes, the majority of patients with metastatic UC are PD-L1 low. (Bellmunt J et al. *Ann Oncol*. 2015;26(4):812-817). Despite significant progress in the advancement of therapeutic options for UC in recent years, including the use of checkpoint inhibitors, there remains an opportunity to improve outcomes.

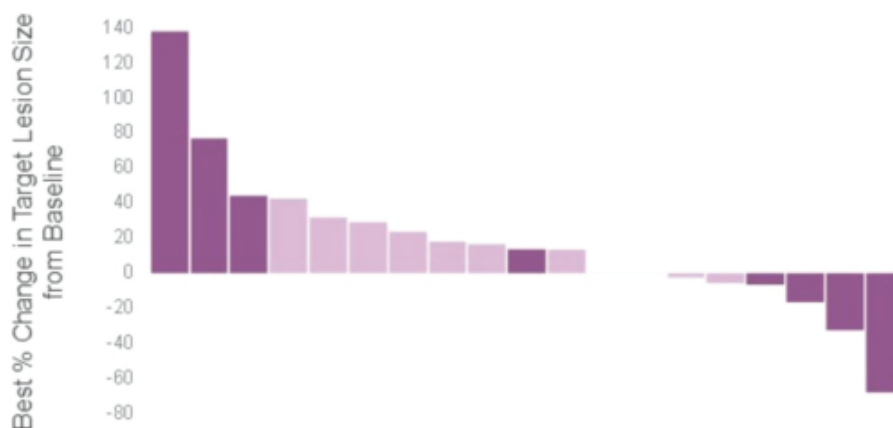
### **MARIO-1**

MARIO-1, Infinity’s Phase 1/1b clinical study designed to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, and activity for eganelisib – both as a monotherapy and in combination with nivolumab – in 224 patients with advanced solid tumors, reached primary completion in December 2021. The study included a dose escalation portion and a combination therapy expansion portion evaluating patients dosed at 40 mg daily (“QD”) of eganelisib in combination with the standard regimen of nivolumab in the following forms of cancer: non-small cell lung cancer, melanoma, HNSCC, TNBC, mesothelioma, adrenocortical carcinoma, and those with high baseline blood levels of MDSCs.

As of the study’s December 13, 2021 database lock, an mPFS rate of 3.7 months (1.9, 5.5) was observed in the HNSCC cohort in patients with immediate prior progression on CPI therapy. The mPFS for all patients receiving pembrolizumab monotherapy was 2.3 months in KEYNOTE-048, the benchmark study investigating pembrolizumab monotherapy, pembrolizumab plus chemotherapy, or “cetuximab” plus chemotherapy as a first-line therapy in recurrent or metastatic HNSCC patients. However, Infinity cautions you that the risks in cross-trial comparisons limit its ability to reach definitive conclusions without a prospective, adequately powered, randomized controlled trial. Consequently, the data and results from the HNSCC cohort in MARIO-1 may not be comparable to KEYNOTE-048 for reasons including, but not limited to, differences in clinical trial protocols, patient characteristics, safety management, sample sizes, duration of treatment, median duration of follow up, and other factors. Further, in MARIO-1, a DCR of 36.4% (4 of 11 patients), an ORR of 18.2% (2 of 11 patients), and an mPFS rate of 5.3 months (1.9, 11.1) were observed in the HNSCC cohort in patients with immediate prior progression on CPI therapy and two or fewer prior lines of therapy.

These findings build on data released regarding the HNSCC cohort at the 2020 Annual Meeting of the Society for Immunotherapy of Cancers, which demonstrated clinical activity of the combination therapy in patients not expected to benefit from CPI alone having progressed on an immediate prior CPI therapy prior to entering MARIO-1.

**MARIO-1: Activity of Eganelisib in Combination with Nivolumab in HNSCC Patients Having Progressed on Immediate Prior Check-Point Inhibitor Therapy**



Source: Cohen, et al., SITC 2020

Safety data across all eganelisib combination cohorts suggests the combination therapy was generally well tolerated and associated with a manageable safety profile at all eganelisib doses tested, up to and including the selected combination therapy expansion dose of eganelisib at 40 mg QD plus the standard regimen of nivolumab. No maximum tolerated dose was determined, and there were no treatment-related deaths. The pharmacokinetic/pharmacodynamic profile of eganelisib (up to the recommended combination expansion dose of 40 mg QD) was unaffected by nivolumab co-administration, and eganelisib in combination with nivolumab reduced immune suppression and increased immune activation, as indicated by analyses of peripheral blood. In eganelisib as monotherapy, no Grade 3 or higher drug related toxicity was observed at eganelisib doses of 10 to 40 mg daily. At an eganelisib monotherapy dose of 60 mg daily, Grade 3 or higher drug-related adverse events were observed, consisting of mainly reversible hepatic enzyme elevations and skin rash. Additional data demonstrated that eganelisib as a monotherapy reduced immune suppression and increased immune activation, as indicated by analyses of peripheral blood.

**Alliances, Collaborations, and Other Arrangements**

Since Infinity’s inception, corporate alliances, license agreements and other strategic arrangements, as well as the sale of securities, have been integral to its strategy. Many of these arrangements have provided access to breakthrough science, significant research and development support and funding, supply of clinical trial materials, and innovative drug development programs, all intended to help Infinity realize the full potential of its product pipeline. For more information related to the arrangements described below, please see Note 9 (Liabilities Related to Sale of Future Royalties) and Note 11 (Strategic Agreements) to Infinity’s consolidated financial statements and related notes included elsewhere in this joint proxy statement/prospectus.

***Mundipharma and Purdue***

Infinity is obligated to pay Mundipharma International Corporation Limited (“Mundipharma”) and Purdue Pharmaceutical Products L.P. (“Purdue”) a 4% royalty in the aggregate on worldwide net sales of eganelisib, duvelisib (“Copiktra®”), a product Infinity out-licensed in 2016; and IPI-926, or patidegib, a product Infinity out-licensed in 2013. After a threshold is met the royalty will be reduced to a 1% royalty on net sales in the United States of such products.

***Verastem, Secura Bio, and HCR***

In 2016, Infinity and Verastem Inc. (“Verastem”) entered into a license agreement (the “Verastem Agreement”) under which Infinity granted to Verastem an exclusive worldwide license for the research, development,

## Table of Contents

commercialization, and manufacture of duvelisib, and products containing duvelisib, which Infinity refers to as the Licensed Products, in each case in oncology indications. In September 2020, Verastem completed a disposition of its rights, title, and interest in and to duvelisib to Secura Bio, Inc. (“Secura Bio”) wherein Secura Bio assumed all liabilities and obligations under the Verastem Agreement, including obligations to pay Infinity royalties on worldwide net sales of Licensed Products ranging from the mid-single digits to the high-single digits, a portion of which Infinity is obligated to share as described in the section below entitled “Takeda.” Infinity now refers to the Verastem Agreement as the Secura Bio Agreement.

In 2019, Infinity and HealthCare Royalty Partners III, L.P. (“HCR”) entered into a purchase and sale agreement (the “HCR Transaction”) providing for the acquisition by HCR of Infinity’s interest in certain royalty payments (the “Purchased Assets”), based on worldwide annual net sales of Licensed Products pursuant to the Secura Bio Agreement. See Note 9 of the notes to Infinity’s consolidated financial statements and related notes included elsewhere in this joint proxy statement/prospectus, for details of the HCR transaction.

Secura Bio is obligated to pay Infinity a royalty of 4% on worldwide net sales of Licensed Products to cover the obligations owed by Infinity to Mundipharma and Purdue, which will reduce to a 1% royalty of net sales in the United States after a certain threshold is met.

### ***PellePharm / Sol-Gel Technologies***

In June 2013, Infinity entered into a license agreement with PellePharm, Inc. (“PellePharm”) under which Infinity granted PellePharm exclusive global development and commercialization rights to its hedgehog inhibitor program, including patidegib. In January 2023, PellePharm announced that such license agreement was assigned to Sol-Gel Technologies, Ltd. (“Sol-Gel”) upon Sol-Gel acquiring all rights and obligations under the license agreement. Infinity now refers to the license agreement with PellePharm as the Sol-Gel Agreement and products covered by the Sol-Gel Agreement as Hedgehog Products. Infinity assessed this arrangement in accordance with ASC 606 and concluded that at the date of contract inception there was only one performance obligation, consisting of the license, which was satisfied at contract inception.

Under the Sol-Gel Agreement, Sol-Gel is obligated to pay Infinity up to \$9.0 million in remaining regulatory and commercial-based milestone payments through the first commercial sale of a Hedgehog Product. Sol-Gel is also obligated to pay Infinity up to \$37.5 million in success-based milestone payments upon the achievement of certain annual net sales thresholds, as well as a share of certain revenue received by Sol-Gel in the event that Sol-Gel sublicenses its rights under the Sol-Gel Agreement and tiered royalties on annual net sales of Hedgehog Products subject to specified conditions. The remaining milestones have not been recognized as they represent variable consideration that is constrained. In making this assessment, Infinity considered numerous factors, including the fact that achievement of the milestones is outside of its control and contingent upon the future success of clinical trials, Sol-Gel’s actions, and the receipt of regulatory approval. As the single performance obligation was previously satisfied, all regulatory and commercial-based milestones will be recognized as revenue in full in the period in which the constraint is removed. Any consideration related to sales-based milestone payments, including royalties, will be recognized when the related sales occur as these amounts have been determined to relate predominantly to the license granted to Sol-Gel and therefore are recognized at the later of when the performance obligation is satisfied, or “the related sales” occur.

Sol-Gel is also obligated to pay Infinity tiered royalties on annual net sales of Hedgehog Products, which are subject to reduction after a certain aggregate funding threshold has been achieved. On January 8, 2020, Infinity entered into the BVF Funding Agreement, as further described in Note 9, pursuant to which Infinity sold its interest in all royalty payments based on worldwide annual net sales of the BVF Licensed Product, excluding Trailing Mundipharma Royalties related to patidegib.

### ***Takeda***

In 2010, Infinity entered into a development and license agreement with Intellikine, Inc. (“Intellikine”) under which Infinity obtained rights to discover, develop and commercialize pharmaceutical products targeting the

## Table of Contents

gamma and/or delta isoforms of PI3K, including eganelisib and duvelisib. In January 2012, Intellikine was acquired by Takeda. In December 2012, Infinity amended and restated its development and license agreement with Takeda and further amended the agreement in July 2014, September 2016, July 2017, and March 2019.

### *Eganelisib*

Pursuant to the Takeda Agreement, Infinity is obligated to pay Takeda the remaining \$3.0 million success-based development milestone and up to \$165.0 million in remaining success-based regulatory and commercial milestones for one product candidate other than duvelisib that inhibits the PI3K pathway, which could be eganelisib.

The Takeda Agreement expires on the later of the expiration of certain patents and the expiration of the royalty payment terms for the products, unless earlier terminated in accordance with its terms. Either party may terminate the Takeda Agreement on 75 days' prior written notice if the other party materially breaches the agreement and fails to cure such breach within the applicable notice period, provided that the notice period is reduced to 30 days where the alleged breach is non-payment. Takeda may also terminate the Takeda Agreement if Infinity is not diligent in developing or commercializing the licensed products and does not, within three months after notice from Takeda, demonstrate to Takeda's reasonable satisfaction that Infinity has not failed to be diligent. The foregoing periods are subject to extension in certain circumstances. Additionally, Takeda may terminate the Takeda Agreement upon 30 days' prior written notice if Infinity or a related party bring an action challenging the validity of any of the licensed patents, provided that Infinity has not withdrawn such action before the end of the 30-day notice period. Infinity may terminate the agreement at any time upon 180 days' prior written notice. The Takeda Agreement also provides for customary reciprocal indemnification obligations of the parties.

### **Intellectual Property**

Infinity's intellectual property consists of patents, trademarks, trade secrets and know-how. Infinity's ability to compete effectively depends in large part on its ability to obtain patents and trademarks for its technologies and products, maintain trade secrets, operate without infringing the rights of others and prevent others from infringing its proprietary rights. Infinity will be able to protect its proprietary technologies from unauthorized use by third parties only to the extent that they are covered by valid and enforceable patents, or are effectively maintained as trade secrets. As a result, patents or other proprietary rights are an essential element of Infinity's business.

Infinity has sixteen issued or allowed U.S. patents related to its PI3K-gamma program, which expire on various dates between 2033 and 2037, excluding any potential patent term extension. In addition, Infinity has approximately 115 patents and patent applications pending worldwide related to its PI3K-gamma program. Any patents that may issue from its pending patent applications would expire between 2033 and 2041, excluding any potential patent term extension. These patents and patent applications disclose compositions of matter, pharmaceutical compositions, methods of use and synthetic methods.

The term of individual patents depends upon the legal term for patents in the countries in which they are obtained. In most countries, including the United States, the patent term is 20 years from the earliest filing date of a non-provisional patent application. In the United States, a patent's term may be extended by patent term adjustment, which compensates a patentee for administrative delays by the United States Patent and Trademark Office ("USPTO") in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier filed patent. The term of a patent that covers a drug or biological product may also be eligible for patent term extension when FDA approval is granted, provided statutory and regulatory requirements are met. In the future, if and when Infinity's product candidates receive approval by the FDA or foreign regulatory authorities, it expects to apply for patent term extensions on issued patents covering those drugs, depending upon the length of the clinical trials for each drug and other factors. There can be no assurance that any of Infinity's pending patent applications will issue or that it will benefit from any patent term extension or favorable adjustment to the term of any of its patents.

As with other biotechnology and pharmaceutical companies, Infinity's ability to maintain and solidify its proprietary and intellectual property position for its product candidates and technologies will depend on its success in obtaining effective patent claims and enforcing those claims, if granted. However, Infinity's pending patent applications, and any patent applications that it may in the future file or license from third parties may not result in the issuance of patents. Infinity also cannot predict the breadth of claims that may be allowed or enforced in its patents. Any issued patents that Infinity may receive in the future may be challenged, invalidated or circumvented. For example, Infinity cannot be certain of the priority of inventions covered by pending third-party patent applications. If third parties prepare and file patent applications in the United States that also claim technology or therapeutics to which Infinity has rights, it may have to participate in interference proceedings in the USPTO to determine priority of invention, which could result in substantial costs to Infinity, even if the eventual outcome is favorable, which is highly unpredictable. In addition, because of the extensive time required for clinical development and regulatory review of a product candidate Infinity may develop, it is possible that, before any of Infinity's product candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby limiting protection such patent would afford the respective product and any competitive advantage such patent may provide.

Infinity's policy is to obtain and enforce the patents and proprietary technology rights that are commercially important to its business, and Infinity intends to continue to file patent applications to protect such technology and compounds in countries where it believes it is commercially reasonable and advantageous to do so. Infinity also relies on trade secrets to protect its technology where patent protection is deemed inappropriate or unobtainable. Infinity seeks to protect its proprietary information, in part, by executing confidentiality agreements with its collaborators and scientific advisors, and non-competition, non-solicitation, confidentiality, and invention assignment agreements with its employees and consultants. Infinity also has executed agreements requiring assignment of inventions with selected scientific advisors and collaborators. The confidentiality agreements Infinity enters into are designed to protect its proprietary information, and the agreements or clauses requiring assignment of inventions to Infinity are designed to grant it ownership of technologies that are developed through its relationship with the respective counterparty. Infinity cannot guarantee, however, that these agreements will afford it adequate protection of its intellectual property and proprietary information rights.

### **Competition**

The pharmaceutical and biotechnology industries are intensely competitive, including the field of IO, within which Infinity is competing directly. Many companies are actively engaged in the research and development of drugs for the treatment of the same diseases and conditions as Infinity's current and potential future product candidates, and many have substantially greater financial and other resources, larger research and development staffs, and more extensive marketing and manufacturing organizations than Infinity. In addition, some of them have considerably more experience than Infinity in preclinical testing, clinical trials and other regulatory approval procedures. There are also academic institutions, governmental agencies and other research organizations that are conducting research in areas in which Infinity is working. They may also develop products that may be competitive with Infinity's product candidates, either on their own or through collaborative efforts.

Infinity expects to encounter significant competition for any drugs it develops. Companies that complete clinical trials, obtain required regulatory approvals and commence commercial sales of their products before their competitors may achieve a significant competitive advantage. Infinity is aware that many other companies or institutions are pursuing the development of drugs in the areas in which it is currently seeking to develop its own product candidates, and there may be other companies working on competitive projects of which Infinity is not aware.

Infinity's competitors may commence and complete clinical testing of their product candidates, obtain regulatory approvals and begin commercialization of their products sooner than Infinity may for its own product candidates. These competitive products may have superior safety or efficacy, or be manufactured less expensively, than Infinity's product candidates. If Infinity is unable to compete effectively against these companies on the basis of safety, efficacy or cost, then it may not be able to commercialize its product candidates or achieve a competitive position in the market. This would adversely affect its business.



## [Table of Contents](#)

Selective inhibition of PI3K-gamma by egealisib has been shown in preclinical studies to reprogram macrophages from a pro-tumor, immunosuppressive function, to an anti-tumor, immune activating function and to enhance the activity of, and overcome resistance to, immune checkpoint inhibitors. Infinity believes the following competitors are also investigating drug or product candidates targeting one or more aspects of macrophage reprogramming biology: Arcus Biosciences, Inc. (PI3K-gamma inhibitor, pre-clinical); AstraZeneca plc (PI3K-gamma, pre-clinical); Jounce Therapeutics, Inc.; Macomics Ltd; Merck & Co.; Nanjing Zenshine Pharmaceuticals, Co. Ltd. (PI3K-gamma, clinical); Pathios Therapeutics Ltd; and Pionyr Immunotherapeutics, Inc.

Subject to the successful close of the Merger, the combined company plans to initiate in the third quarter of 2023, subject to U.S. Food and Drug Administration review, a global, randomized, controlled Phase 2 clinical trial of egealisib plus pembrolizumab versus pembrolizumab for the potential treatment of first line relapsed or metastatic HNSCC. Many additional companies have therapies in clinical development in HNSCC, including but not limited to: Eisai Co. Ltd., Immutep Ltd., Vaccinex Inc., Calliditas Therapeutics AB, Seagen Inc., Incyte Corp., BioNTech SE, Gilead Sciences Inc., Exelixis Inc.

Further, the broader field of IO is crowded with innovative therapies that may compete with egealisib, including checkpoint inhibitor therapies, including: PD-1 inhibitors such as nivolumab, pembrolizumab, and cemiplimab; PD-L1 inhibitors such as atezolizumab, avelumab, and durvalumab; CTLA-4 inhibitors such as ipilimumab, and tremelimumab; and LAG3 inhibitors such as relatlimab. Many of these checkpoint inhibitor therapies are being evaluated in combination with other non-checkpoint inhibitor IO product candidates. For instance, nivolumab, which Infinity is currently testing in combination with egealisib, is being evaluated by others in multiple clinical trials in combination with non-checkpoint inhibitor candidates such as sitravatinib, a small-molecule inhibitor of tyrosine kinases including Tyro3, MER, AXL, VEGFR, and KIT; linrodostat, a small-molecule inhibitor of IDO; elotuzumab, a CD319 antibody; urelumab, a CD137 antibody; and cabiralizumab, an anti-CSF1R antibody. In January 2021, the FDA approved the combination of nivolumab and cabozantinib, Exelixis, Inc's small-molecule inhibitor of tyrosine kinases, including MET, AXL, VEGFR, and RET, as first-line treatment for patients with advanced RCC. The success of competing IO therapies may limit the number of patients available for enrollment in Infinity's clinical trials.

### **Research and Development**

As of March 31, 2023, Infinity's research and development group consisted of 17 employees, of whom eight hold Ph.D. or M.D. degrees and eight hold a master's degree. Infinity's research and development group is focused on preclinical research, translational medicine, clinical trials and manufacturing technologies. In addition, Infinity relies on several consultants to fill strategic and tactical roles that support its research and development group.

### **Manufacturing and Supply**

Infinity relies on third parties and, in some instances, it relies on only one third party, to manufacture critical raw materials, drug substance and final drug product for its research, preclinical development and clinical trial activities. Commercial quantities of any drugs Infinity seeks to develop will have to be manufactured in facilities and by processes that comply with regulations of the FDA and other foreign regulatory authorities, and Infinity plans to rely on third parties to manufacture commercial quantities of any products it successfully develops.

Throughout the COVID-19 pandemic, Infinity's manufacturing processes have continued uninterrupted, and it has established contingency strategies intended to prevent potential supply chain interruptions related to the COVID-19 pandemic and any future pandemic. To date, Infinity believes it has enough egealisib drug product to conduct its current clinical trials. Further, Infinity believes that it has enough drug product intermediate for additional drug product manufacturing necessary to support its clinical development program and potential preclinical studies, and Infinity estimates that drug substance currently being manufactured may be available by the end of 2023. Infinity expects COVID-19 to have limited impact to existing manufacturing operations because all egealisib drug product necessary to conduct its current clinical trials has been manufactured or is scheduled

## [Table of Contents](#)

to be manufactured with sufficient lead times to accommodate potential delays. However, variants of the SARS-COV-2 virus have continued to develop, and potential future variants could be more virulent or more contagious than variants to date. Such variants may worsen or prolong the impact of the COVID-19 pandemic or any future pandemic, and may be so extreme that Infinity cannot fully mitigate their impact on its manufacturing timeline.

### **Sales and Marketing**

Infinity currently has no marketing, commercial sales, or “distribution capabilities”. Infinity does, however, currently have worldwide commercialization rights for eganelisib. In order to commercialize eganelisib, if and when it is approved for sale, Infinity will need to develop the necessary marketing, sales and distribution capabilities or establish a collaboration with a company that has commercial capabilities.

### **Government Regulation and Product Approvals**

Government authorities in the United States, at the federal, state and local level, and in other countries and jurisdictions, including the EU, extensively regulate, among other things, the research, development, testing, manufacture, pricing, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, sales, pricing, reimbursement, post-approval monitoring and reporting, and import and export of biopharmaceutical products. The processes for obtaining marketing approvals in the United States and in foreign countries and jurisdictions, along with compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

#### *Approval and Regulation of Drugs in the United States*

In the United States, drug products are regulated under the FDCA, and applicable implementing regulations and guidance. A company, institution, or organization which takes responsibility for the initiation and management of a clinical development program for such products, and for their regulatory approval, is typically referred to as a sponsor. The failure of a sponsor to comply with the applicable regulatory requirements at any time during the product development process, including non-clinical testing, clinical testing, the approval process or post-approval process, may result in delays to the conduct of a study, regulatory review and approval and/or administrative or judicial sanctions.

A sponsor seeking approval to market and distribute a new drug in the United States generally must satisfactorily complete each of the following steps before the product candidate will be approved by the FDA:

- preclinical testing including laboratory tests, animal studies and formulation studies, which must be performed in accordance with the FDA’s GLP, regulations and standards;
- design of a clinical protocol and submission to the FDA of an IND for human clinical testing, which must become effective before human clinical trials may begin;
- approval by an independent IRB representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials to establish the safety, potency and purity of the product candidate for each proposed indication, in accordance with current GCP;
- preparation and submission to the FDA of an NDA for a drug product which includes not only the results of the clinical trials, but also, detailed information on the chemistry, manufacture and quality controls for the product candidate and proposed labeling for one or more proposed indication(s);
- review of the product candidate by an FDA advisory committee, where appropriate or if applicable;
- satisfactory completion of any FDA audits of the non-clinical and clinical trial sites to assure compliance with GCP and the integrity of clinical data in support of the NDA;
- compliance with any post-approval requirements, including the potential requirement to implement a REMS and the potential requirement to conduct any post-approval studies required by the FDA;

## Table of Contents

- satisfactory completion of an FDA inspection of the manufacturing facility or facilities, including those of third parties, at which the product candidate or components thereof are manufactured to assess compliance with current good manufacturing practices (“cGMP”), requirements and to assure that the facilities, methods and controls are adequate to preserve the product’s identity, strength, quality and purity; and
- payment of user fees and securing FDA approval of the NDA to allow marketing of the new drug product.

### *Preclinical Studies and Investigational New Drug Application*

Before a sponsor begins testing a product candidate with potential therapeutic value in humans, the product candidate enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, formulation and stability, as well as other studies to evaluate, among other things, the toxicity of the product candidate. These studies are generally referred to as IND-enabling studies. The conduct of the preclinical tests and formulation of the compounds for testing must comply with federal regulations and requirements, including GLP regulations and standards and the United States Department of Agriculture’s Animal Welfare Act, if applicable. The results of the preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND. Some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, and long-term toxicity studies, may continue after the IND is submitted.

### *The IND and IRB Processes*

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include, among other things, the requirement that all research subjects provide their voluntary informed consent in writing before their participation in any clinical trial. Clinical trials are conducted under written study protocols detailing, among other things, the inclusion and exclusion criteria, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND.

An IND is an exemption from the FDCA that allows an unapproved product candidate to be shipped in interstate commerce for use in an investigational clinical trial and a request for FDA authorization to administer such investigational product to humans. Such authorization must be secured prior to interstate shipment and administration of any product candidate that is not the subject of an approved NDA. In support of a request for an IND, sponsors must submit a protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. The FDA requires a 30-day waiting period after the filing of each IND before clinical trials may begin. This waiting period is designed to allow the FDA to review the IND to determine whether human research subjects will be exposed to unreasonable health risks. At any time during this 30-day period, or thereafter, the FDA may raise concerns or questions about the conduct of the trials as outlined in the IND and impose a clinical hold or partial clinical hold. In this case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin.

Following commencement of a clinical trial under an IND, the FDA may also place a clinical hold or partial clinical hold on that trial. Clinical holds are imposed by the FDA whenever there is concern for patient safety and may be a result of new data, findings, or developments in clinical, nonclinical, and/or chemistry, manufacturing, and controls, commonly known as CMC, matters. A clinical hold is an order issued by the FDA to the sponsor to delay a proposed clinical investigation or to suspend an ongoing investigation. A partial clinical hold is a delay or suspension of only part of the clinical work requested under the IND. For example, a specific protocol or part of a protocol is not allowed to proceed, while other protocols may do so. No more than 30 days after imposition of a clinical hold or partial clinical hold, the FDA will provide the sponsor a written explanation of the basis for the hold.

Following issuance of a clinical hold or partial clinical hold, an investigation may only resume after the FDA has notified the sponsor that the investigation may proceed. The FDA will base that determination on information provided by the sponsor correcting the deficiencies previously cited or otherwise satisfying the FDA that the investigation can proceed.

A sponsor may choose, but is not required, to conduct a foreign clinical study under an IND. When a foreign clinical study is conducted under an IND, all FDA IND requirements must be met unless waived. When a foreign clinical study is not conducted under an IND, the sponsor must ensure that the study complies with certain regulatory requirements of the FDA in order to use the study as support for an IND or application for marketing approval. The FDA's regulations are intended to help ensure the protection of human subjects enrolled in non-IND foreign clinical studies, as well as the quality and integrity of the resulting data. They further help ensure that non-IND foreign studies are conducted in a manner comparable to that required for IND studies.

In addition to the foregoing IND requirements, an IRB representing each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must conduct continuing review and reapprove the study at least annually. The IRB must review and approve, among other things, the study protocol and informed consent information to be provided to study subjects. An IRB must operate in compliance with FDA regulations. An IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the product candidate has been associated with unexpected serious harm to patients.

Additionally, some trials are overseen by an independent group of qualified experts organized by the trial sponsor, known as a data safety monitoring board or committee ("DSMB"). This group provides authorization as to whether or not a trial may move forward at designated check points based on access that only the group maintains to available data from the study. Suspension or termination of development during any phase of clinical trials can occur if it is determined that the participants or patients are being exposed to an unacceptable health risk. Other reasons for suspension or termination may be made by Infinity based on evolving business objectives and/or competitive climate.

### *Expanded Access to an Investigational Drug for Treatment Use*

Expanded access, sometimes called "compassionate use," is the use of investigational new drug products outside of clinical trials to treat patients with serious or immediately life-threatening diseases or conditions when there are no comparable or satisfactory alternative treatment options. The rules and regulations related to expanded access are intended to improve access to investigational drugs for patients who may benefit from investigational therapies. FDA regulations allow access to investigational drugs under an IND by the company or the treating physician for treatment purposes on a case-by-case basis for: individual patients (single-patient IND applications for treatment in emergency settings and non-emergency settings); intermediate-size patient populations; and larger populations for use of the drug under a treatment protocol or Treatment IND Application.

When considering an IND application for expanded access to an investigational product with the purpose of treating a patient or a group of patients, the sponsor and treating physicians or investigators will determine suitability when all of the following criteria apply: patient(s) have a serious or immediately life-threatening disease or condition, and there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition; the potential patient benefit justifies the potential risks of the treatment and the potential risks are not unreasonable in the context or condition to be treated; and the expanded use of the investigational drug for the requested treatment will not interfere initiation, conduct, or completion of clinical investigations that could support marketing approval of the product or otherwise compromise the potential development of the product.

There is no obligation for a sponsor to make its drug products available for expanded access; however, as required by the 21st Century Cures Act (the "Cures Act"), passed in 2016, sponsors are required to make policies for evaluating and responding to requests for expanded access for patients publicly available upon the earlier of initiation of a Phase 2 or Phase 3 clinical trial, or 15 days after the investigational drug or biologic receives designation as a breakthrough therapy, fast track product, or regenerative medicine advanced therapy.

In addition, on May 30, 2018, the Right to Try Act was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a

## [Table of Contents](#)

Phase I clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a drug manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act, but the manufacturer must develop an internal policy and respond to patient requests according to that policy.

### *Human Clinical Trials in Support of an NDA*

Clinical trials involve the administration of the investigational product candidate to human subjects under the supervision of a qualified investigator in accordance with GCP requirements which include, among other things, the requirement that all research subjects provide their informed consent in writing before their participation in any clinical trial. Clinical trials are conducted under written clinical trial protocols detailing, among other things, the objectives of the study, inclusion and exclusion criteria, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated.

Human clinical trials are typically conducted in three sequential phases, but the phases may overlap or be combined. Additional studies may also be required after approval.

*Phase 1* clinical trials are initially conducted in a limited population to test the product candidate for safety, including adverse effects, dose tolerance, absorption, metabolism, distribution, excretion and pharmacodynamics in healthy humans or in patients. During Phase 1 clinical trials, information about the investigational drug product's pharmacokinetics and pharmacological effects may be obtained to permit the design of well-controlled and scientifically valid Phase 2 clinical trials.

*Phase 2* clinical trials are generally conducted in a limited patient population to identify possible adverse effects and safety risks, evaluate the efficacy of the product candidate for specific targeted indications and determine dose tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more costly Phase 3 clinical trials. Phase 2 clinical trials are well controlled, closely monitored and conducted in a limited patient population.

*Phase 3* clinical trials proceed if the Phase 2 clinical trials demonstrate that a dose range of the product candidate is potentially effective and has an acceptable safety profile. Phase 3 clinical trials are undertaken within an expanded patient population to further evaluate dosage, provide substantial evidence of clinical efficacy and further test for safety in an expanded and diverse patient population at multiple, geographically dispersed clinical trial sites. A well-controlled, statistically robust Phase 3 clinical trial may be designed to deliver the data that regulatory authorities will use to decide whether or not to approve, and, if approved, how to appropriately label a drug. Such Phase 3 studies are referred to as "pivotal."

A clinical trial may combine the elements of more than one phase and the FDA often requires more than one Phase 3 trial to support marketing approval of a product candidate. A company's designation of a clinical trial as being of a particular phase is not necessarily indicative that the study will be sufficient to satisfy the FDA requirements of that phase because this determination cannot be made until the protocol and data have been submitted to and reviewed by the FDA. Moreover, as noted above, a pivotal trial is a clinical trial that is believed to satisfy FDA requirements for the evaluation of a product candidate's safety and efficacy such that it can be used, alone or with other pivotal or non-pivotal trials, to support regulatory approval. Generally, pivotal trials are Phase 3 trials, but they may be Phase 2 trials if the design provides a well-controlled and reliable assessment of clinical benefit, particularly in an area of unmet medical need.

In December 2022, with the passage of FDORA, Congress required sponsors to develop and submit a diversity action plan for each Phase 3 clinical trial or any other "pivotal study" of a new drug or biological product. These plans are meant to encourage the enrollment of more diverse patient populations in late-stage clinical trials of FDA-regulated products. Specifically, actions plans must include the sponsor's goals for enrollment, the underlying rationale for those goals, and an explanation of how the sponsor intends to meet them. In addition to these requirements, the legislation directs the FDA to issue new guidance on diversity action plans.

## Table of Contents

In some cases, the FDA may approve an NDA for a product candidate but require the sponsor to conduct additional clinical trials to further assess the product candidate's safety and effectiveness after approval. Such post-approval trials are typically referred to as Phase 4 clinical trials. These studies are used to gain additional experience from the treatment of a larger number of patients in the intended treatment group and to further document a clinical benefit in the case of drugs approved under accelerated approval regulations. Failure to exhibit due diligence with regard to conducting Phase 4 clinical trials could result in withdrawal of approval for products.

In March 2022, the FDA released a final guidance entitled "Expansion Cohorts: Use in First-In-Human Clinical Trials to Expedite Development of Oncology Drugs and Biologics," which outlines how sponsors can utilize an adaptive trial design in the early stages of oncology product development (i.e., the first-in-human clinical trial) to compress the first two traditional phases of trials into one continuous trial called an expansion cohort trial. Information to support the design of individual expansion cohorts are included in IND applications and assessed by FDA. Expansion cohort trials can potentially bring efficiency to product development and reduce developmental costs and time.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. In addition, IND safety reports must be submitted to the FDA for any of the following: serious and unexpected suspected adverse reactions; findings from other studies or animal or *in vitro* testing that suggest a significant risk in humans exposed to the product; and any clinically important increase in the case of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. The FDA will typically inspect one or more clinical sites to assure compliance with GCP and the integrity of the clinical data submitted.

Finally, sponsors of clinical trials are required to register and disclose certain clinical trial information on a public registry ([clinicaltrials.gov](https://clinicaltrials.gov)) maintained by the U.S. NIH. In particular, information related to the product, patient population, phase of investigation, study sites and investigators and other aspects of the clinical trial is made public as part of the registration of the clinical trial. The failure to submit clinical trial information to [clinicaltrials.gov](https://clinicaltrials.gov), as required, is a prohibited act under the FDCA with violations subject to potential civil monetary penalties of up to \$10,000 for each day the violation continues. Although the FDA has historically not enforced these reporting requirements due to the HHS' long delay in issuing final implementing regulations, those regulations have now been issued and the FDA has issued several Notices of Noncompliance to manufacturers since April 2021.

### *Manufacturing and Other Regulatory Requirements*

Concurrent with clinical trials, companies often complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, must develop methods for testing the identity, strength, quality, purity, and potency of the final drug. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

The FDA's regulations also require that pharmaceutical products be manufactured in specific approved facilities and in accordance with cGMPs. The cGMP regulations include requirements relating to organization of personnel, buildings and facilities, equipment, control of components and product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports and returned or salvaged products. Manufacturers and other entities involved in the manufacture and distribution of approved pharmaceuticals are required to register their establishments with the FDA and some state agencies, and they are subject to periodic unannounced inspections by the FDA for compliance with cGMPs and other requirements. Inspections must follow a "risk-based schedule" that may result

in certain establishments being inspected more frequently. Manufacturers may also have to provide, on request, electronic or physical records regarding their establishments. Delaying, denying, limiting, or refusing inspection by the FDA may lead to a product being deemed to be adulterated. Changes to the manufacturing process, specifications or container closure system for an approved product are strictly regulated and often require prior FDA approval before being implemented. The FDA's regulations also require, among other things, the investigation and correction of any deviations from cGMP and the imposition of reporting and documentation requirements upon the sponsor and any third-party manufacturers involved in producing the approved product. The PREVENT Pandemics Act, which was enacted in December 2022, clarifies that foreign drug manufacturing establishments are subject to registration and listing requirements even if a drug undergoes further manufacture, preparation, propagation, compounding, or processing at a separate establishment outside the United States prior to being imported or offered for import into the United States.

### *Pediatric Studies*

Under the PREA, a BLA or supplement thereto must contain data that are adequate to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. Sponsors must also submit pediatric study plans prior to the assessment data. Those plans must contain an outline of the proposed pediatric study or studies the sponsor plans to conduct, including study objectives and design, any deferral or aiver requests, and other information required by regulation. The sponsor, the FDA, and the FDA's internal review committee must then review the information submitted, consult with each other, and agree upon a final plan. The FDA or the sponsor may request an amendment to the plan at any time.

The FDA may, on its own initiative or at the request of the sponsor, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. A deferral may be granted for several reasons, including a finding that the product or therapeutic candidate is ready for approval for use in adults before pediatric trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric trials begin. Pursuant to the Food and Drug Administration Safety and Innovation Act of 2012 (the "FDASIA"), the FDA must send a PREA Non-Compliance letter to sponsors who have failed to submit their pediatric assessments required under PREA, have failed to seek or obtain a deferral or deferral extension or have failed to request approval for a required pediatric formulation. It further requires the FDA to publicly post the PREA Non-Compliance letter and sponsor's response. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan designation, although FDA has recently taken steps to limit what it considers abuse of this statutory exemption.

### *Review and Approval of an NDA*

In order to obtain approval to market a drug product in the United States, a marketing application must be submitted to the FDA that provides sufficient data establishing the safety, purity and potency of the proposed drug product for its intended indication. The application includes all relevant data available from pertinent preclinical and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls and proposed labeling, among other things. Data can come from company-sponsored clinical trials intended to test the safety and effectiveness of a use of a product, or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the drug product to the satisfaction of the FDA.

The NDA is a vehicle through which sponsors formally propose that the FDA approve a new product for marketing and sale in the United States for one or more indications. Every new drug product candidate must be the subject of an approved NDA before it may be commercialized in the United States. Under federal law, the submission of most NDAs is subject to an application user fee, which for federal fiscal year 2023 is approximately \$3.25 million for an application requiring clinical data. The sponsor of an approved NDA is also



## [Table of Contents](#)

subject to an annual program fee, which for federal fiscal year 2023 is \$394,000. Certain exceptions and waivers are available for some of these fees, such as an exception from the application fee for products with orphan designation and a waiver for certain small businesses.

Following submission of an NDA, the FDA conducts a preliminary review of the application within 60 calendar days of its receipt and it must inform the sponsor by that time or before as to whether the application is sufficiently complete to permit substantive review. In the event that the FDA determines that an application does not satisfy this standard, it will issue a Refuse to File (“RTF”) determination to the sponsor. The FDA may request additional information rather than accept the application for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA has agreed to specified performance goals in the review process of NDAs. Under that agreement, 90% of applications seeking approval of New Molecular Entities (“NMEs”) are meant to be reviewed within ten months from the date on which the FDA accepts the application for filing, and 90% of applications for NMEs that have been designated for “priority review” are meant to be reviewed within six months of the filing date.

In connection with its review of an application, the FDA typically will inspect the facility or facilities where the product is or will be manufactured. These pre-approval inspections may cover all facilities associated with an NDA submission, including component manufacturing, finished product manufacturing and control testing laboratories. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Under the FDA Reauthorization Act of 2017, the FDA must implement a protocol to expedite review of responses to inspection reports pertaining to certain applications, including applications for products in shortage or those for which approval is dependent on remediation of conditions identified in the inspection report. Further, with passage of FDORA, Congress clarified FDA’s authority to conduct inspections by expressly permitting inspection of facilities involved in the preparation, conduct, or analysis of clinical and non-clinical studies submitted to FDA as well as other persons holding study records or involved in the study process.

In addition, as a condition of approval, the FDA may require a sponsor to develop a REMS. REMS use risk minimization strategies beyond the professional labeling to ensure that the benefits of the product outweigh the potential risks. To determine whether a REMS is needed, the FDA will consider the size of the population likely to use the product, seriousness of the disease, expected benefit of the product, expected duration of treatment, seriousness of known or potential adverse events and whether the product is a new molecular entity.

The FDA may refer an application for a novel product to an advisory committee or explain why such referral was not made. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

### *Expedited Review Programs*

The FDA is authorized to expedite the review of NDAs in several ways. Under the Fast Track program, the sponsor of a product candidate may request the FDA to designate the product for a specific indication as a Fast Track product concurrent with or after the filing of the IND. Candidate products are eligible for Fast Track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to the combination of the product candidate and the specific indication for which it is being studied. In addition to other benefits, such as the ability to have greater interactions with the FDA, the FDA may initiate review of sections of a Fast Track application before the application is complete, a process known as rolling review.

## Table of Contents

Any product candidate submitted to the FDA for marketing, including under a Fast Track program, may be eligible for other types of FDA programs intended to expedite development and review, such as breakthrough therapy designation, priority review and accelerated approval.

- *Breakthrough therapy designation.* To qualify for the breakthrough therapy program, product candidates must be intended to treat a serious or life-threatening disease or condition and preliminary clinical evidence must indicate that such product candidates may demonstrate substantial improvement on one or more clinically significant endpoints over existing therapies. The FDA will seek to ensure the sponsor of a breakthrough therapy product candidate receives intensive guidance on an efficient drug development program, intensive involvement of senior managers and experienced staff on a proactive, collaborative and cross-disciplinary review and rolling review.
- *Priority review.* A product candidate is eligible for priority review if it treats a serious condition and, if approved, it would be a significant improvement in the safety or effectiveness of the treatment, diagnosis or prevention compared to marketed products. FDA aims to complete its review of priority review applications within six months as opposed to 10 months for standard review.
- *Accelerated approval.* Drug or biologic products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval. Accelerated approval means that a product candidate may be approved on the basis of adequate and well controlled clinical trials establishing that the product candidate has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity and prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a drug or biologic product candidate receiving accelerated approval perform adequate and well controlled post-marketing clinical trials. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials.

With passage of FDORA in December 2022, Congress modified certain provisions governing accelerated approval of drug and biologic products. Specifically, the new legislation authorized the FDA to: require a sponsor to have its confirmatory clinical trial underway before accelerated approval is awarded, require a sponsor of a product granted accelerated approval to submit progress reports on its post-approval studies to FDA every six months (until the study is completed), and use expedited procedures to withdraw accelerated approval of an NDA or BLA after the confirmatory trial fails to verify the product's clinical benefit. Further, FDORA requires the agency to publish on its website "the rationale for why a post-approval study is not appropriate or necessary" whenever it decides not to require such a study upon granting accelerated approval.

- *Regenerative advanced therapy.* With passage of the Cures Act, in December 2016, Congress authorized the FDA to accelerate review and approval of products designated as regenerative advanced therapies. A product is eligible for this designation if it is a regenerative medicine therapy that is intended to treat, modify, reverse or cure a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product candidate has the potential to address unmet medical needs for such disease or condition. The benefits of a regenerative advanced therapy designation include early interactions with the FDA to expedite development and review, benefits available to breakthrough therapies, potential eligibility for priority review and accelerated approval based on surrogate or intermediate endpoints.

None of these expedited programs change the standards for approval but they may help expedite the development or approval process of product candidates.

### *Project Optimus*

Project Optimus is an initiative of the Oncology Center of Excellence at FDA. This project focuses on dose optimization and dose selection in oncology drug development, and whether the current paradigm based on cytotoxic chemotherapeutics leads to doses and schedules of molecularly targeted therapies that provide more

## [Table of Contents](#)

toxicity without additional efficacy, among other things. By participating in Project Optimus, drug developments have the opportunity to meet with FDA's Oncology Review Divisions early in development programs, well before conducting trials intended for registration, to discuss dose-finding and dose optimization. The program thus allows sponsors to develop strategies for dose finding and dose optimization that leverages nonclinical and clinical data in dose selection, including randomized evaluations of a range of doses in trials, with the objective of performing these studies as early as possible in the development program to bring promising new therapies to patients.

### *The FDA's Decision on an NDA*

After evaluating the application and all related information, including the advisory committee recommendations, if any, and inspection reports of manufacturing facilities and clinical trial sites, the FDA will issue either a Complete Response Letter ("CRL") or an approval letter. To reach this determination, the FDA must determine that the drug is effective and that its expected benefits outweigh its potential risks to patients. This "benefit-risk" assessment is informed by the extensive body of evidence about the product's safety and efficacy in the NDA. This assessment is also informed by other factors, including: the severity of the underlying condition and how well patients' medical needs are addressed by currently available therapies; uncertainty about how the premarket clinical trial evidence will extrapolate to real-world use of the product in the post-market setting; and whether risk management tools are necessary to manage specific risks.

A CRL indicates that the review cycle of the application is complete, and the application will not be approved in its present form. The CRL generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. For those seeking to challenge FDA's CRL decision, the agency has indicated that sponsors may request a formal hearing on the CRL or they may file a request for reconsideration or a request for a formal dispute resolution.

An approval letter, on the other hand, authorizes commercial marketing of the product with specific prescribing information for specific indications. The agency may require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms such as REMS to help ensure that the benefits of the product outweigh the potential risks. REMS can include medication guides, communication plans for health care professionals, and elements to assure safe use ("ETASU"). ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patent registries. The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs. After approval, many types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

### *Post-Approval Regulation*

If regulatory approval for marketing of a product or new indication for an existing product is obtained, the sponsor will be required to comply with all regular post-approval regulatory requirements as well as any post-approval requirements that the FDA may have imposed as part of the approval process. The sponsor will be required to report, among other things, certain adverse reactions and manufacturing problems to the FDA, provide updated safety and efficacy information and comply with requirements concerning advertising and promotional labeling requirements. Manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMP regulations, which impose certain procedural and documentation requirements upon manufacturers. Accordingly,

## Table of Contents

the sponsor and its third-party manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain compliance with cGMP regulations and other regulatory requirements.

A product may also be subject to official lot release, meaning that the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release, the manufacturer must submit samples of each lot, together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot, to the FDA. The FDA may in addition perform certain confirmatory tests on lots of some products before releasing the lots for distribution. Finally, the FDA will conduct laboratory research related to the safety, purity, potency and effectiveness of pharmaceutical products.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates the marketing, labeling, advertising and promotion of prescription drug products placed on the market. This regulation includes, among other things, standards and regulations for direct-to-consumer advertising, communications regarding unapproved uses, industry-sponsored scientific and educational activities, and promotional activities involving the Internet and social media. Promotional claims about a drug's safety or effectiveness are prohibited before the drug is approved. After approval, a drug product generally may not be promoted for uses that are not approved by the FDA, as reflected in the product's prescribing information. In the United States, health care professionals are generally permitted to prescribe drugs for such uses not described in the drug's labeling, known as off-label uses, because the FDA does not regulate the practice of medicine. However, FDA regulations impose rigorous restrictions on manufacturers' communications, prohibiting the promotion of off-label uses. In September 2021, the FDA published final regulations which describe the types of evidence that the agency will consider in determining the intended use of a drug product.

If a company is found to have promoted off-label uses, it may become subject to adverse public relations and administrative and judicial enforcement by the FDA, the DOJ, or the Office of the Inspector General of the Department of Health and Human Services, as well as state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes drug products. The federal government has levied large civil and criminal fines against companies for alleged improper promotion, and has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

### *Pediatric Exclusivity*

Pediatric exclusivity is another type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of regulatory exclusivity to the term of any existing

## [Table of Contents](#)

patent or regulatory exclusivity, including orphan exclusivity. This six-month exclusivity may be granted if an NDA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover the product are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application.

### *Orphan Drug Designation and Exclusivity*

Under the Orphan Drug Act, the FDA may designate a drug product as an "orphan drug" if it is intended to treat a rare disease or condition, generally meaning that it affects fewer than 200,000 individuals in the United States, or more in cases in which there is no reasonable expectation that the cost of developing and making a product available in the United States for treatment of the disease or condition will be recovered from sales of the product. A company must seek orphan drug designation before submitting an NDA for the candidate product. If the request is granted, the FDA will disclose the identity of the therapeutic agent and its potential use. Orphan drug designation does not shorten the PDUFA goal dates for the regulatory review and approval process, although it does convey certain advantages such as tax benefits and exemption from the PDUFA application fee.

If a product with orphan designation receives the first FDA approval for the disease or condition for which it has such designation or for a select indication or use within the rare disease or condition for which it was designated, the product generally will receive orphan drug exclusivity. Orphan drug exclusivity means that the FDA may not approve another sponsor's marketing application for the same drug for the same condition for seven years, except in certain limited circumstances. Orphan exclusivity does not block the approval of a different product for the same rare disease or condition, nor does it block the approval of the same product for different conditions. If a drug designated as an orphan drug ultimately receives marketing approval for an indication broader than what was designated in its orphan drug application, it may not be entitled to exclusivity.

Orphan drug exclusivity will not bar approval of another product under certain circumstances, including if the company with orphan drug exclusivity is not able to meet market demand or the subsequent product with the same drug for the same condition is shown to be clinically superior to the approved product on the basis of greater efficacy or safety, or providing a major contribution to patient care. This is the case despite an earlier court opinion holding that the Orphan Drug Act unambiguously required the FDA to recognize orphan drug exclusivity regardless of a showing of clinical superiority. Under Omnibus legislation signed by President Trump on December 27, 2020, the requirement for a product to show clinical superiority applies to drugs and biologics that received orphan drug designation before enactment of FDARA in 2017, but have not yet been approved or licensed by FDA.

In September 2021, the Court of Appeals for the 11th Circuit held that, for the purpose of determining the scope of market exclusivity, the term "same disease or condition" in the statute means the designated "rare disease or condition" and could not be interpreted by the FDA to mean the "indication or use." Thus, the court concluded, orphan drug exclusivity applies to the entire designated disease or condition rather than the "indication or use." Although there have been legislative proposals to overrule this decision, they have not been enacted into law. On January 23, 2023, FDA announced that, in matters beyond the scope of that court order, FDA will continue to apply its existing regulations tying orphan-drug exclusivity to the uses or indications for which the orphan drug was approved.

### *Section 505(b)(2) NDAs*

NDAs for most new drug products are based on two full clinical studies which must contain substantial evidence of the safety and efficacy of the proposed new product for the proposed use. These applications are submitted under Section 505(b)(1) of the FDCA. The FDA is, however, authorized to approve an alternative type of NDA

## Table of Contents

under Section 505(b)(2) of the FDCA. This type of application allows the sponsor to rely, in part, on the FDA's previous findings of safety and efficacy for a similar product, or "published literature". Specifically, Section 505(b)(2) applies to NDAs for a drug for which the investigations made to show whether or not the drug is safe for use and effective in use and relied upon by the sponsor for approval of the application "were not conducted by or for the sponsor and for which the sponsor has not obtained a right of reference or use from the person by or for whom the investigations were conducted."

Section 505(b)(2) thus authorizes the FDA to approve an NDA based on safety and effectiveness data that were not developed by the sponsor. NDAs filed under Section 505(b)(2) may provide an alternate and potentially more expeditious pathway to FDA approval for new or improved formulations or new uses of previously approved products. If the 505(b)(2) sponsor can establish that reliance on the FDA's previous approval is scientifically appropriate, the sponsor may eliminate the need to conduct certain preclinical or clinical studies of the new product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new drug candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) sponsor

### *Abbreviated New Drug Applications for Generic Drugs*

In 1984, with passage of the Hatch-Waxman Amendments to the FDCA, Congress established an abbreviated regulatory scheme authorizing the FDA to approve generic drugs that are shown to contain the same active ingredients as, and to be bioequivalent to, drugs previously approved by the FDA pursuant to NDAs.

In order for an ANDA to be approved, the FDA must find that the generic version is identical to the drug product previously approved under an NDA (the reference-listed drug ("RLD")), with respect to the active ingredients, the route of administration, the dosage form, the strength of the drug and the conditions of use of the drug. At the same time, the FDA must also determine that the generic drug is "bioequivalent" to the innovator drug. Under the statute, a generic drug is bioequivalent to a RLD if "the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug." Upon approval of an ANDA, the FDA indicates whether the generic product is "therapeutically equivalent" to the RLD in its publication "Approved Drug Products with Therapeutic Equivalence Evaluations," also referred to as the ("Orange Book)." Physicians and pharmacists consider a therapeutic equivalent generic drug to be fully substitutable for the RLD.

Under the Hatch-Waxman Amendments, the FDA may not approve an ANDA until any applicable period of non-patent exclusivity for the RLD has expired. The FDCA provides a period of five years of non-patent data exclusivity for a new drug containing a new chemical entity. For the purposes of this provision, an NCE is a drug that contains no active moiety that has previously been approved by the FDA in any other NDA. An active moiety is the molecule or ion responsible for the physiological or pharmacological action of the drug substance. In cases where such NCE exclusivity has been granted, an ANDA may not be filed with the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification, in which case the sponsor may submit its application four years following the original product approval. The FDCA also provides for a period of three years of exclusivity if the NDA includes reports of one or more new clinical investigations, other than bioavailability or bioequivalence studies, that were conducted by or for the sponsor and are essential to the approval of the application.

### *Hatch-Waxman Patent Certification and the 30-Month Stay*

Upon approval of an NDA or a supplement thereto, NDA sponsors are required to list with the FDA each patent with claims that cover the sponsor's product or an approved method of using the product. Each of the patents listed by the NDA sponsor is published in the Orange Book. When an ANDA sponsor files its application with the FDA, the sponsor is required to certify to the FDA concerning any patents listed for the reference product in the Orange Book, except for patents covering methods of use for which the ANDA sponsor is not seeking approval. To the extent that the Section 505(b)(2) sponsor is relying on studies conducted for an already

## [Table of Contents](#)

approved product, the sponsor is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA sponsor would.

Specifically, the sponsor must certify with respect to each patent that:

- the required patent information has not been filed;
- the listed patent has expired;
- the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or
- the listed patent is invalid, unenforceable or will not be infringed by the new product.

A certification that the new product will not infringe the already approved product's listed patents or that such patents are invalid or unenforceable is called a Paragraph IV certification. If the sponsor does not challenge the listed patents or indicates that it is not seeking approval of a patented method of use, the application will not be approved until all the listed patents claiming the referenced product have expired (other than method of use patents involving indications for which the sponsor is not seeking approval).

If the ANDA sponsor has provided a Paragraph IV certification to the FDA, the sponsor must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days after the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months after the receipt of the Paragraph IV notice, expiration of the patent, or a decision in the infringement case that is favorable to the ANDA sponsor.

### *Patent Term Restoration and Extension*

A patent claiming a new drug product may be eligible for a limited patent term extension under the Hatch-Waxman Act, which permits a patent restoration of up to five years for patent term lost during product development and the FDA regulatory review. The restoration period granted on a patent covering a product is typically one-half the time between the effective date for the IND for the clinical investigation and the submission date of an application, plus the time between the submission date of an application and the ultimate approval date. Patent term restoration cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date. Only one patent applicable to an approved product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent in question. A patent that covers multiple products for which approval is sought can only be extended in connection with one of the approvals. The USPTO reviews and approves the application for any patent term extension or restoration in consultation with the FDA.

### *Health Care Law and Regulation*

Health care providers and third-party payors play a primary role in the recommendation and prescription of drug products that are granted marketing approval. Arrangements with providers, consultants, third-party payors and customers are subject to broadly applicable fraud and abuse, anti-kickback, false claims laws, patient privacy laws and regulations and other health care laws and regulations that may constrain business and/or financial arrangements.

Restrictions under applicable federal and state health care laws and regulations include the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, paying, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal health care program such as Medicare and Medicaid; the federal civil and criminal false claims laws, including the civil False Claims Act, and civil



monetary penalties laws, which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false, fictitious or fraudulent or knowingly making, using or causing to be made or used a false record or statement to avoid, decrease or conceal an obligation to pay money to the federal government; HIPAA, which prohibits, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters; the FCPA, which prohibits companies and their intermediaries from making, or offering or promising to make, improper payments to non-U.S. officials for the purpose of obtaining or retaining business or otherwise seeking favorable treatment; and the federal transparency requirements known as the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to CMS within the United States Department of Health and Human Services, information related to payments and other transfers of value made by that entity to physicians (as defined under the Sunshine Act), other healthcare providers and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.

Further, some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures. Additionally, some state and local laws require the registration of pharmaceutical sales representatives in the jurisdiction. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, which also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information, thus complicating compliance efforts.

### ***Pharmaceutical Insurance Coverage and Health Care Reform***

In the United States and markets in other countries, patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Significant uncertainty exists as to the coverage and reimbursement status of products approved by the FDA and other government authorities. Thus, even if a product candidate is approved, sales of the product will depend, in part, on the extent to which third-party payors, including government health programs in the United States such as Medicare and Medicaid, commercial health insurers and managed care organizations, provide coverage and establish adequate reimbursement levels for, the product. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the prices charged, examining the medical necessity and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the approved products for a particular indication.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable marketing approvals. Nonetheless, product candidates may not be considered medically necessary or cost effective. A decision by a third-party payor not to cover a product could reduce physician utilization once the product is approved and have a material adverse effect on sales, results of operations and financial condition. Additionally, a payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement can differ significantly from payor to payor.

## [Table of Contents](#)

The containment of healthcare costs also has become a priority of federal, state and foreign governments and the prices of products have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit a company's revenue generated from the sale of any approved products. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which a company or its collaborators receive marketing approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

In March 2010, the United States Congress enacted the ACA, which, among other things, includes changes to the coverage and payment for drug products under government health care programs. Other legislative changes have been proposed and adopted since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2031 under the CARES Act. These Medicare sequester reductions were suspended and reduced through the end of June 2022, with the full 2% cut resuming thereafter. The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices Infinity may obtain for any of its product candidates for which it may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used. Indeed, under current legislation, the actual reductions in Medicare payments may vary up to 4%.

Since enactment of the ACA, there have been, and continue to be, numerous legal challenges and congressional actions to repeal and replace provisions of the law. For example, with enactment of the Tax Cuts and Jobs Act of 2017, which was signed by President Trump on December 22, 2017, Congress repealed the "individual mandate." The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, became effective in 2019. On December 14, 2018, a U.S. District Court judge in the Northern District of Texas ruled that the individual mandate portion of the PPACA is an essential and inseparable feature of the PPACA, and therefore because the mandate was repealed as part of the Tax Act, the remaining provisions of the PPACA are invalid as well. The U.S. Supreme Court heard this case on November 10, 2020 and, on June 17, 2021, dismissed this action after finding that the plaintiffs do not have standing to challenge the constitutionality of the ACA. Litigation and legislation over the PPACA are likely to continue, with unpredictable and uncertain results.

The Trump Administration also took executive actions to undermine or delay implementation of the ACA, including directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. On January 28, 2021, however, President Biden rescinded those orders and issued a new Executive Order which directs federal agencies to reconsider rules and other policies that limit Americans' access to health care, and consider actions that will protect and strengthen that access. Under this Order, federal agencies are directed to re-examine: policies that undermine protections for people with pre-existing conditions, including complications related to COVID-19; demonstrations and waivers under Medicaid and the ACA that may reduce coverage or undermine the programs, including work requirements; policies that undermine the Health Insurance Marketplace or other markets for health insurance; policies that make it more difficult to enroll in Medicaid and the ACA; and policies that reduce affordability of coverage or financial assistance, including for dependents.

*Pharmaceutical Prices*

The prices of prescription pharmaceuticals have also been the subject of considerable discussion in the United States. There have been several recent U.S. congressional inquiries, as well as proposed and enacted state and federal legislation designed to, among other things, bring more transparency to pharmaceutical pricing, review the relationship between pricing and manufacturer patient programs, and reduce the costs of pharmaceuticals under Medicare and Medicaid. In 2020, President Trump issued several executive orders intended to lower the costs of prescription products and certain provisions in these orders have been incorporated into regulations. These regulations include an interim final rule implementing a most favored nation model for prices that would tie Medicare Part B payments for certain physician-administered pharmaceuticals to the lowest price paid in other economically advanced countries, effective January 1, 2021. That rule, however, has been subject to a nationwide preliminary injunction and, on December 29, 2021, CMS issued a final rule to rescind it. With issuance of this rule, CMS stated that it will explore all options to incorporate value into payments for Medicare Part B pharmaceuticals and improve beneficiaries' access to evidence-based care.

In addition, in October 2020, the HHS and the FDA published a final rule allowing states and other entities to develop a SIP to import certain prescription products from Canada into the United States. The final rule is currently the subject of ongoing litigation, but at least six states (Vermont, Colorado, Florida, Maine, New Mexico, and New Hampshire) have passed laws allowing for the importation of products from Canada with the intent of developing SIPs for review and approval by the FDA. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The final rule would also eliminate the current safe harbor for Medicare drug rebates and create new safe harbors for beneficiary point-of-sale discounts and PBM service fees. It originally was set to go into effect on January 1, 2022, but with passage of the Inflation Reduction Act has been delayed by Congress to January 1, 2032.

In September 2021, acting pursuant to an executive order signed by President Biden, the HHS released its plan to reduce pharmaceutical prices. The key features of that plan are to: (a) make pharmaceutical prices more affordable and equitable for all consumers and throughout the health care system by supporting pharmaceutical price negotiations with manufacturers; (b) improve and promote competition throughout the prescription pharmaceutical industry by supporting market changes that strengthen supply chains, promote biosimilars and generic drugs, and increase transparency; and (c) foster scientific innovation to promote better healthcare and improve health by supporting public and private research and making sure that market incentives promote discovery of valuable and accessible new treatments.

More recently, on August 16, 2022, the IRA was signed into law by President Biden. The new legislation has implications for Medicare Part D, which is a program available to individuals who are entitled to Medicare Part A or enrolled in Medicare Part B to give them the option of paying a monthly premium for outpatient prescription drug coverage. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years.

Specifically, with respect to price negotiations, Congress authorized Medicare to negotiate lower prices for certain costly single-source drug and biologic products that do not have competing generics or biosimilars and are reimbursed under Medicare Part B and Part D. CMS may negotiate prices for ten high-cost drugs paid for by Medicare Part D starting in 2026, followed by 15 Part D drugs in 2027, 15 Part B or Part D drugs in 2028, and 20 Part B or Part D drugs in 2029 and beyond.

## [Table of Contents](#)

This provision applies to drug products that have been approved for at least 9 years and biologics that have been licensed for 13 years, but it does not apply to drugs and biologics that have been approved for a single rare disease or condition. Further, the legislation subjects drug manufacturers to civil monetary penalties and a potential excise tax for failing to comply with the legislation by offering a price that is not equal to or less than the negotiated “maximum fair price” under the law or for taking price increases that exceed inflation. The legislation also requires manufacturers to pay rebates for drugs in Medicare Part D whose price increases exceed inflation. The new law also caps Medicare out-of-pocket drug costs at an estimated \$4,000 a year in 2024 and, thereafter beginning in 2025, at \$2,000 a year.

At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for Infinity’s products, once approved, or put pressure on its product pricing. Infinity expects that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for its product candidates or additional pricing pressures.

In the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular drug candidate to currently available therapies or so-called health technology assessments, in order to obtain reimbursement or pricing approval. For example, the European Union provides options for its member states to restrict the range of products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. European Union member states may approve a specific price for a product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other member states allow companies to fix their own prices for products, but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Recently, many countries in the European Union have increased the amount of discounts required on pharmaceuticals and these efforts could continue as countries attempt to manage healthcare expenditures, especially in light of the severe fiscal and debt crises experienced by many countries in the European Union. The downward pressure on health care costs in general, particularly prescription drugs, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union member states, and parallel trade, i.e., arbitrage between low-priced and high-priced member states, can further reduce prices. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any products, if approved in those countries.

### ***Review and Approval of Medicinal Products in the European Union***

In order to market any product outside of the United States, a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of products. Whether or not it obtains FDA approval for a product, a sponsor will need to obtain the necessary approvals by the comparable non-U.S. regulatory authorities before it can commence clinical trials or marketing of the product in those countries or jurisdictions. Specifically, the process governing approval of medicinal products in the EU generally follows the same lines as in the United States. It entails satisfactory completion of

preclinical studies and adequate and well-controlled clinical trials to establish the safety and efficacy of the product for each proposed indication. It also requires the submission to the relevant competent authorities of a marketing authorization application (“MAA”) and granting of a marketing authorization by these authorities before the product can be marketed and sold in the EU.

### *Clinical Trial Approval*

On January 31, 2022, the new Clinical Trials Regulation (EU) No 536/2014 became effective in the European Union and replaced the prior Clinical Trials Directive 2001/20/EC. The new regulation aims at simplifying and streamlining the authorization, conduct and transparency of clinical trials in the European Union. Under the new coordinated procedure for the approval of clinical trials, the sponsor of a clinical trial to be conducted in more than one EU Member State will only be required to submit a single application for approval. The submission will be made through the Clinical Trials Information System, a new clinical trials portal overseen by the EMA and available to clinical trial sponsors, competent authorities of the EU Member States and the public.

Beyond streamlining the process, the new Regulation includes a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors, and a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts. Part I is assessed by the competent authorities of all EU Member States in which an application for authorization of a clinical trial has been submitted (Member States concerned). Part II is assessed separately by each Member State concerned. Strict deadlines have been established for the assessment of clinical trial applications. The role of the relevant ethics committees in the assessment procedure will continue to be governed by the national law of the concerned EU Member State. However, overall related timelines will be defined by the Clinical Trials Regulation.

The new regulation did not change the preexisting requirement that a sponsor must obtain prior approval from the competent national authority of the EU Member State in which the clinical trial is to be conducted. If the clinical trial is conducted in different EU Member States, the competent authorities in each of these EU Member States must provide their approval for the conduct of the clinical trial. Furthermore, the sponsor may only start a clinical trial at a specific study site after the applicable ethics committee has issued a favorable opinion.

As in the United States, similar requirements for posting clinical trial information are present in the European Union (EudraCT) website: <https://eudract.ema.europa.eu/> and other countries.

### *Pediatric Studies*

Prior to obtaining a marketing authorization in the European Union, sponsors must demonstrate compliance with all measures included in an EMA-approved PIP covering all subsets of the pediatric population, unless the EMA has granted a product-specific waiver, a class waiver, or a deferral for one or more of the measures included in the PIP. The respective requirements for all marketing authorization procedures are laid down in Regulation (EC) No 1901/2006, the so-called Paediatric Regulation. This requirement also applies when a company wants to add a new indication, pharmaceutical form or route of administration for a medicine that is already authorized. The Paediatric Committee of the EMA (“PDCO”) may grant deferrals for some medicines, allowing a company to delay development of the medicine for children until there is enough information to demonstrate its effectiveness and safety in adults. The PDCO may also grant waivers when development of a medicine for children is not needed or is not appropriate, such as for diseases that only affect the elderly population. Before an MAA can be filed, or an existing marketing authorization can be amended, the EMA determines that companies actually comply with the agreed studies and measures listed in each relevant PIP.

### *PRIME Designation in the EU*

In March 2016, the EMA launched an initiative to facilitate development of product candidates in indications, often rare, for which few or no therapies currently exist. The PRiority MEDicines (“PRIME”) scheme is intended to encourage drug development in areas of unmet medical need and provides accelerated assessment of products

representing substantial innovation reviewed under the centralized procedure. Products from small- and medium-sized enterprises may qualify for earlier entry into the PRIME scheme than larger companies. Many benefits accrue to sponsors of product candidates with PRIME designation, including, but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and accelerated marketing authorization application assessment once a dossier has been submitted. Importantly, a dedicated Agency contact and rapporteur from the Committee for Human Medicinal Products (“CHMP”) or Committee for Advanced Therapies are appointed early in PRIME scheme facilitating increased understanding of the product at EMA’s Committee level. A kick-off meeting initiates these relationships and includes a team of multidisciplinary experts at the EMA to provide guidance on the overall development and regulatory strategies.

### *Marketing Authorization*

To obtain a marketing authorization for a product under EU regulatory systems, a sponsor must submit an MAA either under a centralized procedure administered by the EMA, or one of the procedures administered by competent authorities in the EU Member States (decentralized procedure, national procedure or mutual recognition procedure). A marketing authorization may be granted only to a sponsor established in the EU. Regulation (EC) No 1901/2006 provides that prior to obtaining a marketing authorization in the EU, sponsors have to demonstrate compliance with all measures included in an EMA-approved Paediatric Investigation Plan (“PIP”) covering all subsets of the pediatric population, unless the EMA has granted (1) a product-specific waiver, (2) a class waiver or (3) a deferral for one or more of the measures included in the PIP.

The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid across the European Economic Area (i.e. the EU as well as Iceland, Liechtenstein and Norway). Pursuant to Regulation (EC) No 726/2004, the centralized procedure is compulsory for specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy medicinal products, and products with a new active substance indicated for the treatment of certain diseases, including products for the treatment of cancer. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, the centralized procedure may be optional. The centralized procedure may at the request of the sponsor also be used in certain other cases. Infinity anticipates that the centralized procedure will be mandatory for the product candidates it is developing.

Under the centralized procedure, the CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing marketing authorization. Under the centralized procedure in the EU, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops, when additional information or written or oral explanation is to be provided by the sponsor in response to questions of the CHMP. Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation. If the CHMP accepts such request, the time limit of 210 days will be reduced to 150 days but it is possible that the CHMP can revert to the standard time limit for the centralized procedure if it considers that it is no longer appropriate to conduct an accelerated assessment. At the end of this period, the CHMP provides a scientific opinion on whether or not a marketing authorization should be granted in relation to a medicinal product. Within 15 calendar days of receipt of a final opinion from the CHMP, the European Commission must prepare a draft decision concerning an application for marketing authorization. This draft decision must take the opinion and any relevant provisions of EU law into account. Before arriving at a final decision on an application for centralized authorization of a medicinal product the European Commission must consult the Standing Committee on Medicinal Products for Human Use. The Standing Committee is composed of representatives of the EU member states and chaired by a non-voting European Commission representative. The European Parliament also has a related “droit de regard”. The European Parliament’s role is to ensure that the European Commission has not exceeded its powers in deciding to grant or refuse to grant a marketing authorization.

The European Commission may also grant a so-called “conditional marketing authorization” prior to obtaining the comprehensive clinical data required for an application for a full marketing authorization. Such conditional marketing authorizations may be granted for product candidates (including medicines designated as orphan medicinal products), if (i) the risk-benefit balance of the product candidate is positive, (ii) it is likely that the sponsor will be in a position to provide the required comprehensive clinical trial data, (iii) the product fulfills an unmet medical need and (iv) the benefit to public health of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data are still required. A conditional marketing authorization may contain specific obligations to be fulfilled by the marketing authorization holder, including obligations with respect to the completion of ongoing or new studies, and with respect to the collection of pharmacovigilance data. Conditional marketing authorizations are valid for one year, and may be renewed annually, if the risk-benefit balance remains positive, and after an assessment of the need for additional or modified conditions and/or specific obligations. The timelines for the centralized procedure described above also apply with respect to the review by the CHMP of applications for a conditional marketing authorization.

The EU medicines rules expressly permit the EU Member States to adopt national legislation prohibiting or restricting the sale, supply or use of any medicinal product containing, consisting of or derived from a specific type of human or animal cell, such as embryonic stem cells. While the products Infinity has in development do not make use of embryonic stem cells, it is possible that the national laws in certain EU Member States may prohibit or restrict Infinity from commercializing its products, even if they have been granted an EU marketing authorization.

Unlike the centralized authorization procedure, the decentralized marketing authorization procedure requires a separate application to, and leads to separate approval by, the competent authorities of each EU Member State in which the product is to be marketed. This application is identical to the application that would be submitted to the EMA for authorization through the centralized procedure. The reference EU Member State prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. The resulting assessment report is submitted to the concerned EU Member States who, within 90 days of receipt, must decide whether to approve the assessment report and related materials. If a concerned EU Member State cannot approve the assessment report and related materials due to concerns relating to a potential serious risk to public health, disputed elements may be referred to the European Commission, whose decision is binding on all EU Member States.

The mutual recognition procedure similarly is based on the acceptance by the competent authorities of the EU Member States of the marketing authorization of a medicinal product by the competent authorities of other EU Member States. The holder of a national marketing authorization may submit an application to the competent authority of an EU Member State requesting that this authority recognize the marketing authorization delivered by the competent authority of another EU Member State.

### *Regulatory Data Protection in the EU*

In the EU, innovative medicinal products approved on the basis of a complete independent data package qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity pursuant to Directive 2001/83/EC. Regulation (EC) No 726/2004 repeats this entitlement for medicinal products authorized in accordance the centralized authorization procedure. Data exclusivity prevents sponsors for authorization of generics of these innovative products from referencing the innovator’s data to assess a generic (abridged) application for a period of eight years. During an additional two-year period of market exclusivity, a generic marketing authorization application can be submitted and authorized, and the innovator’s data may be referenced, but no generic medicinal product can be placed on the EU market until the expiration of the market exclusivity. The overall ten-year period will be extended to a maximum of 11 years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant



clinical benefit in comparison with existing therapies. Even if a compound is considered to be a new chemical entity so that the innovator gains the prescribed period of data exclusivity, another company nevertheless could also market another version of the product if such company obtained marketing authorization based on an MAA with a complete independent data package of pharmaceutical tests, preclinical tests and clinical trials.

### *Periods of Authorization and Renewals*

A marketing authorization has an initial validity for five years in principle. The marketing authorization may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the EU Member State. To this end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least six months before the marketing authorization ceases to be valid. The European Commission or the competent authorities of the EU Member States may decide, on justified grounds relating to pharmacovigilance, to proceed with one further five-year period of marketing authorization. Once subsequently definitively renewed, the marketing authorization shall be valid for an unlimited period. Any authorization which is not followed by the actual placing of the medicinal product on the EU market (in case of centralized procedure) or on the market of the authorizing EU Member State within three years after authorization ceases to be valid.

### *Orphan Drug Designation and Exclusivity*

Regulation (EC) No. 141/2000, as implemented by Regulation (EC) No. 847/2000, provides that a drug can be designated as an orphan drug by the European Commission if its sponsor can establish that the product is intended for the diagnosis, prevention or treatment of (1) a life-threatening or chronically debilitating condition affecting not more than five in ten thousand persons in the EU when the application is made, or (2) a life-threatening, seriously debilitating or serious and chronic condition in the EU and that without incentives it is unlikely that the marketing of the drug in the EU would generate sufficient return to justify the necessary investment. For either of these conditions, the sponsor must demonstrate that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the EU or, if such method exists, the drug will be of significant benefit to those affected by that condition.

Once authorized, orphan medicinal products are entitled to 10 years of market exclusivity in all EU Member States and a range of other benefits during the development and regulatory review process, including scientific assistance for study protocols, authorization through the centralized marketing authorization procedure covering all member countries and a reduction or elimination of registration and marketing authorization fees. However, marketing authorization may be granted to a similar medicinal product with the same orphan indication during the 10-year period with the consent of the marketing authorization holder for the original orphan medicinal product or if the manufacturer of the original orphan medicinal product is unable to supply sufficient quantities. Marketing authorization may also be granted to a similar medicinal product with the same orphan indication if this product is safer, more effective or otherwise clinically superior to the original orphan medicinal product. The period of market exclusivity may, in addition, be reduced to six years if it can be demonstrated on the basis of available evidence that the original orphan medicinal product is sufficiently profitable not to justify maintenance of market exclusivity.

### *Pediatric Exclusivity*

If a sponsor obtains a marketing authorization in all EU Member States, or a marketing authorization granted in the centralized procedure by the European Commission, and the study results for the pediatric population are included in the product information, even when negative, the medicine is then eligible for an additional six-month period of qualifying patent protection through extension of the term of the Supplementary Protection Certificate (“SPC”).

*Regulatory Requirements after a Marketing Authorization has been Obtained*

In case an authorization for a medicinal product in the EU is obtained, the holder of the marketing authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products. These include:

- Compliance with the EU's stringent pharmacovigilance or safety reporting rules must be ensured. These rules can impose post-authorization studies and additional monitoring obligations.
- The manufacturing of authorized medicinal products, for which a separate manufacturer's license is mandatory, must also be conducted in strict compliance with the applicable EU laws, regulations and guidance, including Directive 2001/83/EC, Directive 2003/94/EC, Regulation (EC) No 726/2004 and the European Commission Guidelines for Good Manufacturing Practice. These requirements include compliance with EU cGMP standards when manufacturing medicinal products and active pharmaceutical ingredients, including the manufacture of active pharmaceutical ingredients outside of the EU with the intention to import the active pharmaceutical ingredients into the EU.
- The marketing and promotion of authorized drugs, including industry-sponsored continuing medical education and advertising directed toward the prescribers of drugs and/or the general public, are strictly regulated in the EU notably under Directive 2001/83/EC, as amended, and EU Member State laws. Direct-to-consumer advertising of prescription medicines is prohibited across the EU.

*Brexit and the Regulatory Framework in the United Kingdom*

The United Kingdom's withdrawal from the EU took place on January 31, 2020. The EU and the U.K. reached an agreement on their new partnership in the Trade and Cooperation Agreement (the "Agreement"), which was applied provisionally beginning on January 1, 2021 and which entered into force on May 1, 2021. The Agreement focuses primarily on free trade by ensuring no tariffs or quotas on trade in goods, including healthcare products such as medicinal products. Thereafter, the EU and the U.K. will form two separate markets governed by two distinct regulatory and legal regimes. As such, the Agreement seeks to minimize barriers to trade in goods while accepting that border checks will become inevitable as a consequence that the U.K. is no longer part of the single market. As of January 1, 2021, the MHRA became responsible for supervising medicines and medical devices in Great Britain, comprising England, Scotland and Wales under domestic law whereas Northern Ireland continues to be subject to EU rules under the Northern Ireland Protocol. The MHRA will rely on the HMR as the basis for regulating medicines. The HMR has incorporated into the domestic law the body of EU law instruments governing medicinal products that pre-existed prior to the U.K.'s withdrawal from the EU. The MHRA may rely on a decision taken by the European Commission on the approval of a new marketing authorization via the centralized procedure, until December 31, 2023.

As with other issues related to Brexit, there are open questions about how personal data will be protected in the UK and whether personal information can transfer from the EU to the UK. Following the withdrawal of the U.K. from the EU, the U.K. Data Protection Act 2018 applies to the processing of personal data that takes place in the U.K. and includes parallel obligations to those set forth by the GDPR. While the Data Protection Act of 2018 in the United Kingdom that "implements" and complements the GDPR has achieved Royal Assent on May 23, 2018 and is now effective in the United Kingdom, it is still unclear whether transfer of data from the EEA to the United Kingdom will remain lawful under the GDPR. The United Kingdom government has already determined that it considers all European Union and EEA member states to be adequate for the purposes of data protection, ensuring that data flows from the United Kingdom to the European Union/EEA remain unaffected. In addition, a recent decision from the European Commission appears to deem the UK as being "essentially adequate" for purposes of data transfer from the EU to the UK, although this decision may be re-evaluated in the future. Infinity may, however, incur liabilities, expenses, costs, and other operational losses under the GDPR and applicable EU Member States and the United Kingdom privacy laws in connection with any measures it takes to comply with them.

## ***Data Privacy Regulation***

### *U.S. Privacy Law*

There are multiple privacy and data security laws that may impact Infinity’s business activities, in the United States and in other countries where Infinity conduct trials or where it may do business in the future. These laws are evolving and may increase both Infinity’s obligations and its regulatory risks in the future. In the health care industry generally, for example, under HIPAA, the HHS has issued regulations to protect the privacy and security of protected health information (“PHI”) used or disclosed by specific covered entities including certain healthcare providers, health plans and healthcare clearinghouses. HIPAA also imposes certain obligations on the business associates of covered entities that obtain protected health information in providing services to or on behalf of covered entities. HIPAA may apply to Infinity in certain circumstances and may also apply to Infinity’s business partners in ways that may impact its relationships with them. Infinity’s clinical trials are or will be regulated by the Common Rule, which also includes specific privacy-related provisions. In addition to federal privacy regulations, there are a number of state laws governing confidentiality and security of health information that may be applicable to Infinity’s business. In addition to possible federal civil and criminal penalties for HIPAA violations, state attorneys general are authorized to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorney’s fees and costs associated with pursuing federal civil actions. In addition, state attorneys general (along with private plaintiffs) have brought civil actions seeking injunctions and damages resulting from alleged violations of HIPAA’s privacy and security rules. State attorneys general also have authority to enforce state privacy and security laws. Moreover, new laws and regulations governing privacy and security may be adopted in the future as well.

There have been several developments in recent years with respect to U.S. state data privacy laws. In 2018, California passed into law the California Consumer Privacy Act (the “CCPA”), which took effect on January 1, 2020 and imposed many requirements on businesses that process the personal information of California residents. The CCPA’s requirements include requiring businesses to provide notice to data subjects regarding the information collected about them and how such information is used and shared, and providing data subjects the right to request access to such personal information and, in certain cases, request the erasure of such personal information. The CCPA also affords California residents the right to opt-out of “sales” of their personal information. The CCPA contains significant penalties for companies that violate its requirements. It also provides California residents a private right of action in certain circumstances, including the ability to seek statutory damages, in the event of a breach involving their personal information. Compliance with the CCPA is a rigorous and time-intensive process that may increase the cost of doing business or require companies to change their business practices to ensure full compliance. . In November 2020, California voters passed a ballot initiative for the California Privacy Rights Act (the “CPRA”), which went into effect on January 1, 2023 and significantly expanded the CCPA to incorporate additional GDPR-like provisions including requiring that the use, retention, and sharing of personal information of California residents be reasonably necessary and proportionate to the purposes of collection or processing, granting additional protections for sensitive personal information, and requiring greater disclosures related to notice to residents regarding retention of information. The CPRA also created a new enforcement agency – the California Privacy Protection Agency – whose sole responsibility is to enforce the CPRA, which will further increase compliance risk. The provisions in the CPRA may apply to some of Infinity’s business activities. In addition, other states, including Virginia, Colorado, Utah, and Connecticut already have passed state privacy laws. Virginia’s privacy law also went into effect on January 1, 2023, and the laws in the other three states will go into effect later in the year. Other states will be considering these laws in the future, and Congress has also been debating passing a federal privacy law. These laws may impact Infinity’s business activities, including its identification of research subjects, relationships with business partners and ultimately the marketing and distribution of its products.

### *General Data Protection Regulation*

The collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the EU, including personal health data, is subject to the GDPR, which became effective on May 25, 2018. The GDPR is

wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the EU, including the U.S., and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. Compliance with the GDPR is a rigorous and time-intensive process that may increase the cost of doing business or require companies to change their business practices to ensure full compliance.

There are ongoing concerns about the ability of companies to transfer personal data from the EU to other countries. In July 2020, the CJEU invalidated the EU-U.S. Privacy Shield framework, one of the mechanisms used to legitimize the transfer of personal data from the EEA to the United States. The CJEU decision also drew into question the long-term viability of an alternative means of data transfer, the standard contractual clauses, for transfers of personal data from the EEA to the United States. This CJEU decision may lead to increased scrutiny on data transfers from the EU to the U.S. generally and increase Infinity's costs of compliance with data privacy legislation as well as its costs of negotiating appropriate privacy and security agreements with its vendors and business partners.

Additionally, in October 2022, President Biden signed an executive order to implement the EU-U.S. Data Privacy Framework, which would serve as a replacement to the EU-US Privacy Shield. The EC initiated the process to adopt an adequacy decision for the EU-US Data Privacy Framework in December 2022. It is unclear if and when the framework will be finalized and whether it will be challenged in court. The uncertainty around this issue may further impact Infinity's business operations in the EU.

As a result of these uncertainties, there is increased scrutiny on the extent to which clinical trial sites located in the EEA should apply the GDPR to transfers of personal data from such sites to countries that are considered to lack an adequate level of data protection, such as the United States. The GDPR also permits data protection authorities to require destruction of improperly gathered or used personal information and/or impose substantial fines for violations of the GDPR, which can be up to four percent of global revenues or 20 million Euros, whichever is greater, and it also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR provides that EU Member States may make their own further laws and regulations limiting the processing of personal data, including genetic, biometric or health data.

Beyond the GDPR, there are privacy and data security laws in a growing number of countries around the world. While many loosely follow the GDPR as a model, other laws contain different or conflicting provisions. These laws will impact Infinity's ability to conduct its business activities, including both its clinical trials and any eventual sale and distribution of commercial products. These laws also impose compliance obligations and related costs and may complicate both Infinity's business activities overall and its relationships with its business partners and service providers.

For these laws, both now and in the future, there is a wide range of enforcement agencies at the state, federal and international levels that can review companies for privacy and data security concerns based on general consumer protection laws. The Federal Trade Commission and state Attorneys General all are aggressive in reviewing privacy and data security protections for consumers. New laws also are being considered at both the state and federal levels. For example, the CCPA, which went into effect on January 1, 2020, is creating similar risks and obligations as those created by the GDPR, though the CCPA does exempt certain information collected as part of a clinical trial subject to the Federal Policy for the Protection of Human Subjects (the "Common Rule"). Many

other states are considering similar legislation. A broad range of legislative measures also have been introduced at the federal level. Accordingly, failure to comply with federal and state laws (both those currently in effect and future legislation) regarding privacy and security of personal information could expose Infinity to fines and penalties under such laws. There also is the threat of consumer class actions related to these laws and the overall protection of personal data. Even if Infinity is not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm Infinity's reputation and its business.

In addition to the foregoing, any breach of privacy laws or data security laws, particularly resulting in a significant security incident or breach involving the misappropriation, loss or other unauthorized use or disclosure of sensitive or confidential patient or consumer information, could have a material adverse effect on Infinity's business, reputation and financial condition. As a data controller, Infinity will be accountable for any third-party service providers it engages to process personal data on its behalf, including its CROs. There is no assurance that privacy and security-related safeguards Infinity implements will protect it from all risks associated with the third-party processing, storage and transmission of such information. In certain situations, both in the United States and in other countries, Infinity also may be obligated as a result of a security breach to notify individuals and/or government entities about these breaches.

New privacy and security legislation continues to be proposed or enacted across the United States. These laws impose, or have the potential to impose, additional obligations on companies that collect, store, use, retain, disclose, transfer and otherwise process confidential, sensitive and personal information, and will continue to shape the data privacy environment nationally. State laws are changing rapidly and there is discussion in Congress of a new federal data protection and privacy law to which Infinity would become subject if it is enacted. There is also discussion of an executive order on cybersecurity that could affect how Infinity collects and processes information. All of these evolving compliance and operational requirements impose significant costs that are likely to increase over time, may require Infinity to modify its data processing practices and policies, divert resources from other initiatives and projects, and could restrict the way products and services involving data are offered, all of which could significantly harm its business, financial condition, results of operations and prospects. Further, certain state laws may be more stringent or broader in scope, or offer greater individual rights, with respect to confidential, sensitive and personal information than federal, international or other state laws, and such laws may differ from each other, which may complicate compliance efforts.

Given the breadth and depth of changes in data protection obligations, preparing for and complying with such requirements is rigorous and time intensive and requires significant resources and a review of Infinity's technologies, systems and practices, as well as those of any third-party collaborators, service providers, contractors or consultants that process or transfer personal data. The GDPR and other changes in laws or regulations associated with the enhanced protection of certain types of sensitive data, such as healthcare data or other personal information from Infinity's clinical trials, could require Infinity to change its business practices and put in place additional compliance mechanisms, may interrupt or delay Infinity's development, regulatory and commercialization activities and increase its cost of doing business, and could lead to government enforcement actions, private litigation and significant fines and penalties against Infinity and could have a material adverse effect on its business, financial condition or results of operations.

### ***Pricing Decisions for Approved Products***

In the EU, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies or so-called health technology assessments, in order to obtain reimbursement or pricing approval. For example, the EU provides options for its member states to restrict the range of products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. Member states may approve a specific price for a product or it may instead adopt a system of direct

## [Table of Contents](#)

or indirect controls on the profitability of the company placing the product on the market. Other member states allow companies to fix their own prices for products, but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Recently, many countries in the EU have increased the amount of discounts required on pharmaceuticals and these efforts could continue as countries attempt to manage health care expenditures, especially in light of the severe fiscal and debt crises experienced by many countries in the EU. The downward pressure on health care costs in general, particularly prescription products, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various member states, and parallel trade, i.e., arbitrage between low-priced and high-priced member states, can further reduce prices. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any products, if approved in those countries.

### **Human Capital**

As of March 31, 2023, Infinity had 30 full-time employees, 17 of whom were engaged in research and development and 13 of whom were engaged in general business management, administration and finance. Approximately 80% of Infinity's employees hold advanced degrees, including 10 that hold Ph.D., M.D., or other professional degrees and 14 that hold a master's degree. Infinity's success depends, in part, on its ability to recruit and retain talented and trained scientific and business personnel and senior leadership, as well as its ability to leverage key consultants in supporting strategic and tactical roles. Infinity believes that it has been successful to date in obtaining and retaining these individuals, but it does not know whether it will be successful in doing so in the future. None of Infinity's employees are represented by a labor union or covered by a collective bargaining agreement, nor has Infinity experienced work stoppages.

### **Corporate Information**

Infinity was incorporated in California on March 22, 1995 under the name IRORI and, in 1998, Infinity changed its name to Discovery Partners International, Inc. ("DPI"). In July 2000, Infinity reincorporated in Delaware. On September 12, 2006, DPI completed a merger with Infinity Pharmaceuticals, Inc. ("IPI") pursuant to which a wholly owned subsidiary of DPI merged with and into IPI. IPI, the surviving corporation in the merger, changed its name to Infinity Discovery, Inc. ("IDI"), and became a wholly owned subsidiary of DPI. In addition, Infinity changed its corporate name from Discovery Partners International, Inc. to Infinity Pharmaceuticals, Inc., and Infinity's ticker symbol on the Nasdaq Global Market to "INFI." Infinity's common stock currently trades on the Nasdaq Global Select Market.

Infinity's principal executive offices are located at 1100 Massachusetts Avenue, Floor 4, Cambridge Massachusetts 02138, and its telephone number is (617) 453-1000.

The Infinity logo and all other Infinity product names are trademarks of Infinity Pharmaceuticals, Inc. or its subsidiaries in the United States and in other select countries. Infinity may indicate U.S. trademark registrations and U.S. trademarks with the symbols "®" and "™", respectively. Other third-party logos and product/trade names are registered trademarks or trade names of their respective owners.

### **Available Information**

Infinity's Internet website is <http://www.infi.com>. Infinity makes available free of charge through its website its annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Sections 13(a) and 15(d) of the Exchange Act. Infinity makes these reports available through its website as soon as reasonably practicable after it electronically files such reports with, or furnish such reports to, the SEC. In addition, Infinity regularly uses its website to post information regarding its business, product development programs and governance, and Infinity encourages investors to use its website, particularly the information in the section entitled ("Investors/Media"), as a source of information about Infinity.

---

[Table of Contents](#)

Infinity's Code of Conduct and Ethics and the charters of the Audit, Compensation, Nominating & Corporate Governance and Research & Development Committees of the Infinity board of directors are all available on its website at <http://www.infi.com> at the "Investors/Media" section under ("Corporate Governance"). Stockholders may request a free copy of any of these documents by writing to Investor Relations, Infinity Pharmaceuticals, Inc., 1100 Massachusetts Avenue, Floor 4, Cambridge, Massachusetts 02138, U.S.A.

The foregoing references to Infinity's website are not intended to, nor shall they be deemed to, incorporate information on its website into this joint proxy statement/prospectus by reference.



## MEI MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*The following discussion and analysis of MEI's financial condition and results of operations should be read in conjunction with MEI's financial statements and related notes thereto appearing elsewhere in this joint proxy statement/prospectus. MEI's actual results and timing of certain events may differ materially from the results discussed, projected, anticipated, or indicated in any forward-looking statements. MEI cautions you that forward-looking statements are not guarantees of future performance and that its actual results of operations, financial condition and liquidity, and the development of the industry in which MEI operates, may differ materially from the forward-looking statements contained in this joint proxy statement/prospectus. In addition, even if MEI's results of operations, financial condition and liquidity, and the development of the industry in which it operates are consistent with the forward-looking statements contained in this joint proxy statement/prospectus, they may not be predictive of results or developments in future periods.*

*The following information and any forward-looking statements should also be considered in light of risks identified under the caption "Risk Factors" in this joint proxy statement/prospectus. MEI cautions you not to place undue reliance on any forward-looking statements made by it, which speak only as of the date they are made. MEI disclaims any obligation, except as specifically required by law and the rules of the SEC, to publicly update or revise any such statements to reflect any change in its expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.*

### Overview

MEI Pharma, Inc. (Nasdaq: MEIP) is a clinical stage pharmaceutical company focused on developing potential new therapies for cancer. MEI Pharma's portfolio of drug candidates includes clinical-stage candidates with differentiated or novel mechanisms of action intended to address unmet medical needs and deliver improved benefit to patients, either as standalone treatments or in combination with other therapeutic options. MEI's common stock is listed on the Nasdaq Capital Market under the symbol "MEIP."

In November 2022, MEI announced plans to realign its clinical development efforts after jointly deciding with its development partner, Kyowa Kirin Co., Ltd. ("Kyowa Kirin"), to discontinue development of MEI's lead drug candidate, zandelisib, outside of Japan. In connection with the realignment, MEI is focusing its development efforts on its two earlier stage clinical assets, voruciclib and ME-334. Additionally, MEI initiated a staggered workforce reduction, affecting 28 employees in December 2022 (representing approximately 27% of its workforce) and an additional nine employees as of April 21, 2023. Following completion of the close of the zandelisib development program, workforce reductions completed to date and any further workforce reductions necessary to fully align resources going forward, MEI expects that its existing cash, cash equivalents and short-term investments will be sufficient to fund operations for approximately two years.

### Clinical Development Programs

MEI's business strategy is to build its pipeline by licensing or acquiring promising cancer agents and creating value in programs through development, strategic partnerships and commercialization, as appropriate. MEI's objective is to leverage the mechanisms and properties of its pipeline drug candidates to optimize the balance between efficacy and tolerability to meet the needs of patients with cancer. MEI's drug candidate pipeline includes voruciclib, an oral cyclin-dependent kinase 9 ("CDK9") inhibitor and ME-344, an intravenous small molecule targeting the oxidative phosphorylation pathway.

## Table of Contents

INVESTIGATIONAL AGENTS	THERAPEUTIC AREA	COMBINATION	PHASE 1/1B	PHASE 2	PHASE 3
<b>Voruciclib</b> Oral CDK9 Inhibitor	B-Cell Malignancies & AML Relapsed/refractory (2L+)	Monotherapy Venclexta®	 		
<b>ME-344</b> Mitochondrial Inhibitor	Colorectal Cancer <sup>1</sup> Relapsed	Avastin®			

### 1. Study pending initiation

#### *Voruciclib: Potent Orally Administered CDK9 Inhibitor in Phase 1 Studies*

Voruciclib is a potent orally administered CDK9 inhibitor. Voruciclib is being evaluated in a Phase 1b trial evaluating dose and schedule in patients with AML and B-cell malignancies. Voruciclib is also being evaluated in pre-clinical studies to explore the potential synergistic activity in various solid tumor cancers of voruciclib in combination with drug-candidates that targets in the RAS signaling pathway, including KRAS.

#### *Voruciclib Scientific Overview: Cell Cycle Signaling*

CDK9 has important functions in cell cycle regulation, including the modulation of two therapeutic targets in cancer:

- CDK9 is a transcriptional regulator of the myeloid leukemia cell differentiation protein (“MCL1”), a member of the family of anti-apoptotic proteins which, when elevated, may prevent the cell from undergoing cell death. Inhibition of CDK9 blocks the production of MCL1, which is an established resistance mechanism to the B-cell lymphoma (“BCL2”) inhibitor venetoclax (marketed as Venclexta®).
- CDK9 is a transcriptional regulator of the MYC proto-oncogene protein (“MYC”) which regulates cell proliferation and growth. Upregulation of MYC is implicated in many human cancers and is frequently associated with poor prognosis and unfavorable patient survival. CDK9, in addition to being a transcription factor for MYC, also decreases phosphorylation of MYC protein that is implicated in stabilizing MYC in KRAS mutant cancers.

Targeting MYC directly has historically been difficult, but CDK9 is a promising approach to target this oncogene.

#### *Voruciclib: Inhibition of MCL1*

In pre-clinical studies voruciclib shows dose-dependent suppression of MCL1; in December 2017, a study of voruciclib published in the journal Nature Scientific Reports reported that the combination of voruciclib plus the BCL-2 inhibitor venetoclax was capable of inhibiting two master regulators of cell survival, MCL-1 and BCL-2, and achieved synergistic antitumor effect in an aggressive subset of DLBCL pre-clinical models.

In a peer reviewed manuscript published in 2020 by Luedtke et al, it was reported that the inhibition of CDK9 by voruciclib synergistically enhances cell death induced by the Bcl-2 selective inhibitor venetoclax in preclinical models of AML. The data demonstrated that voruciclib synergizes with venetoclax to induce programmed cell death, or apoptosis, in both AML cell lines and primary patient samples. It was also demonstrated that voruciclib downregulates MCL1, which is relevant for the synergy between voruciclib and venetoclax, and further that voruciclib also downregulates MYC, which also contributes to the synergies with venetoclax.

The research presented suggests that voruciclib is an attractive therapeutic target for treating cancers in combination with venetoclax or other BCL-2 inhibitors, and is supportive of MEI’s ongoing clinical evaluation of voruciclib in B-cell malignancies and AML.

*Voruciclib: Inhibition of MYC*

Many cancers are associated with overexpression of MYC, a transcription factor regulating cell proliferation and growth. CDK9 is a known regulator of MYC transcription and a modulator of MYC protein phosphorylation. Data reported at the American Association for Cancer Research (“AACR”) Annual Meeting 2021 in preclinical models demonstrates that voruciclib:

- Results in a rapid decrease in the phosphorylation of proteins that promote MYC transcription;
- Rapidly decreases phosphorylation of MYC protein on Ser62, a site implicated in stabilizing MYC in KRAS mutant cancers;
- Possesses single agent activity against multiple KRAS mutant cancer cell lines both in vitro and in vivo; and
- Synergistically inhibits KRAS G12C mutant cancer cell lines in combination with KRAS G12C inhibitors, both in vitro and in vivo.

The research presented suggests that voruciclib could be an attractive therapeutic agent for cancers, including solid tumors, dependent on the activity of MYC.

*Clinical Program*

MEI is evaluating patients with hematological malignancies in a Phase 1b clinical trial evaluating the dose and schedule of voruciclib. The trial started with the evaluation of dose and schedule of voruciclib as a monotherapy in patients with relapsed and refractory B-cell malignancies and AML after failure of prior standard therapies to determine the safety, preliminary efficacy and maximum tolerated dose. MEI is now also evaluating the dose and schedule of voruciclib in combination with venetoclax, a BCL2 inhibitor, initially in patients with AML and subsequently across multiple indications where BCL2 inhibition has been shown to be effective. The primary goal of the Phase 1b study is to assess the safety, and possible synergies, of voruciclib administered in combination with venetoclax. MEI is planning to report key interim clinical data from this trial around calendar year-end 2023.

As reported at the American Society of Hematology 2021 annual meeting in a poster presentation, data to date from the Phase 1 study evaluating voruciclib as a monotherapy on an optimized schedule of 14 consecutive days in a 28-day cycle was well tolerated. No dose limiting toxicities were observed and no significant myelosuppression was seen in patients with B-cell malignancies, suggesting a lower likelihood of additive toxicities in combination with venetoclax. Disease stabilization was observed in heavily pretreated patients and differentiation syndrome was observed in AML patients, which is indicative of biologic activity.

Voruciclib was also previously evaluated in more than 70 patients with solid tumors in multiple Phase 1 studies. The totality of the clinical data, along with data from pre-clinical studies, suggests voruciclib’s ability to inhibit its molecular target at a projected dose as low as 150 mg daily. In one clinical study, voruciclib was evaluated in combination with vemurafenib (marketed as Zelboraf®) in nine patients with BRAF mutated advanced/inoperable malignant melanoma. All three BRAF/MEK naive patients achieved a response: two partial responses and one complete response. In this study voruciclib was dosed at 150 mg daily plus vemurafenib 720 mg or 960 mg twice daily in 28-day cycles. The most common adverse events were fatigue, constipation, diarrhea, arthralgia and headache. One instance of grade 3 fatigue was dose limiting and no serious adverse events related to voruciclib were reported. Other clinical studies evaluated voruciclib at doses up to 850 mg in patients with solid tumors, demonstrating additional evidence of potential biologic activity and an adverse event profile generally consistent with other drugs in its class.

*ME-344: Clinical Stage Mitochondrial Inhibitor with Combinatorial Potential*

ME-344 is MEI’s novel isoflavone-derived mitochondrial inhibitor drug candidate that demonstrates tumor selective activity in pre-clinical studies. It targets the oxidative phosphorylation pathway involved in ATP

## [Table of Contents](#)

production in the mitochondria. ME-344 has been evaluated in clinical studies, including an investigator-initiated, multi-center, randomized, window of opportunity clinical trial in combination with the vascular endothelial growth factor (“VEGF”) inhibitor bevacizumab (marketed as Avastin<sup>®</sup>) that enrolled a total of 42 patients with human epidermal growth factor receptor 2 (“HER2”) negative breast cancer.

### *ME-344 Scientific Overview: Cancer Metabolism*

Tumor cells often display a high metabolic rate to support cell division and growth. This heightened metabolism requires a continual supply of energy in the form of ATP. The two major sources of ATP are the specialized cellular organelles termed mitochondria and through the metabolism of carbohydrates via the glycolysis pathway, which is frequently unregulated in cancer cells in a phenomenon called the Warburg Effect.

ME-344 was identified through a screen of more than 400 new chemical structures originally created based on the central design of naturally occurring plant isoflavones. MEI believes that some of these synthetic compounds, including MEI’s drug candidate ME-344, interact with specific mitochondrial enzyme targets, resulting in the inhibition of ATP generation. When these compounds interact with their target, a rapid reduction in ATP occurs, which leads to a cascade of biochemical events within the cell and ultimately to cell death.

### *Clinical Program*

ME-344 demonstrated evidence of single agent activity against refractory solid tumors in a Phase 1 trial, and in pre-clinical studies tumor cells treated with ME-344 resulted in a rapid loss of ATP and cancer cell death. In addition to single agent activity, ME-344 may also have significant potential in combination with anti-angiogenic therapeutics. In pre-clinical studies, it was shown that one outcome of anti-angiogenics was to reduce the rate of glycolysis in tumors as a mechanism to slow tumor growth. However, tumor metabolism was able to shift to mitochondrial metabolism for energy production to support continued tumor proliferation. In such cases of tumor plasticity in the presence of treatment with anti-angiogenics, targeting the alternative metabolic source with ME-344 may open an important therapeutic opportunity.

Support for this combinatorial use of ME-344 was first published in the June 2016 edition of Cell Reports; pre-clinical data from a collaboration with the Spanish National Cancer Research Centre in Madrid demonstrated mitochondria-specific effects of ME-344 in cancer cells, including substantially enhanced anti-tumor activity when combined with agents that inhibit the activity of VEGF. These data demonstrating the potential anti-cancer effects of combining ME-344 with a VEGF inhibitor due to an inhibition of both mitochondrial and glycolytic metabolism provided a basis for commencement of an investigator-initiated trial of ME-344 in combination with bevacizumab in HER2 negative breast cancer patients.

Results published in the November 2019 issue of Clinical Cancer Research from a multicenter, investigator-initiated, randomized, open-label, clinical trial that evaluated the combination of ME-344 and bevacizumab in 42 women with early HER2-negative breast cancer further support the combinatorial use of ME-344 with anti-angiogenic therapeutics.

The primary objective of the trial was to show proof of ME-344 biologic activity as measured by Ki67 reductions in the presence of the nuclear protein Ki67 (expression of which is strongly associated with tumor cell proliferation and growth) from days 0 to 28 compared to the control group who received bevacizumab alone. Secondary objectives included determining whether ME-344 biologic activity correlates with vascular normalization. The data demonstrate significant biologic activity in the ME-344 treatment group:

- In ME-344 treated patients, mean absolute Ki67 decreases were 13.3 compared to an increase of 1.1 in the bevacizumab monotherapy group (P=0.01).
- In ME-344 treated patients, mean relative Ki67 decreases were 23% compared to an increase of 186% in the bevacizumab monotherapy group (P < 0.01).
- The mean relative Ki67 reduction in patients experiencing vascular normalization in the ME-344 treated patients was 33%, compared to an increase of 11.8% in normalized patients from the

bevacizumab monotherapy group (P=0.09). Approximately one-third of patients in each arm had vascular normalization.

Treatment was generally well tolerated; three grade 3 adverse events of high blood pressure were reported, two in the ME-344 arm and one in the bevacizumab monotherapy arm.

Results from MEI's earlier, first-in-human, single-agent Phase 1 clinical trial of ME-344 in patients with refractory solid tumors were published in the April 1, 2015 edition of *Cancer*. The results indicated that eight of 21 evaluable patients (38%) treated with ME-344 achieved stable disease or better, including five who experienced progression-free survival that was at least twice the duration of their last prior treatment before entry into the trial. In addition, one of these patients, a heavily pre-treated patient with small cell lung cancer, achieved a confirmed partial response and remained on study for two years. ME-344 was generally well tolerated at doses equal to or less than 10 mg/kg delivered on a weekly schedule for extended durations. Treatment-related adverse events included nausea, dizziness and fatigue. Dose-limiting toxicities were observed at both the 15 mg/kg and 20 mg/kg dose levels, consisting primarily of grade 3 peripheral neuropathy.

MEI is planning to advance ME-344 in combination with the anti-angiogenic antibody bevacizumab in a Phase 1b study evaluating patients with relapsed colorectal cancer in the first half of calendar year 2023. The study will enroll patients with progressive disease after failure of standard therapies with patients treated until disease progression or intolerance. The primary objective is progression free survival. Secondary endpoints include overall response rate, duration of response, overall survival and safety. MEI is planning to report key interim clinical data from this trial around calendar year-end 2023.

Additionally, ME-344 may also have clinical potential against hematological malignancies. At the AACR Annual Meeting 2022, a poster presentation reported results from preclinical studies exploring the ability of ME-344 to enhance the activity of venetoclax against AML. Data from the in vitro and in vivo preclinical studies evaluating the combination of ME-344 with venetoclax in standard-of-care-resistant AML cell lines and relapsed or refractory AML patient samples suggest that ME-344, both alone and in combination with venetoclax, inhibits purine biosynthesis, suppresses oxidative phosphorylation, induces apoptosis and decreases MCL-1, which together target metabolic vulnerabilities of AML cells. The data demonstrated that ME-344 and venetoclax prolong survival in MV4-11 and MV4-11/AraC-R-derived xenograft AML models. The poster concludes that ME-344 enhances venetoclax activity against AML cells including resistant AML.

#### *Zandelisib: PI3Kd Inhibitor Overview*

Zandelisib is an oral, once-daily, selective PI3Kd inhibitor that MEI is jointly developing with Kyowa Kirin under a global license, development and commercialization agreement entered into in April 2020.

In March 2022, MEI and Kyowa Kirin reported the outcome of an end of Phase 2 meeting with the FDA wherein the agency discouraged a filing based on data from a single-arm Phase 2 trial, called TIDAL, evaluating zandelisib in patients with relapsed or refractory follicular lymphoma. At this meeting, the FDA stated that data generated from single arm studies such as the Phase 2 TIDAL trial are insufficient to adequately assess the risk/benefit of PI3K inhibitors evaluating indolent non-Hodgkin lymphoma. At that time the FDA emphasized that the companies continue efforts with the ongoing randomized Phase 3 COASTAL trial evaluating patients with relapsed or refractory follicular or marginal zone lymphomas. Subsequently, at an April 2022 meeting of the FDA Oncology Drugs Advisory Committee, the committee voted that future approvals of PI3K inhibitors for hematologic malignancies should be supported by randomized data.

In November 2022, MEI and Kyowa Kirin met with the FDA in a follow-up meeting to the March 2022 end of Phase 2 meeting. At this meeting, the FDA provided further guidance regarding the design and statistical analysis for the COASTAL trial. Following the November meeting, the companies jointly concluded that a clinical trial consistent with the recent FDA guidance, including modification of the ongoing COASTAL trial, would likely not be feasible to complete within a time period that would support further investment or with sufficient certainty of the regulatory requirements for approval to justify continued global development efforts. As a result, MEI and

## [Table of Contents](#)

Kyowa Kirin jointly decided to discontinue global development of zandelisib for indolent forms of non-Hodgkin lymphoma outside of Japan. The discontinuation of zandelisib development outside of Japan was a business decision based on the most recent regulatory guidance from the FDA and is not related to the zandelisib clinical data generated to date.

In March 2023, Kyowa Kirin met with the Pharmaceuticals and Medical Devices Agency, or PMDA, the equivalent to the FDA in Japan, to discuss the continuing development of zandelisib in Japan. Kyowa Kirin is currently evaluating whether to continue developing zandelisib in Japan.

MEI and Kyowa Kirin have begun closing all ongoing zandelisib clinical studies outside of Japan, including the Phase 3 COASTAL trial, the Phase 2 TIDAL trial, and the Phase 2 CORAL trial. Depending on the achievement of certain regulatory and commercial milestones in Japan, MEI may be eligible for additional payments from Kyowa Kirin under the current agreement. MEI may also be entitled to royalties on any sales of zandelisib in Japan.

### *Kyowa Kirin License, Development and Commercialization Agreement*

In April 2020, MEI entered into the Kyowa Kirin Commercialization Agreement under which MEI granted to Kyowa Kirin a co-exclusive, sublicensable, payment-bearing license under certain patents and know-how controlled by MEI to develop and commercialize zandelisib and any pharmaceutical product containing zandelisib for all human indications in the U.S. (the “U.S. License”), and an exclusive (subject to certain retained rights to perform obligations under the Kyowa Kirin Commercialization Agreement), sublicensable, payment-bearing, license under certain patents and know-how controlled by MEI to develop and commercialize zandelisib and any pharmaceutical product containing zandelisib for all human indications in countries outside of the U.S. (the “Ex-U.S.” and the “Ex-U.S. License”). Kyowa Kirin granted to MEI a co-exclusive, sublicensable, license under certain patents and know-how controlled by Kyowa Kirin to develop and commercialize zandelisib for all human indications in the U.S., and a co-exclusive, sublicensable, royalty-free, fully paid license under certain patents and know-how controlled by Kyowa Kirin to perform MEI’s obligations in the Ex-U.S. under the Kyowa Kirin Commercialization Agreement. Kyowa Kirin paid MEI an initial payment of \$100.0 million. Additionally, in Japan, the Kyowa Kirin Commercialization Agreement included potential regulatory and commercialization milestone payments plus royalties on net sales of zandelisib in Japan, which are tiered beginning in the teens.

Kyowa Kirin is responsible for the development and commercialization of zandelisib in the Ex-U.S. and, subject to certain exceptions, is solely responsible for all costs related thereto. MEI will also provide to Kyowa Kirin certain drug supplies necessary for the development and commercialization of zandelisib in the Ex-U.S., with the understanding that Kyowa Kirin will assume responsibility for manufacturing for the Ex-U.S. as soon as practicable. MEI and Kyowa Kirin will reevaluate the Kyowa Kirin Commercialization Agreement once Kyowa Kirin makes a decision on its plans to develop zandelisib in Japan.

### **Critical Accounting Policies and Management Estimates**

Management’s discussion and analysis of MEI’s financial condition and results of operations is based on MEI’s financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S. The preparation of these financial statements requires MEI to make estimates and assumptions that affect the reported amounts of assets, liabilities, expenses and related disclosures. Actual results could differ from those estimates. Management believes the following accounting policies to be critical to the judgments and estimates used in the preparation of MEI’s financial statements.

### **Revenue Recognition**

#### *Revenues from Customers*

MEI recognizes revenue in accordance with Accounting Standards Codification (“ASC”) Topic 606, *Revenue from Contracts with Customers* (“Topic 606”) when control of the promised goods or services is transferred to

## Table of Contents

MEI's customers, in an amount that reflects the consideration MEI expects to be entitled to in exchange for those goods or services. For enforceable contracts with customers, MEI first identifies the distinct performance obligations – or accounting units – within the contract. Performance obligations are commitments in a contract to transfer a distinct good or service to the customer.

Payments received under commercial arrangements, such as licensing technology rights, may include non-refundable fees at the inception of the arrangements, cost reimbursements, milestone payments for specific achievements designated in the agreements, and royalties on the sale of products. At the inception of arrangements that include variable consideration, MEI uses judgment to estimate the amount of variable consideration to include in the transaction price using the most likely method. If it is probable that a significant revenue reversal will not occur, the estimated amount is included in the transaction price. Milestone payments that are not within MEI's or the licensee's control, such as regulatory approvals, are not included in the transaction price until those approvals are received. At the end of each reporting period, MEI re-evaluates estimated variable consideration included in the transaction price and any related constraint and, as necessary, adjusts MEI's estimate of the overall transaction price.

MEI develops estimates of the stand-alone selling price for each distinct performance obligation. Variable consideration that relates specifically to its efforts to satisfy specific performance obligations is allocated entirely to those performance obligations. Other components of the transaction price are allocated based on the relative stand-alone selling price, over which management has applied significant judgment. MEI develops assumptions that require judgment to determine the stand-alone selling price for license-related performance obligations, which may include forecasted revenues, development timelines, reimbursement rates for personnel costs, discount rates and probabilities of technical, regulatory and commercial success. MEI estimates the stand-alone selling price for research and development performance obligation by forecasting the expected costs of satisfying a performance obligation plus an appropriate margin.

In the case of a license that is a distinct performance obligation, MEI recognizes revenue allocated to the license from non-refundable, up-front fees at the point in time when the license is transferred to the licensee and the licensee can use and benefit from the license. For licenses that are bundled with other distinct or combined obligations, MEI uses judgment to assess the nature of the performance obligation to determine whether the performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. If the performance obligation is satisfied over time, MEI evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

The selection of the method to measure progress towards completion requires judgment and is based on the nature of the products or services to be provided. Revenue is recorded proportionally as costs are incurred. MEI generally uses the cost-to-cost measure of progress because it best depicts the transfer of control to the customer which occurs as MEI incurs costs. Under the cost-to-cost measure of progress, the extent of progress towards completion is measured based on the ratio of costs incurred to date to the total estimated costs at completion of the performance obligation (an "input method" under Topic 606). MEI uses judgment to estimate the total cost expected to complete the research and development performance obligations, which include subcontractors' costs, labor, materials, other direct costs and an allocation of indirect costs. MEI evaluates these cost estimates and the progress each reporting period and, as necessary, adjusts the measure of progress and related revenue recognition.

### *Revenues from Collaborators*

At contract inception, MEI assesses whether the collaboration arrangements are within the scope of ASC Topic 808, *Collaborative Arrangements* ("ASC 808") to determine whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities. This assessment is performed based on the responsibilities of all parties in the arrangement. For collaboration arrangements within the scope of ASC 808



## [Table of Contents](#)

that contain multiple units of account, MEI first determines which units of account within the arrangement are within the scope of ASC 808 and which elements are within the scope of Topic 606. For units of account within collaboration arrangements that are accounted for pursuant to ASC 808, an appropriate recognition method is determined and applied consistently, by analogy to authoritative accounting literature. For units of account within collaboration arrangements that are accounted for pursuant to ASC 606, MEI recognizes revenue as discussed above. Consideration received that does not meet the requirements to satisfy Topic 606 revenue recognition criteria is recorded as deferred revenue on the balance sheets, classified as either current or long-term deferred revenue based on MEI's best estimate of when such amounts will be recognized.

### **Research and Development Costs**

Research and development costs are expensed as incurred and include costs paid to third party contractors to perform research, conduct clinical trials and develop and manufacture drug materials. Clinical trial costs, including costs associated with third party contractors, are a significant component of research and development expenses. MEI expenses research and development costs based on work performed. In determining the amount to expense, management relies on estimates of total costs based on contract components completed, the enrollment of subjects, the completion of trials, and other events. Costs incurred related to the purchase or licensing of in-process research and development for early-stage products or products that are not commercially viable and ready for use, or have no alternative future use, are charged to expense in the period incurred.

### **Share-Based Compensation**

Share-based compensation expense stock options and restricted stock units, ("RSUs"), granted to employees and directors is recognized in the Statements of Operations based on estimated amounts. For stock options, MEI estimates the grant date fair value using a Black-Scholes valuation model, which requires the use of multiple subjective inputs including estimated future volatility, expected forfeitures and the expected term of the awards. MEI estimates the expected future volatility based on the stock's historical price volatility. The stock's future volatility may differ from the estimated volatility at the grant date. For RSUs, MEI estimates the grant date fair value using its closing stock price on the date of grant. MEI recognizes the effect of forfeitures in share-based compensation expense when the forfeitures occur. MEI recognizes the value of the awards over the awards' requisite service or performance periods. The requisite service period is generally the time over which share-based awards vest.

### **Warrant Liability**

Pursuant to the terms of the warrants, MEI could be required to settle its warrants in cash in the event of an acquisition of MEI and, as a result, the warrants are required to be measured at fair value and reported as a liability in the balance sheets. MEI recorded the fair value of the warrants upon issuance using the Black-Scholes valuation model and are required to revalue the warrants at each reporting date with any changes in fair value recorded on the Statements of Operations. Inputs used to determine the estimated fair value of the warrant liabilities include the estimated fair value of the underlying stock at the valuation date, the estimated term of the warrants, risk-free interest rates, expected dividends and the expected volatility of the underlying stock.

### **Leases**

At the inception of a leasing arrangement, MEI determines whether the arrangement is or contains a lease based on the unique facts and circumstances within the arrangement. A lease is identified where an arrangement conveys the right to control the use of identified property, plant, and equipment for a period of time in exchange for consideration. Leases which are identified within the scope of ASC 842 and which have a term greater than one year are recognized on the balance sheets as ROU assets and operating lease liabilities. Operating lease liabilities and their corresponding ROU assets are recorded based on the present value of lease payments over the expected remaining lease term. The lease term includes any renewal options and termination options that are reasonably certain to exercise. Certain adjustments to the ROU asset may be required for items such as initial direct costs paid or incentives received. The present value of lease payments is determined by using the interest

## [Table of Contents](#)

rate implicit in the lease, if that rate is readily determinable; otherwise, MEI uses its incremental borrowing rate. The interest rate implicit in lease contracts to calculate the present value is typically not readily determinable. As such, significant management judgment is required to estimate the incremental borrowing rate.

### **Income Taxes**

MEI's income tax expense consists of current and deferred income tax expense or benefit. Current income tax expense or benefit is the amount of income taxes expected to be payable or refundable for the current year. A deferred income tax asset or liability is recognized for the future tax consequences attributable to tax credits and loss carryforwards and to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized. As of December 31, 2022, June 30, 2022 and 2021, MEI has established a valuation allowance to fully reserve its net deferred tax assets. Changes in its ownership may limit the amount of net operating loss carryforwards that can be utilized in the future to offset taxable income.

### **Results of Operations**

#### *Comparison of six months ended December 31, 2022 and 2021*

**Revenue:** MEI recognized revenue of \$41.5 million for the six months ended December 31, 2022 compared to \$19.6 million for the six months ended December 31, 2021. As a result of the discontinuation of the zandelisib program, MEI updated its estimated costs to complete each performance obligation, resulting in a higher progress towards completion based on the ratio of costs incurred to date to the total estimated costs, resulting in the recognition of \$16.6 million of previously deferred revenue related to performance obligations that are being closed. MEI also recognized \$8.6 million of previously deferred revenue related to performance obligations associated with clinical trials that have not commenced and will no longer be initiated.

**Research and Development:** The following is a summary of MEI's research and development expenses to supplement the more detailed discussion below. The dollar values in the following table are in thousands.

	Six Months Ended December 31,	
	2022	2021
Research and development expenses		
Zandelisib	\$ 19,871	\$ 27,012
Voruciclib	1,161	2,586
ME-344	849	1,784
Other	12,895	10,102
Total research and development expenses	<u>\$ 34,776</u>	<u>\$ 41,484</u>

Research and development expenses consist primarily of clinical trial costs (including payments to contract research organizations "CROs"), pre-clinical study costs, and costs to manufacture MEI's drug candidates for non-clinical and clinical studies. Other research and development expenses consist primarily of salaries and personnel costs, share-based compensation, legal costs, and other costs not allocated to specific drug programs. Costs related to zandelisib decreased primarily as a result of lower drug manufacturing costs, lower professional services costs, and lower clinical costs as MEI began the discontinuation of the zandelisib program during the six months ended December 31, 2022. Costs related to voruciclib decreased for the due to lower drug manufacturing costs and clinical costs related to the Phase 1b study. Costs related to ME-344 decreased due to decreased drug manufacturing costs and clinical costs related to the Phase 1b study. The increase in other research and development costs is primarily due to personnel costs, including severance costs related to the reduction in force, offset by lower share-based compensation expenses.

**General and Administrative:** General and administrative expenses increased by \$0.2 million to \$16.0 million for the six months ended December 31, 2022 compared to \$15.8 million for the six months ended December 31,

## [Table of Contents](#)

2021. The increase is primarily due to severance costs related to the reduction in force and corporate overhead costs, offset by decreased share-based compensation costs related to the reduction in force.

**Other income or expense:** MEI recorded a non-cash gain of \$1.6 million during the six months ended December 31, 2022 due to a change in the fair value of its warrant liability. The change in the warrant liability is primarily due to changes in MEI's stock price. Additionally, MEI received interest and dividend income of \$1.3 million for the six months ended December 31, 2022 compared to \$18,000 for the six months ended December 31, 2021. The increase is primarily due to higher yields during the six months ended December 31, 2022 compared to the six months ended December 31, 2021.

### Results of Operations

#### Comparison of Years Ended June 30, 2022 and 2021

**Revenue:** Revenue increased by \$5.9 million primarily due to increased reimbursement of expenses from Kyowa Kirin due to research and development activity related to zandelisib.

**Research and Development:** The following table illustrates the components of MEI's research and development expenses for the years presented (in thousands):

	Years Ended June 30,	
	2022	2021
Zandelisib	\$ 54,764	\$ 46,052
Voruciclib	5,475	2,939
ME-344	2,915	960
Other	22,487	19,447
Total research and development expenses	<u>\$ 85,641</u>	<u>\$ 69,398</u>

Research and development expenses consist primarily of clinical trial costs, including payments to contract research organizations, pre-clinical study costs, and costs to manufacture MEI's drug candidates for non-clinical and clinical studies. Other research and development expenses consist primarily of salaries and personnel costs, share-based compensation, legal costs, and other costs not allocated to specific drug programs. Costs related to zandelisib increased for the year ended June 30, 2022 primarily as a result of higher professional services and drug manufacturing costs offset by decreased costs for the COASTAL study as a result of higher start-up costs during the prior year. Costs related to voruciclib increased for the year ended June 30, 2022 compared with the year ended June 30, 2021 primarily due to increased costs associated with the Phase 1 study and drug manufacturing costs. Cost related to ME-344 increased for the year ended June 30, 2022 compared with the year ended June 30, 2021 primarily due to increased drug manufacturing costs and start-up costs for the Phase 2 study. Other research and development costs increased for the year ended June 30, 2022 compared with the year ended June 30, 2021 primarily due to higher levels of personnel costs associated with increased headcount to support MEI's clinical activities.

**General and Administrative:** The increase in general and administrative expenses of \$6.1 million was primarily due to increases in personnel costs of \$2.5 million, external professional services of \$2.0 million and corporate overhead costs of \$1.6 million.

**Other Income, Net:** Other income, net, increased by \$1.9 million was primarily due to the increase in non-cash gains of \$2.6 million related to the changes in the fair value of MEI's warrant liability for warrants issued in connection with its private placement of shares of common stock, primarily as a result of changes in its stock price. Interest and dividend income decreased by \$0.2 million for the year ended June 30, 2022 as compared to the year ended June 30, 2021 due to lower average short-term investment balances during the year ended June 30, 2022 as compared to the year ended June 30, 2021.

## **Liquidity and Capital Resources**

### ***Comparison of six months ended December 31, 2022 and 2021***

MEI has accumulated losses of \$380.5 million since inception and expect to incur operating losses and generate negative cash flows from operations for the foreseeable future. As of December 31, 2022, MEI had \$124.2 million in cash and cash equivalents, and short-term investments. MEI believes that these resources will be sufficient to fund its operations for at least 12 months from the issuance of this joint proxy statement/prospectus. MEI's current business operations are focused on continuing the clinical development of its drug candidates. Changes to MEI's research and development plans or other changes affecting its operations and operating expenses may affect actual future use of existing cash resources. MEI cannot determine with certainty costs associated with ongoing and future clinical trials or the regulatory approval process. The duration, costs and timing associated with the development of MEI's product candidates will depend on a variety of factors, including uncertainties associated with the results of its clinical trials.

To date, MEI has obtained cash and funded its operations primarily through equity financings and license agreements. In order to continue the development of its drug candidates, at some point in the future MEI expects to pursue one or more capital transactions, whether through the sale of equity securities, debt financing, license agreements or entry into strategic partnerships. There can be no assurance that MEI will be able to continue to raise additional capital in the future.

### ***Sources and Uses of Cash***

Net cash used in operating activities for the six months ended December 31, 2022 was \$29.1 million as compared to net cash used in operating activities of \$16.3 million for the six months ended December 31, 2021. The increase in net cash used in operating activities period over period reflects the receipt of two \$10.0 million milestones during the six months ended December 31, 2021, related to the Kyowa Kirin Commercialization Agreement, with no corresponding receipt for the six months ended December 31, 2022, as well as other changes in working capital.

Net cash provided by investing activities for the six months ended December 31, 2022 was \$24.3 million as compared to \$28.4 million used in investing activities for the six months ended December 31, 2021. The change was primarily due to increased proceeds from maturities of short-term investments in 2022, net of purchases.

Net cash used in financing activities during the six months ended December 31, 2022 was \$40,000 compared with \$48.7 million provided by financing activities during the six months ended December 31, 2021. Cash used during the six months ended December 31, 2022 was due to the payment of RSU tax withholdings in exchange for common shares surrendered by RSU holders. Cash raised during the six months ended December 31, 2021 reflected \$48.7 million of net proceeds from the issuance of common stock.

### ***Comparison of Years Ended June 30, 2022 and 2021***

MEI has accumulated losses of \$374.2 million since inception and expect to incur operating losses and generate negative cash flows from operations for the foreseeable future. As of June 30, 2022, MEI had \$153.3 million in cash, cash equivalents and short-term investments. MEI believes that these resources will be sufficient to fund its operations for at least 12 months from the issuance of its Annual Report. MEI's current business operations are focused on continuing the clinical development of its drug candidates. Changes to MEI's research and development plans or other changes affecting its operating expenses may affect actual future use of existing cash resources. MEI's research and development expenses are expected to increase in the foreseeable future. MEI cannot determine with certainty costs associated with ongoing and future clinical trials or the regulatory approval process. The duration, costs and timing associated with the development of MEI's product candidates will depend on a variety of factors, including uncertainties associated with the results of its clinical trials.

## [Table of Contents](#)

To date, MEI has obtained cash and funded operations primarily through equity financings and license agreements. In order to continue the development of its drug candidates, at some point in the future MEI expects to pursue one or more capital transactions, whether through the sale of equity securities, debt financing, license agreements or entry into strategic partnerships. There can be no assurance that MEI will be able to continue to raise additional capital in the future.

### *Sources and Uses of Cash*

Net cash used in operating activities for the year ended June 30, 2022 was \$48.7 million (\$68.7 million, net of \$20.0 million of milestone payments received from Kyowa Kirin) compared to \$32.0 million (\$52.4 million, net of \$20.4 million received from the Japanese government for tax withholdings) for the year ended June 30, 2021. The increase in net cash used in operating activities was due to increased research and development and general and administrative activities as well as other changes in working capital. Net cash provided by operating activities for the year ended June 30, 2020 was \$34.3 million (\$45.3 million, net of a \$79.6 million license fee received from Kyowa Kirin).

Net cash provided by investing activities for the year ended June 30, 2022 was \$6.9 million compared to \$24.7 million for the year ended June 30, 2021. The decrease in net cash provided by investing activities was primarily due to lower maturities and purchases of short-term investments during the year ended June 30, 2022.

Net cash provided by financing activities for the year ended June 30, 2022 was \$49.1 million compared to \$3.5 million for the year ended June 30, 2021. Cash raised during the years ended June 30, 2022 and 2021 included \$48.7 million and \$3.1 million, respectively, of net proceeds from the issuance of common stock.

### **Contractual Obligations**

MEI has contracted with various consultants and third parties to assist it in pre-clinical research and development and clinical trials work for its leading drug compounds. The contracts are terminable at any time but obligate MEI to reimburse the providers for any time or costs incurred through the date of termination. Additionally, MEI has employment agreements with certain current employees that provide for severance payments and accelerated vesting for share-based awards if their employment is terminated under specified circumstances.

MEI leases office space in San Diego, California under non-cancelable operating leases. The leases are subject to additional variable non-lease component charges (e.g., common area maintenance, maintenance, etc.). See Note 8 *Leases* of the unaudited condensed financial statements for additional details related to MEI's lease obligations.

### *Presage License Agreement*

In September 2017, MEI entered into the Presage License Agreement. Under the terms of the Presage License Agreement, Presage granted to MEI exclusive worldwide rights to develop, manufacture and commercialize voruciclib, a clinical-stage, oral and selective CDK inhibitor, and related compounds. In exchange, MEI paid Presage \$2.9 million. With respect to the first indication, an incremental \$2.0 million payment, due upon dosing the first subject in the first registration trial will be owed to Presage, for total payments of \$4.9 million prior to receipt of marketing approval of the first indication in the U.S., E.U. or Japan. Additional potential payments of up to \$179 million will be due upon the achievement of certain development, regulatory and commercial milestones. MEI will also pay mid-single-digit tiered royalties on the net sales of any product successfully developed. As an alternative to milestone and royalty payments related to countries in which MEI sublicenses product rights, it will pay to Presage a tiered percent (which decreases as product development progresses) of amounts received from such sublicensees. As of December 31 2022 and June 30, 2022, MEI had not accrued any amounts for potential future payments.

*COVID-19*

As a result of the ongoing COVID-19 pandemic, various public health orders and guidance measures have been implemented across much of the U.S., and across the globe, including in the locations of MEI's office, clinical trial sites, key vendors and partners. Despite the relaxation of many governmental orders earlier this year, COVID-19 still impacts the normal conduct of business.

While MEI continues to enroll and dose patients in clinical trials, its clinical development program timelines may continue to be subject to potential negative impacts from the ongoing pandemic in the U.S. and globally. The extent to which the ongoing pandemic continues to impact MEI's business, including preclinical studies, CMC studies, manufacturing, and clinical trials, will depend on future developments, which are highly uncertain and cannot be predicted with confidence.

MEI may experience enrollment delays and suspensions, patient withdrawals, postponement of planned clinical or preclinical studies, redirection of site resources from studies, and study deviations or noncompliance. MEI may also need to maintain or implement study modifications, suspensions, or terminations, the introduction of additional remote study procedures and modified informed consent procedures, study site changes, direct delivery of investigational products to patient homes or alternative sites, which may require state licensing, and changes or delays in site monitoring. The foregoing may require that MEI consults with relevant review and ethics committees, IRBs, and the FDA. The foregoing may also impact the integrity of MEI's study data. The ongoing COVID-19 pandemic may further increase the need for clinical trial patient monitoring and regulatory reporting of adverse effects, and may delay regulatory authority meetings, inspections, or the regulatory review of marketing or investigational applications or submissions.

The ongoing COVID-19 pandemic may also impact MEI's ability to procure the necessary supply of its investigational drug products, as well as any ancillary supplies necessary for the conduct of its studies. Third party manufacturers may also need to implement measures and changes or deviate from typical manufacturing requirements that may otherwise adversely impact MEI's product candidates.

In light of the ongoing COVID-19 pandemic, the FDA issued a number of new guidance documents. Specifically, as a result of the potential effect of the ongoing COVID-19 pandemic on many clinical trial programs in the U.S. and globally, the FDA issued guidance concerning potential impacts on clinical trial programs, which guidance FDA has continually updated. In addition, the EMA as well as various country regulatory authorities (EU and UK) have issued similar guidance. MEI has adapted the FDA and EMA/UK guidance for study procedures, data collection, and oversight resulting from the ongoing COVID-19 pandemic.

## INFINITY MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion of Infinity's financial condition and results of operations should be read in conjunction with its consolidated financial statements and related notes included elsewhere in this joint proxy statement/prospectus. Some of the information contained in this discussion and analysis and set forth elsewhere in this joint proxy statement/prospectus, including information with respect to Infinity's plans and strategy for its business, includes forward-looking statements that involve risks and uncertainties. You should review the section titled "Risk Factors" in this joint proxy statement/prospectus for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

### Business Overview

Infinity is a clinical-stage innovative biopharmaceutical company dedicated to developing novel medicines for people with cancer. Infinity combines proven scientific expertise with a passion for developing novel small molecule drugs that target disease pathways for potential applications in oncology. Infinity is focused on advancing eganelisib, also known as IPI-549, an orally administered, clinical-stage, immuno-oncology product candidate that reprograms macrophages through selective inhibition of PI3K-gamma. Infinity has retained worldwide development and commercialization rights to eganelisib, subject to certain success-based milestone payment obligations to Infinity's licensor, Takeda, as described in more detail below.

On February 23, 2023, MEI, Infinity, and Merger Sub entered into the Merger Agreement, pursuant to which, among other matters, and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into Infinity, with Infinity continuing as a wholly owned subsidiary of MEI and the surviving corporation of the Merger, which transaction is referred to herein as the Merger. If the Merger is completed, the combined company will combine the expertise and resources of MEI and Infinity to advance a pipeline of three clinical-stage oncology drug candidates.

Infinity expects to devote significant time and resources to the completion of the Merger. However, there can be no assurances that such activities will result in the completion of the Merger. Further, the completion of the Merger may ultimately not deliver the anticipated benefits or enhance shareholder value. If the Merger is not completed, Infinity will consider alternative courses of action. Infinity considers one of the following courses of action to be the most likely alternatives if the Merger is not completed:

- *Pursue another strategic transaction.* Infinity may resume the process of evaluating a potential strategic transaction, including the sale of the company or its assets. Based on its prior assessment, Infinity does not expect that it would have the necessary time or financial resources to pursue another strategic transaction like the proposed Merger.
- *Wind down the company.* If the Merger does not close and Infinity is unable to enter into another strategic transaction, Infinity's board of directors may conclude that it is in the best interest of stockholders to cease normal operations and wind down the company through bankruptcy or dissolution proceedings. In such case, there would be no assurances as to the amount or timing of available cash remaining, if any, to distribute to stockholders after paying its obligations and setting aside funds for reserves.

### Merger Agreement

The Merger is intended to qualify as a reorganization within the meaning of Section 368(a) of the Code. Upon the terms and subject to the conditions set forth in the Merger Agreement, at the Effective Time, each share of Infinity Common Stock will be converted into the right to receive 0.052245 (the "Exchange Ratio") shares of MEI Common Stock. Holders of Infinity Common Stock will receive cash in lieu of fractional shares. At the Effective Time, Infinity's common stockholders will own approximately 42%, and MEI's common stockholders will own approximately 58%, of the outstanding shares of common stock of the combined company on a fully diluted basis.



## [Table of Contents](#)

In addition, as of the Effective Time, MEI will assume each Infinity incentive plan and each outstanding option to purchase shares of Infinity Common Stock, excluding options granted under the Infinity 2013 Employee Stock Purchase Plan, as amended. Each such option so assumed by MEI will continue to have, and be subject to, the same terms and conditions applicable to such option immediately prior to the Effective Time (after giving effect to the full acceleration of vesting of such options applicable to the option in connection with the Merger), except that (A) such option will be exercisable for that number of shares of MEI Common Stock equal to the number of shares of Infinity Common Stock subject to such option immediately prior to the Effective Time of the Merger multiplied by the Exchange Ratio and rounded down to the nearest whole share, and (B) the exercise price per share will be the exercise price per share in effect for that option immediately prior to the Effective Time divided by the Exchange Ratio and rounded up to the nearest whole cent.

Consummation of the Merger is subject to certain closing conditions, including, among other things, the (1) approval by the stockholders of MEI of the MEI Stock Issuance, (2) the adoption by the stockholders of Infinity of the Merger Agreement, (3) authorization for listing on The Nasdaq Capital Market of the shares of MEI Common Stock (including the shares to be issued in the Merger), subject to official notice of issuance, (4) effectiveness of the Registration Statement and (5) the absence of any law, judgment, order, injunction, ruling, writ award or decree by any governmental entity of competent jurisdiction restraining, enjoining or otherwise prohibiting consummation of the Merger. Each party's obligation to consummate the Merger is also subject to other specified customary conditions, including (1) the representations and warranties of the other party being true and correct as of the date of the Merger Agreement and as of the Closing Date, generally subject to an overall material adverse effect qualification, (2) the performance in all material respects by the other party of its obligations under the Merger Agreement required to be performed on or prior to the date of the closing of the Merger, and (3) the absence of a continuing material adverse effect with respect to the other party. Infinity's obligation to consummate the Merger is also subject to the condition that MEI's final net cash is greater than or equal to \$80,000,000 at closing if closing occurs on or before June 30, 2023, \$78,000,000 at closing if closing occurs after June 30, 2023 but on or before July 31, 2023 and \$76,000,000 at closing if closing occurs after July 31, 2023 but on or before August 31, 2023. MEI's obligation to consummate the Merger is also subject to the condition that Infinity's final net cash is greater than or equal to \$4,000,000 at closing if closing occurs on or before June 30, 2023, \$3,000,000 at closing if closing occurs after June 30, 2023 but on or before July 31, 2023, and \$2,000,000 at closing if closing occurs after July 31, 2023 but on or before August 31, 2023.

The Merger Agreement contains certain termination rights for both Infinity and MEI. Upon termination of the Merger Agreement by MEI under specified circumstances, MEI may be required to pay Infinity a termination fee of \$4,000,000 and/or reimburse Infinity's reasonable out of pocket fees and expenses incurred in connection with the Merger Agreement and the transaction contemplated thereby up to a maximum of \$1,000,000. Upon termination of the Merger Agreement by Infinity under specified circumstances, Infinity may be required to pay MEI a termination fee of \$2,900,000 and/or reimburse MEI's reasonable out of pocket fees and expenses incurred in connection with the Merger Agreement and the transaction contemplated thereby up to a maximum of \$1,000,000.

MEI and Infinity have agreed to use reasonable best efforts and take all necessary action such that, as of the Effective Time, the board of directors of the combined company will consist of eight members, with four such members designated by MEI, 3 such members designated by Infinity (one of whom shall be designated by Infinity as the chair of the board of directors of the combined company) and one such member designated jointly by MEI and Infinity, with at least one MEI designee and one Infinity designee appointed to each of the three classes of the MEI classified board and MEI's fourth designee and the jointly designated designee appointed to the class of MEI directors whose terms expire at the next annual meeting of MEI's stockholders. The parties have also agreed that David M. Urso will be elected as Chief Executive Officer, Robert Ilaria, Jr. will be elected as Chief Medical Officer, and Stéphane Peluso will be elected as Chief Scientific Officer.

## Clinical Development Overview

### 2023 Eganelisib Development Strategy

Subject to the successful close of the Merger, the combined company plans to initiate in the third quarter of 2023, subject to U.S. Food and Drug Administration review, a global, randomized, controlled Phase 2 clinical trial of eganelisib plus pembrolizumab versus pembrolizumab for the potential treatment of first line relapsed or metastatic HNSCC.



The primary endpoint of the Phase 2 study is anticipated to be overall survival, and Infinity plans to have initial safety and PFS data in the second half of 2024. This planned study is intended to address a clear medical need, as patients with recurrent or metastatic HNSCC with a PD-L1 CPS of 1 or greater have relatively short median progression free survival (3.2 months) and overall survival (12.3 months) when treated with pembrolizumab monotherapy. CPS is a scoring system used to determine the proportion of cells (includes tumor and immune cells) that stain positive for PD-L1 relative to all viable tumor cells.

This study follows an encouraging signal from Infinity’s MARIO-1, Infinity’s Phase 1/1b clinical study designed to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, and activity for eganelisib - both as a monotherapy and in combination with nivolumab - in 224 patients with advanced solid tumors. As of the study’s December 13, 2021 database lock, the mPFS rate of 3.7 months (1.9, 5.5) was observed in the HNSCC cohort in patients with immediate prior progression on CPI therapy. The mPFS for all patients receiving pembrolizumab monotherapy was 2.3 months in KEYNOTE-048, the benchmark study investigating pembrolizumab monotherapy and pembrolizumab plus chemotherapy or cetuximab plus chemotherapy as a first-line therapy in advanced HNSCC patients. However, Infinity cautions you that the risks in cross-trial comparisons limit its ability to reach definitive conclusions without a prospective, adequately powered, randomized controlled trial. Consequently, the data and results from the HNSCC cohort in MARIO-1 may not be comparable to KEYNOTE-048 for reasons including, but not limited to, differences in clinical trial protocols, patient characteristics, safety management, sample sizes, duration of treatment, median duration of follow up, and other factors. Further, in MARIO-1, a DCR of 36.4% (4 of 11 patients), an ORR of 18.2% (2 of 11 patients), and an mPFS rate of 5.3 months (1.9, 11.1) were observed in the HNSCC cohort in patients with immediate prior progression on CPI therapy and two or fewer prior lines of therapy.

### MARIO-3

MARIO-3 is a multi-arm Phase 2 study designed to evaluate eganelisib in the front-line treatment for mTNBC and mRCC. Infinity has completed enrollment in both cohorts. The mTNBC cohort is evaluating eganelisib in combination with atezolizumab, an anti-PD-L1 monoclonal antibody also known as Tecentriq®, and nab-paclitaxel, an albumin-bound chemotherapy drug also known as Abraxane®, in approximately 60 patients with unresectable locally advanced or mTNBC. The mRCC cohort is evaluating eganelisib in combination with atezolizumab and bevacizumab, also known as Avastin®, in approximately 30 patients with mRCC. Using the same cutoff standard used in the F. Hoffmann-La Roche Ltd. (“Roche”) benchmark IMpassion130 study for PD-L1, tumors that test below 1% PD-L1 at baseline are referred to herein as “PD-L1(-) tumors” and tumors that test equal to or greater than 1% are referred to herein as “PD-L1(+) tumors.” Infinity has entered into clinical supply agreements with Roche, under which Roche has agreed to supply atezolizumab and bevacizumab for Infinity’s use in MARIO-3.

## [Table of Contents](#)

As of an October 8, 2022 data cut from the mTNBC cohort, 62 patients were enrolled and evaluable for safety, and 57 patients were evaluable for efficacy, with a median duration of follow-up of 10.0 (8.1,14.2) months. Of the 57 evaluable patients:

- 35 patients (61.4%) had PD-L1(-) tumors;
- 18 patients (31.6%) had PD-L1(+) tumors; and
- 4 patients (7.0%) had tumors of undetermined PD-L1 status

The October 8, 2022 data snapshot suggests a potential long-term PFS benefit with a one-year PFS rate of 36.0% (23.7, 49.3) in MARIO-3, including in patients with both PD-L1(+) and PD-L1(-) tumors, compared to 23.7% (19.6, 27.9) in the benchmark IMpassion130 study evaluating atezolizumab in combination with nab-paclitaxel compared to placebo with nab-paclitaxel in patients with mTNBC. Infinity designed the MARIO-3 trial to be substantially similar to the IMpassion130 study with respect to inclusion and exclusion criteria, PD-L1 diagnostic, and other factors; however, the risks in cross-trial comparisons limit its ability to reach definitive conclusions without a prospective, adequately powered, randomized controlled trial. Consequently, the data and results from MARIO-3 may not be comparable to IMpassion130 for reasons including differences in clinical trial protocols, safety management, sample sizes, duration of treatment, median duration of follow up, and other factors.

### **MARIO-275**

MARIO-275 is Infinity's global, randomized, placebo-controlled Phase 2 study evaluating the effect of adding eganelisib to nivolumab, also known as Opdivo®, in checkpoint-naïve advanced UC patients whose cancer has progressed or recurred following treatment with platinum-based chemotherapy. Nivolumab is an immune checkpoint inhibitor therapy commercialized by BMS that targets PD-1 a checkpoint protein that helps regulate the body's immune system. MARIO-275 is complete and all sites have been closed.

Infinity presented MARIO-275 data at the ASCO GU, in February 2021, and presented updates on overall survival data in July 2021 and January 2022, as well as a two-year landmark analysis announced in a press release issued on August 9, 2022. The data from the 49 patients enrolled in the trial include the following findings:

- At a two-year landmark survival analysis presented on of July 29, 2022, 45% of patients in the eganelisib plus nivolumab arm are alive compared to 24% of patients in the nivolumab control arm. The data also suggests a potential durable survival benefit in the PD-L1(-) subgroup, with 38% of patients alive at two years in the eganelisib plus nivolumab arm versus 17% in the control group. No new safety signals were observed during the extended period on treatment.
- Median overall survival (mOS) in the intent to treat population as presented in July 2021 was 15.4 months (6.2, NE) on the eganelisib plus nivolumab combination arm as compared to 7.9 months (2.3, NE) on the control arm of nivolumab alone with a hazard ratio (HR) 0.62 (0.28, 1.36), reflecting a 38% lower probability of death.
- The mOS in PD-L1(-) patients, as updated in January 2022, was 15.3 months (4.7, NE) on the eganelisib plus nivolumab arm versus 7.9 months (1.9, NE) on the nivolumab control arm with an HR 0.58 (0.21, 1.66), reflecting a 42% lower probability of death.

The most common treatment-emergent adverse events ("TEAEs") for the eganelisib plus nivolumab combination arm across all doses, all causality, were pyrexia (33.3%), decreased appetite (30.3%), pruritus (27.3%), asthenia (27.3%), rash (27.3%), and increased alanine aminotransferase (24.2%); and the most common ≥Grade 3 TEAEs across all doses, all causality, were anemia (12.1%), and hepatic AEs including hepatotoxicity (15.2%), increased ALT (12.1%), and increased AST (12.1%) with no Hy's Law. No treatment-related Grade 5 AEs were reported.

Data presented at ASCO GU demonstrated the greatest benefit of the combination of eganelisib and nivolumab was observed in the patient population (n=23) with tumors expressing low levels of PD-L1, with improvement

## [Table of Contents](#)

over nivolumab monotherapy (n=7) in ORR (26% vs. 14%); DCR (57% vs. 14%); and best responses of CR (9% vs. 0%) and SD (30% vs. 0%). Of patients with PD-L1 low tumors in the combination arm, 58% (11 of 19) achieved a reduction in tumor burden, compared to 17% (1 of 6) in the nivolumab plus placebo arm.

### ***MARIO-1***

MARIO-1, Infinity's Phase 1/1b clinical study designed to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, and activity for eganelisib - both as a monotherapy and in combination with nivolumab - in 224 patients with advanced solid tumors, reached primary completion in December 2021. The study included a dose escalation portion and a combination therapy expansion portion evaluating patients dosed at 40 mg QD of eganelisib in combination with the standard regimen of nivolumab in the following forms of cancer: non-small cell lung cancer, melanoma, HNSCC, TNBC, mesothelioma, adrenocortical carcinoma, and those with high baseline blood levels of MDSCs.

As of the study's December 13, 2021 database lock, an mPFS rate of 3.7 months (1.9, 5.5) was observed in the HNSCC cohort in patients with immediate prior progression on CPI therapy. The mPFS for all patients receiving pembrolizumab monotherapy was 2.3 months in KEYNOTE-048, the benchmark study investigating pembrolizumab monotherapy, pembrolizumab plus chemotherapy, or cetuximab plus chemotherapy as a first-line therapy in recurrent or metastatic HNSCC patients. However, Infinity cautions you that the risks in cross-trial comparisons limit its ability to reach definitive conclusions without a prospective, adequately powered, randomized controlled trial. Consequently, the data and results from the HNSCC cohort in MARIO-1 may not be comparable to KEYNOTE-048 for reasons including, but not limited to, differences in clinical trial protocols, patient characteristics, safety management, sample sizes, duration of treatment, median duration of follow up, and other factors. Further, in MARIO-1 a DCR of 36.4% (4 of 11 patients), an ORR of 18.2% (2 of 11 patients), and an mPFS rate of 5.3 months (1.9, 11.1) were observed in the HNSCC cohort in patients with immediate prior progression on CPI therapy and two or fewer prior lines of therapy. These findings build on data released regarding the HNSCC cohort at the 2020 Annual Meeting of the Society for Immunotherapy of Cancers, which demonstrated clinical activity of the combination therapy in patients not expected to benefit from CPI alone, having progressed on an immediate prior CPI therapy prior to entering MARIO-1.

### **Financial Overview**

#### ***Going Concern***

Infinity believes that there is substantial doubt about its ability to continue as a going concern for at least twelve months from the date its consolidated financial statement were issued on March 28, 2023. The conditions which raise substantial doubt about Infinity's ability to continue as a going concern, as well as its plan to mitigate these conditions is discussed in the section below titled ("Liquidity and Capital Resources)."

#### ***Revenue***

To date, all of Infinity's revenue has been generated under collaboration agreements, including payments to Infinity of upfront license fees, funding or reimbursement of research and development efforts, milestone payments if specified objectives are achieved, and royalties on product sales. In the future, Infinity may generate revenue from a combination of product sales, research and development support services and milestone payments in connection with strategic relationships, as well as royalties resulting from the sales of products developed under licenses of its intellectual property. Infinity expects that any potential future revenue it generates will fluctuate from year to year as a result of the timing and amount of license fees, research and development reimbursement, milestone, royalty and other payments earned under its collaborative or strategic relationships and the amount and timing of payments that it can earn upon the sale of its products, to the extent any are successfully commercialized.

### ***Research and Development Expense***

Infinity is a drug development company. Its research and development expense has historically consisted primarily of the following:

- compensation of personnel associated with research and development activities;
- clinical testing costs, including payments made to contract research organizations;
- costs of combination and comparator drugs used in clinical studies;
- costs of manufacturing product candidates for preclinical testing and clinical studies;
- costs associated with the licensing of research and development programs;
- preclinical testing costs, including costs of toxicology studies;
- fees paid to external consultants;
- fees paid to professional service providers for independent monitoring and analysis of Infinity's clinical trials;
- costs for collaboration partners to perform research and development activities, including development milestones for which a payment is due when achieved;
- depreciation of property and equipment used for research and development activities; and
- allocated costs of facilities.

### ***General and Administrative Expense***

General and administrative expense primarily consists of compensation of personnel in executive, finance, accounting, legal and intellectual property, information technology infrastructure, corporate communications, and human resources functions. Other costs include facilities costs not otherwise included in research and development expense and professional fees for legal and accounting services.

### ***Royalty Expense***

Royalty expense represents the expense associated with amounts owed to third parties as a result of royalty revenue recognized and the amounts owed by Infinity to Takeda in relation to the sale of future royalties.

### ***Other Income and Expense***

Other income and expense typically consist of interest earned on cash, cash equivalents and available-for-sale securities, non-cash interest expense, and changes in fair value of the warrant liability.

### **Critical Accounting Policies and Significant Judgments and Estimates**

The following discussion and analysis of Infinity's financial condition and results of operations is based on its consolidated financial statements and related notes included elsewhere in this joint proxy statement/prospectus, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires Infinity to make judgments, estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. On an ongoing basis, Infinity evaluates its estimates, including those related to cumulative revenue related to variable consideration, accrued expenses, estimates of future net royalty payments used in the calculation of its liability related to the sale of future royalties, and assumptions in the valuation of stock-based compensation. Infinity bases its estimates on historical experience and on various other assumptions that it believes to be reasonable under the circumstances. Actual results could differ from those estimates. Differences between actual and estimated results have not been material and have been adjusted in the period they become known. Infinity believes that the following accounting

## [Table of Contents](#)

policies and estimates are most critical to understanding and evaluating its reported financial results. Please refer to Note 2 to Infinity's consolidated financial statements and related notes included elsewhere in this joint proxy statement/prospectus for a description of its significant accounting policies.

### ***Revenue Recognition***

To date, all of Infinity's revenue has been generated under collaboration agreements, including payments to Infinity of upfront license fees, funding or reimbursement of research and development efforts, milestone payments if specified objectives are achieved, and/or royalties on product sales.

Infinity recognizes revenue when it transfers goods or services to customers in an amount that reflects the consideration that Infinity expects to receive for those goods or services. These principles are applied using a five-step model: 1) identify the customer contract; 2) identify the contract's performance obligations; 3) determine the transaction price; 4) allocate the transaction price to the performance obligations; and 5) recognize revenue when or as a performance obligation is satisfied. Infinity evaluates all promised goods and services within a customer contract and determines which of those are separate performance obligations. This evaluation includes an assessment of whether the good or service is capable of being distinct and whether the good or service is separable from other promises in the contract. When a performance obligation is satisfied, Infinity recognizes as revenue the amount of the transaction price, excluding estimates of variable consideration that are constrained, that is allocated to that performance obligation. For contracts that contain variable consideration, such as milestone payments, Infinity estimates the amount of variable consideration by using either the expected value method or the most likely amount method. In making this assessment, Infinity evaluates factors such as the clinical, regulatory, commercial and other risks that must be overcome to achieve the milestone. Each reporting period Infinity re-evaluates the probability of achievement of such milestones and any related constraints. Infinity will include variable consideration, without constraint, in the transaction price to the extent it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

Infinity recognizes sales-based milestones and royalty revenue based upon net sales by the licensee of licensed products in licensed territories, and in the period the sales occur under the sales- and usage-based royalty exception when the sole or predominate item to which the royalty relates is a license to intellectual property.

In the event of an early termination of a collaboration agreement, any contract liabilities would be recognized in the period in which all of Infinity's obligations under the agreement have been fulfilled.

### ***Accrued Expenses***

As part of the process of preparing financial statements, Infinity is required to estimate accrued expenses. This process involves identifying services that have been performed on Infinity's behalf and estimating the level of service performed and the associated cost incurred for such service as of each balance sheet date. Examples of services for which Infinity must estimate accrued expenses include contract service fees paid to contract manufacturers in conjunction with pharmaceutical development work and to contract research organizations in connection with clinical trials and preclinical studies. In connection with these service fees, Infinity's estimates are most affected by its understanding of the status and timing of services provided. The majority of Infinity's service providers invoice Infinity in arrears for services performed. In the event that Infinity does not identify certain costs that have been incurred by its service providers, or if Infinity under- or over-estimates the level of services performed or the costs of such services in any given period, Infinity's reported expenses for such period would be too low or too high, respectively. Infinity often relies on subjective judgments to determine the date on which certain services commence, the level of services performed on or before a given date and the cost of such services. Infinity makes these judgments based upon the facts and circumstances known to Infinity. Infinity's estimates of expenses in future periods may be under- or over-accrued.

### ***Liabilities Related to Sale of Future Royalties***

Infinity treats the liabilities related to sale of future royalties as debt financings, amortized under the effective interest rate method over the estimated life of the related royalty streams. The liabilities related to sale of future royalties and the debt amortization are based on Infinity's current estimates of future royalties expected to be paid over the life of the arrangements. Infinity will periodically assess the expected royalty payments using projections from external sources. To the extent Infinity's estimates of future royalty payments are greater or less than previous estimates or the estimated timing of such payments is materially different than previous estimates, Infinity will adjust the effective interest rate and recognize related non-cash interest expense on a prospective basis. Non-cash royalty revenue is reflected as royalty revenue, and non-cash amortization of debt is reflected as interest expense in the Consolidated Statements of Operations and Comprehensive Loss included in Infinity's consolidated financial statements and related notes included elsewhere in this joint proxy statement/prospectus.

### **Results of Operations**

The following table summarizes Infinity's results of operations for the years ended December 31, 2022 and 2021, in thousands, together with the change in each item as a percentage.

	<u>2022</u>	<u>2021</u>	<u>% Change</u>
Royalty revenue	\$ 2,593	\$ 1,858	40%
Research and development expense	(32,411)	(31,647)	2%
General and administrative expense	(13,463)	(14,174)	(5)%
Royalty expense	(1,563)	(1,120)	40%
Investment and other income	655	1	65,400%
Non-cash interest expense	(180)	(180)	— %
Net loss	(44,369)	(45,262)	(2)%

### ***Revenue***

For the year ended December 31, 2022, Infinity recognized \$2.6 million in royalty revenue, an increase of 40% as compared to \$1.9 million in royalty revenue for the year ended December 31, 2021. Royalty revenue for both periods is related to royalties on net sales of duvelisib from Secura Bio. A portion of the royalties received is owed to Mundipharma and Purdue. Such portion is referred to as the Trailing Mundipharma Royalties (see Note 11 of the notes to Infinity's consolidated financial statements and related notes included elsewhere in this joint proxy statement/prospectus. Infinity and HCR entered into a purchase and sale agreement in March 2019 (the "HCR Agreement") pursuant to which HCR acquired Infinity's interest in royalties received from Verastem and Secura Bio on net sales of duvelisib, less the Trailing Mundipharma Royalties (see Note 9 of the notes to Infinity's consolidated financial statements and related notes included elsewhere in this joint proxy statement/prospectus.

### ***Research and Development Expense***

Research and development expenses represented approximately 68% and 67% of Infinity's total operating expenses for the years ended December 31, 2022 and 2021, respectively. For the year ended December 31, 2022, Infinity recognized \$32.4 million in research and development expense, an increase of approximately 2% as compared to \$31.6 million in research and development expense for the year ended December 31, 2021. The increase is primarily attributable to an increase in compensation expense of \$1.9 million due primarily to additional staff to support the development of eganelisib, an increase in consulting expenses of \$0.8 million, an increase in information technology support expenses of \$0.3 million, and an increase in insurance and facilities expenses of \$0.3 million, partially offset by a decrease in clinical development expenses of \$2.6 million.

Infinity tracks and accumulates expenses by major program. These expenses primarily relate to payroll and related expenses for personnel working on the programs, process development and manufacturing, preclinical



## Table of Contents

toxicology studies, clinical trial costs and allocated costs of facilities. During the years ended December 31, 2022 and 2021 and in aggregate from January 1, 2006 through December 31, 2022, Infinity estimates that it incurred \$32.4 million, \$31.6 million and \$747.4 million of costs, respectively, on its PI3K inhibitor program, including eganelisib and duvelisib.

Infinity does not believe that the historical costs associated with its drug development programs are indicative of the future costs associated with these programs. Due to the variability in the length of time and scope of activities necessary to develop a product candidate and uncertainties related to Infinity's cost estimates and ability to obtain marketing approval for its product candidates, accurate and meaningful estimates of the total costs required to bring Infinity's product candidates to market are not available.

Because of the risks inherent in drug development, Infinity cannot reasonably estimate or know:

- the nature, timing and estimated costs of the efforts necessary to complete the development of Infinity's programs;
- the completion dates of these programs; or
- the period in which material net cash inflows are expected to commence, if at all, from the programs described above and any potential future product candidates.

There is significant uncertainty regarding Infinity's ability to successfully develop any product candidates. These risks include the uncertainty of:

- the scope, rate of progress and cost of Infinity's clinical trials that Infinity is currently conducting or may commence in the future;
- clinical trial results;
- the cost of establishing clinical supplies of any product candidates;
- the cost and availability of combination and comparator drugs, such as the current global shortage of the MARIO-3 combination drug nab-paclitaxel. Although Infinity expects its current supply of nab-paclitaxel to be adequate to meet MARIO-3 demand through the study completion, the global shortage could impact MARIO-3 if the shortage persists beyond Infinity's current supply;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights relating to Infinity's programs under development;
- the terms and timing of any collaborations, licensing and other arrangements that Infinity has or may establish in the future relating to its programs under development;
- the cost and timing of regulatory approvals;
- the effect of competing technological and market developments; and
- the impact of the COVID-19 pandemic.

### ***General and Administrative Expense***

For the year ended December 31, 2022, Infinity recognized \$13.5 million in general and administrative expense, a decrease of 5% as compared to approximately \$14.2 million in general and administrative expense for the year ended December 31, 2021. The decrease was primarily attributable to a decrease of \$0.6 million in consulting expense and a decrease in compensation expense of \$0.4 million due primarily to a reduction in discretionary bonus compensation, partially offset by an increase of \$0.3 million in information technology support expenses.

### ***Royalty Expense***

For the year ended December 31, 2022, Infinity recognized \$1.6 million in royalty expense, an increase of 40% as compared to approximately \$1.1 million in royalty expense for the year ended December 31, 2021. Royalty expense for both periods is related to royalties paid to Mundipharma, Purdue and Takeda on net sales of duvelisib

## [Table of Contents](#)

by Secura Bio (see Note 11 of the notes to Infinity's consolidated financial statements and related notes included elsewhere in this joint proxy statement/prospectus).

### *Investment and Other Income*

Investment and other income increased by \$0.7 million for the year ended December 31, 2022 as compared to the year ended December 31, 2021 primarily as a result of higher yields on Infinity's cash equivalents and available-for-sale securities.

### *Non-cash Interest Expense*

Non-cash interest expense for the years ended December 31, 2022 and 2021 was the result of the sale of future royalties in relation to the HCR Agreement and BVF Funding Agreement, which Infinity recognized as liabilities that are being amortized using the effective interest method over the life of the arrangements (see Note 9 of the notes to Infinity's consolidated financial statements and related notes included elsewhere in this joint proxy statement/prospectus). Over the course of the arrangements, the non-cash interest expense will be affected by the amount and timing of estimated royalty revenue, if any. Infinity reassesses the effective interest rate on a quarterly basis and adjusts the rate prospectively as needed.

### **Liquidity and Capital Resources**

Infinity has primarily incurred operating losses since inception. Infinity's net loss was \$44.4 million and \$45.3 million for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022, Infinity had an accumulated deficit of \$856.0 million. As Infinity has no approved products, it has not generated any revenue from product sales to date, and does not expect to generate any such revenue for the foreseeable future, if at all. Infinity has instead relied on the proceeds from sales of equity securities, sales of future royalties, issuances of debt, interest on investments, upfront license fees, expense reimbursements, milestones, royalties and cost sharing under its collaborations to fund its operations. Because eganelisib is in clinical development and the outcome of Infinity's effort is uncertain, Infinity cannot estimate the actual amounts necessary to successfully complete the development and commercialization of its product candidate or whether, or when, Infinity may achieve profitability.

Infinity expects to continue to spend significant resources to fund the development and potential commercialization of eganelisib. Infinity expects to incur substantial operating losses over the next several years as its clinical trial and drug manufacturing activities increase. In addition, in connection with seeking and possibly obtaining regulatory approval of eganelisib or any future product candidates Infinity may develop, Infinity expects to incur significant commercialization expenses for product sales, marketing, manufacturing and distribution. As a result, Infinity expects that its accumulated deficit will also increase significantly. These conditions raise substantial doubt about Infinity's ability to continue as a going concern.

The following table summarizes the components of Infinity's financial condition:

	December 31, 2022	December 31, 2021
	(in thousands)	
Cash, cash equivalents and available-for-sale securities	\$ 38,313	\$ 80,726
Working capital	26,674	68,968

## [Table of Contents](#)

	Year Ended December 31,	
	2022	2021
	(in thousands)	
Cash (used in) provided by:		
Operating activities	\$(42,431)	\$(40,618)
Investing activities	(55)	5,489
Financing activities	73	87,105

### ***Cash Flows***

The principal use of cash in operating activities in all periods presented was related to Infinity's research and development programs. Infinity's cash used in operating activities for the year ended December 31, 2022 increased compared to the year ended December 31, 2021 primarily due to increased operating expenses as Infinity continues clinical development of eganelisib.

Infinity's cash used in operating activities in future periods may vary significantly due to various factors, including potential cash inflows from future collaboration agreements and potential cash outflows for licensing new programs from third parties. Infinity cannot be certain whether and when it may enter into any such collaboration agreements or license agreements.

Infinity's cash (used in) provided by investing activities for the years ended December 31, 2022 and 2021 included purchases and proceeds from maturities of available-for-sale securities and purchases of property and equipment. Net cash used in investing activities for the year ended December 31, 2022 was primarily the result of a nominal amount of net purchases of available-for-sale securities during the year. Comparatively, net cash provided by investing activities for the year ended December 31, 2021 was primarily due to net proceeds from maturities of available-for-sale securities of \$5.5 million.

Net cash provided by financing activities for the year ended December 31, 2022 included \$0.1 million in net proceeds from the issuance of common stock to employees. Net cash provided by financing activities for the year ended December 31, 2021 included \$85.8 million in net proceeds from Infinity's public offering in February 2021.

### ***Funding Requirements***

Infinity believes that there is substantial doubt about its ability to continue as a going concern for at least twelve months from the date its consolidated financial statements were issued on March 28, 2023. Infinity's future capital requirements will depend on whether it completes the Merger. If the Merger is not completed, or if Infinity decides to pursue any future product development efforts, Infinity's future funding requirements would depend on, and could increase significantly as a result of many factors, including:

- Infinity's ability to consummate an alternative strategic transaction and the nature and type of such transaction;
- the scope, progress, results and costs of developing eganelisib, currently in clinical development;
- the impact of delays in patient enrollment and site activation related to the COVID-19 pandemic;
- the timing of, and the costs involved in, obtaining regulatory approvals for eganelisib;
- subject to receipt of marketing approval, revenue, if any, received from commercial sales of eganelisib;
- the timing and amount of additional revenues, if any, received from strategic agreements and funding arrangements
- the timing and amount of additional royalty and milestone payments owed to Takeda;

## Table of Contents

- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- any breach, acceleration event or event of default under any agreements with third parties;
- the outcome of any lawsuits that could be brought against Infinity;
- the cost of acquiring raw materials for, and of manufacturing, eganelisib is higher than anticipated;
- the cost or quantity required of comparator or combination drugs used in clinical studies increases;
- the effect of competing technological and market developments;
- any federal government shutdown that prevents or delays the SEC from processing any future registration statements Infinity may file to register shares for capital raising purposes; and
- a loss in Infinity's investments due to general market conditions or other reasons.

If the Merger is not completed, plans to mitigate the conditions which raise substantial doubt about Infinity's ability to continue as a going concern may include, but are not limited to, the process of evaluating opportunities for a potential strategic transaction, including the sale of the company or its assets. Based on Infinity's prior assessment, Infinity does not expect that it would have the necessary time or financial resources to pursue another strategic transaction like the proposed Merger. If Infinity is unsuccessful in its efforts to seek such strategic alternatives or raise additional financing in the near term, Infinity's board of directors may conclude that it is in the best interest of stockholders to cease normal operations and wind down the company through bankruptcy or dissolution proceedings. In such case, there would be no assurances as to the amount or timing of available cash remaining, if any, to distribute to stockholders after paying Infinity's obligations and setting aside funds for reserves.

Historically, Infinity has relied on its collaborations for a significant portion of its research and development funding needs through upfront payments, milestones, royalties, and cost reimbursements.

As of December 31, 2022, Infinity has received \$348.0 million of net proceeds from its public stock offerings, including its common stock sales facility. This includes net proceeds of \$85.8 million Infinity received from its public stock offering in February 2021.

### **Equity Offerings**

On June 28, 2019, Infinity entered into a Capital on Demand Sales Agreement with JonesTrading Institutional Services LLC ("JonesTrading"), and on July 29, 2019 Infinity amended and restated the sales agreement to add B. Riley Securities (f/k/a B. Riley FBR, Inc.) ("B. Riley Securities") as a party to the agreement. On July 27, 2021, Infinity entered into an amendment to the agreement to increase the maximum aggregate offering price of the shares of common stock that Infinity may issue and sell from time to time under the agreement by \$75.0 million to an aggregate of \$95.0 million. The amended and restated sales agreement, as amended, is referred to as the ATM Sales Agreement. During the year ended December 31, 2022, a portion of the aggregate offering price totaling \$11.8 million expired without sale. As of December 31, 2022, Infinity had an aggregate of \$75.0 million available for future sales. Pursuant to the ATM Sales Agreement Infinity may offer and sell shares of its common stock from time to time through JonesTrading or B. Riley Securities, each acting as Infinity's sales agent. Infinity has agreed to pay commissions to the sales agents for their services in acting as agents in the sale of Infinity's common stock in the amount of up to 3.0% of the gross proceeds from sales of Infinity's common stock pursuant to the ATM Sales Agreement. Sales of shares of Infinity's common stock under the ATM Sales Agreement may be made by any method that is deemed to be an "at-the-market-offering" as defined in Rule 415(a)(4) promulgated under the Securities Act. With Infinity's prior written approval, JonesTrading or B. Riley Securities may also sell the shares by any other method permitted by law, including in negotiated transactions. Infinity and JonesTrading or B. Riley Securities may suspend or terminate the offering of shares upon notice to the other parties and subject to other conditions. During the year ended December 31, 2022,

---

## [Table of Contents](#)

Infinity did not sell any shares under the ATM Sales Agreement. During the year ended December 31, 2021, Infinity issued and sold 89,520 shares of common stock at a weighted average price per share of \$3.83 at-the-market pursuant to the ATM Sales Agreement for \$0.3 million in net proceeds.

On February 11, 2021, Infinity entered into a purchase agreement with Piper Sandler & Co., as representative of the underwriters named therein, pursuant to which Infinity issued and sold to the underwriters in an underwritten public offering an aggregate of 24,150,000 shares of its common stock, including 3,150,000 shares of common stock sold in connection with the exercise in full of a 15% over-allotment option by the underwriters. The public offering price was \$3.80 per share. The gross proceeds to Infinity from this offering were approximately \$91.8 million. After underwriting discounts and commissions and offering expenses, Infinity received net proceeds from the offering of approximately \$85.8 million.

### **Inflation**

Infinity does not believe that inflation has had a significant impact on its revenues or results of operations since inception.

**QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

MEI and Infinity are each smaller reporting companies as defined by Rule 12b-2 of the Exchange Act, as amended, and are not required to provide the information under this item.

## MANAGEMENT FOLLOWING THE MERGER

### Executive Officers and Directors

#### *Executive Officers and Directors of the Combined Company Following the Merger*

The following table lists the names, ages (as of April 27, 2023) and positions of the individuals who are expected to serve as executive officers and directors of the combined company upon completion of the Merger:

<u>Name</u>	<u>Age</u>	<u>Position</u>
<i>Executive Officers:</i>		
David M. Urso	58	Director, Chief Executive Officer
Brian G. Drazba	61	Chief Financial Officer
Robert Ilaria Jr., M.D.	62	Chief Medical Officer
Stéphane Peluso, Ph.D.	53	Chief Scientific Officer
<i>Non-Employee Directors:</i>		
Norman C. Selby	71	Director, Chair of the Board
Adelene Q. Perkins	63	Director
Richard Gaynor, M.D.	73	Director
Daniel P. Gold, Ph.D	68	Director
Sujay R. Kango	59	Director
Charles V. Baltic III	62	Director
Thomas C. Reynolds, M.D., Ph.D.	64	Director

### Executive Officers

**David M. Urso** has been Chief Operating Officer and General Counsel of MEI since July 2018 and will become the Chief Executive Officer prior to the consummation of the Merger. Prior to July 2018, Mr. Urso had been MEI's Senior Vice President of Corporate Development and General Counsel since April 2014. Mr. Urso joined MEI with more than two decades of experience in the life science industry, most recently as Chief Operating Officer and General Counsel at Tioga Pharmaceuticals, a privately held drug development company he co-founded in 2005. Previously, he was a Principal at Forward Ventures, where he was responsible for identifying and developing life science venture capital investments. Prior to joining Forward Ventures in 2002, Mr. Urso was Director of Corporate Development and Legal Affairs at DNA Sciences, Inc. Previously, he worked as an attorney in the corporate securities and licensing groups at Wilson Sonsini Goodrich & Rosati LLP and Cooley Godward LLP, after beginning his career as a bench scientist at SmithKline Beecham and the University of Pennsylvania Medical School. Mr. Urso received a J.D. from Harvard Law School and a B.A. in Molecular Biology and Philosophy from Reed College.

**Mr. Brian G. Drazba** has been Chief Financial Officer since April 2017. Mr. Drazba has more than 25 years of financial management experience in the healthcare industry. Previously, he served as Vice President of Finance and Chief Financial Officer of Heron Therapeutics, Inc., a commercial-stage biotechnology company, from October 2013 to March 2017. From 2009 to 2012, he was Vice President of Finance and Chief Accounting Officer for ISTA Pharmaceuticals, a commercial-stage pharmaceutical company. ISTA Pharmaceuticals was acquired by Bausch + Lomb in June 2012. From 1992 to 2009, Mr. Drazba held various positions of increasing responsibility within Insight Health Corp., most recently as Senior Vice President and Chief Accounting Officer. He began his career at Arthur Andersen & Co., a public accounting firm. Mr. Drazba is a licensed Certified Public Accountant (inactive) in California and earned a B.A. degree in Accounting from the University of San Diego.

**Robert Ilaria, Jr., M.D.**, has served as Chief Medical Officer of Infinity since September 2021. Dr. Ilaria joined Infinity from BMS and Celgene Corporation, a pharmaceutical company, where he worked from 2017 to 2021 and focused on immune-oncology drug development, serving leadership roles on the CTLA-4 and PD-1 inhibitor



## [Table of Contents](#)

drug development teams, respectively. Prior to joining Celgene, Dr. Ilaria was at Eli Lilly and Company, a pharmaceutical company, from 2005 to 2017 in leadership roles of increasing responsibility in both early and late phase drug development. During his time at Eli Lilly, Dr. Ilaria was responsible for the clinical strategy of multiple assets ranging from pre-clinical development through regulatory approval. Prior to joining the pharmaceutical industry, Dr. Ilaria had academic clinical and basic science research careers at UT Southwestern and Harvard Medical School. He holds a B.A. in biology and philosophy from Rice University and an M.D. from UT Southwestern Medical School. He did his internal medicine and hematology and medical oncology training at Brigham and Women's Hospital and the Dana Farber Cancer Institute. Dr. Ilaria has remained clinically active during his pharmaceutical career through volunteer oncology staff service at academic teaching institutions.

**Stéphane Peluso, Ph.D.**, has served as Chief Scientific Officer of Infinity since August 2021. Dr. Peluso returned to Infinity from Ipsen Bioscience Inc., a pharmaceutical company, where he was most recently Vice President, Global Head of Oncology External Innovation. Prior to Ipsen, Dr. Peluso worked at Infinity where he held positions of increasing responsibility in medicinal chemistry and drug discovery from 2006 to August 2016, ultimately leading Infinity's early drug discovery and pipeline expansion efforts through both internal R&D and business development. Dr. Peluso started his career as a medicinal chemist at Millennium Pharmaceuticals. He graduated from the Ecole Supérieure de Chimie Industrielle de Lyon (ESCIL), France, obtained his Ph.D. from the University of Lausanne, Switzerland, and completed postdoctoral studies at the Massachusetts Institute of Technology.

### **Appointment of Officers**

The combined company's executive officers will be appointed by, and serve at the discretion of, the combined company's board of directors. There are no family relationships among any of the combined company's proposed directors or executive officers.

### **Board of Directors of the Combined Company Following the Merger**

**David M. Urso's** biography is set forth under the heading "Executive Officer" above. Mr. Urso was appointed Chief Executive Officer pursuant to the Merger Agreement.

**Norman C. Selby** has served as a board member of Infinity since March 2012. Mr. Selby has spent over 35 years in the healthcare industry in various consulting, managerial, investor, and board roles. Currently his primary focus is on Real Endpoints, LLC, a private healthcare information and analytics company he helped to found and where he has been a board member since October 2010. He previously co-founded Paige. AI, an artificial intelligence company focused on computational pathology, where he was a board member from May 2017 to January 2020. Among earlier healthcare roles, Mr. Selby served as the Chief Executive Officer of TransForm Pharmaceuticals from 2001 until 2005 and served as Executive Chairman of Physicians Interactive Holdings from 2008 to 2013. Prior to TransForm Pharmaceuticals, Mr. Selby was an Executive Vice President at Citigroup/Citicorp from 1997 to 2000. Mr. Selby spent the bulk of his career, from 1978 to 1997, at McKinsey & Company where he was Director (Senior Partner) in the firm's New York office. He held several leadership roles at McKinsey, including head of the firm's Global Pharmaceuticals and Medical Products Practice. From 1987 to 1989, Mr. Selby took a leave of absence from McKinsey to serve as Chief Operating Officer of the New York Blood Center, the largest community blood organization in the country, where he led its financial and operational turnaround. Mr. Selby previously served as a member of the board of directors of Escalier Biosciences and Oppilan Pharma, Ltd., each private biotechnology companies, each until January 2021, respectively. Mr. Selby also previously served as a director of Millenium Pharmaceuticals (MLNM) from 2000 to 2008, as well as several privately held healthcare companies. Mr. Selby serves on the Board of Trustees of the Central Park Conservancy and the Memorial Sloan Kettering Cancer Center, and is a member of the Council on Foreign Relations and the advisory board of HBS's Healthcare Initiative. Mr. Selby holds a B.A. in architecture from Yale College and an M.B.A. with Distinction from HBS. We believe Mr. Selby's qualifications to serve on

## [Table of Contents](#)

our board of directors include his extensive experience as a senior business executive in the biopharmaceutical industry, and his expertise in corporate strategy, finance, and commercialization of biopharmaceutical products.

**Adelene Q. Perkins** has served as a board member of Infinity since January 2010, including as Chair of Infinity's board of directors since November 2012, and as Infinity's Chief Executive Officer since January 2010. She has also served as Infinity's President from January 2010 to January 2017, as Infinity's President and Chief Business Officer from October 2008 through December 2009 and as Infinity's Executive Vice President and Chief Business Officer between September 2006 and October 2008. Ms. Perkins served as Executive Vice President of Infinity Discovery, Inc., from February 2006 until the merger with Infinity's predecessor company in September 2006 and Chief Business Officer of Infinity Discovery, Inc., from June 2002 until September 2006. Ms. Perkins served as Vice President of Business and Corporate Development of TransForm Pharmaceuticals, Inc., a privately held specialty pharmaceutical company, from 2000 to 2002. From 1992 to 1999, Ms. Perkins held various positions at Genetics Institute, most recently serving as Vice President of Emerging Business and General Manager of the DiscoverEase® business unit, and from 1985 to 1992 advised clients in the healthcare industry while at Bain & Company, a strategy consulting firm. Ms. Perkins has served on the board of directors for the Biotechnology Industry Organization since 2012; the Bruker Corporation, a publicly traded manufacturer of analytic instruments, since 2017; Massachusetts General Hospital since 2017; and Project Hope, a not-for-profit social services company, since 2013. Ms. Perkins received a B.S. in chemical engineering from Villanova University and an M.B.A. from Harvard Business School, or HBS.

**Richard Gaynor, M.D.** has served as a board member of Infinity since March 16, 2020. Dr. Gaynor has served as the President, Chief of Research and Development, BioNTech US, formerly Neon Therapeutics, a public biotechnology company developing novel neoantigen-targeted T cell therapies, since November 2016. Prior to his tenure at Neon Therapeutics, Dr. Gaynor spent 15 years in a series of senior roles at Lilly Oncology, most recently as Senior Vice President Clinical Development and Medical Affairs, where he chaired the Lilly Oncology Research and Development Committee and helped oversee a variety of collaborations, including with BMS, Merck, AstraZeneca and GE. Prior to that role, Dr. Gaynor also led preclinical and early clinical oncology research at Eli Lilly. Dr. Gaynor began his career in academia, spending nine years on the faculty at University of California, Los Angeles School of Medicine, followed by eleven years on the faculty at the University of Texas Southwestern Medical School, including time serving as the chief of hematology-oncology and director of the Simmons Cancer Center. He holds an M.D. from the University of Texas Southwestern Medical School and, following his residency in internal medicine there, he completed fellowship training in hematology-oncology at the University of California, Los Angeles, School of Medicine. He is the author of nearly 150 publications and participates on numerous advisory boards and committees, including the American Association of Cancer Research, the Stand Up To Cancer scientific advisory committee, and the Damon Runyon Cancer Research Foundation. Dr. Gaynor has served on the board of directors of Alkermes plc., a publicly traded pharmaceutical company specializing in neuroscience and oncology, since September 2019, and Zai Lab Ltd., a publicly traded biopharmaceutical company, since November 2021.

**Daniel P. Gold, Ph.D.** served as MEI's President, Chief Executive Officer and a director from April 2010 until the consummation of the Merger. He joined MEI with approximately 25 years of drug discovery and development experience, most recently as President and Chief Executive Officer of Prospect Therapeutics, a mid-stage oncology company. Prior to his tenure at Prospect, Dr. Gold was founder and Chief Scientific Officer of Favrilite, where he was an integral member of a team that advanced the company's lead oncology candidate through a pivotal Phase 3 clinical trial. He currently serves on the Board of Trustees of the Hope Funds for Cancer Research. Dr. Gold's academic qualifications include Postdoctoral Fellowships at the Dana-Farber Cancer Institute, at the Harvard School of Medicine and the Massachusetts Institute of Technology, Center for Cancer Research. He holds a Ph.D. in Pathology/Immunology from Tufts University, Boston and a bachelor's degree in Biology from the University of California, Los Angeles.

**Sujay R. Kango** has been a director of MEI Pharma since November 2021 and serves as a director of Infinity Pharmaceuticals since March 2022. Mr. Kango is an experienced executive with more than 25 years of experience in the pharmaceutical and biotechnology industries. Mr. Kango currently serves as the President and

## Table of Contents

CEO of Tmunity Therapeutics. He has held senior management positions where he has been instrumental in transforming earlier stage biotechnology companies into fully integrated global biotechnology organizations. Mr. Kango has built commercial infrastructures and teams, while leading multiple global product launches. Mr. Kango joined Acceleron Pharma in 2018, where he most recently served as the executive vice president and chief commercial officer and was responsible for establishing the company's global presence, including its launch of Reblozyl in North America. Mr. Kango played a critical role in Acceleron Pharma's \$11.5 billion acquisition. In addition, Mr. Kango has led multiple global product launches across several therapeutic areas including oncology-hematology, rare diseases, immunology, and virology. Previously Mr. Kango was vice president of global commercial development for oncology at AbbVie, prior to which he served as the executive vice president and chief commercial officer at Infinity Pharmaceuticals. Mr. Kango also served as vice president, global marketing, and sales operations at Onyx Pharmaceuticals, an Amgen subsidiary. Prior to Onyx, he held several leadership positions including vice president sales and marketing-oncology at Merck & Co., global commercial leader-Procrit®/Eprex® at Ortho-Biotech, and various sales and marketing positions at Schering-Plough. Mr. Kango earned a B.S. in Microbiology and an M.B.A. from McNeese State University.

**Charles V. Baltic III** has served as a director of MEI Pharma since October 2011, as Chair of the Board of directors of MEI since January 2023, and as Chair of the Nominating and Governance Committee since 2012. He also serves as a director and Chairman of the Board of AssayQuant Technologies, Inc., a private company focused on kinase-based assay drug development technology licensed from the Massachusetts Institute of Technology. Mr. Baltic was previously affiliated with Needham & Company, LLC as Managing Director and Co-Head of Healthcare Banking from 2009 until 2019 and as Senior Advisor from 2019 to 2022. Mr. Baltic served as acting CEO of Amyndas Pharmaceuticals, a private development-stage biotechnology company focused on immunology and innate immunity complement therapeutics based on technology licensed from the University of Pennsylvania from March 2021 to October 2021. Mr. Baltic served as Executive Vice President and COO of SIDIS Corp. from 2019 to 2021, overseeing the sale of the Propel Labs flow cytometry business to Thermo Fisher Scientific in February 2021. Mr. Baltic was a Managing Director and head of the biotechnology practice at CRT Capital Group from 2006 to 2008. From 2001 to 2006, he served as a Managing Director in Healthcare Investment Banking at Wachovia Securities. Prior to Wachovia, he was with Healthcare Investment Banking at Cowen and Company for six years. Prior to beginning his investment banking career in 1996, Mr. Baltic practiced corporate and securities law with the firm Dewey Ballantine, representing numerous healthcare and securities clients. Mr. Baltic previously served as a director of SIDIS Corp. from 2015 to 2019. Mr. Baltic served as a director of the trade association Life Science Washington from 2013 to 2018. He served as a director of MedVantage Inc., a private health informatics company acquired by IMS Health (now IQVIA Holdings) in 2011. Mr. Baltic served on the U.S. Securities and Exchange Commission's Advisory Committee on Small and Emerging Growth Companies from 2013 to 2015. He served as a founding Trustee of Hope Funds for Cancer Research from 2007 to 2017. Mr. Baltic earned B.A. (honors) and J.D. degrees from Georgetown University and a M.B.A. degree in finance from the Wharton School of the University of Pennsylvania.

**Thomas C. Reynolds, M.D., Ph.D** has been a director of MEI Pharma since February 2013. He is President of Two Paddles Consulting LLC since December 2013, providing consulting services to biotechnology and pharmaceutical companies. Dr. Reynolds served as an independent director of Trillium Therapeutics Inc. (NASDAQ: TRIL; TSX: TR), an immuno-oncology company, until April 2021. Previously, he served as Chief Medical Officer of Seattle Genetics from March 2007 until his retirement in February 2013. While at Seattle Genetics, he was responsible for building and leading an integrated clinical development, regulatory and medical affairs organization, highlighted by the development and approval of ADCETRIS®. From 2002 to 2007, Dr. Reynolds served at ZymoGenetics (acquired by BMS in 2010), most recently as Vice President, Medical Affairs, where he oversaw the clinical development and regulatory filing of RECOTHROM®. Previously, he was Vice President, Clinical Affairs at Targeted Genetics, and before that was at Somatix Therapy (acquired by Cell Genesys in 1997). Dr. Reynolds received his M.D. and Ph.D. in Biophysics from Stanford University and a B.A. in Chemistry from Dartmouth College.

## **Structure and Appointments of the Combined Company Board of Directors**

The MEI COI and the MEI Bylaws provide that the authorized number of directors shall be determined by a resolution of MEI's board of directors, but shall be between two and nine. MEI's board of directors currently consists of seven directors divided into three staggered classes, with one class to be elected at each annual meeting to serve for a three-year term. The staggered structure of the MEI board of directors will remain in place for the combined company following the completion of the Merger. It is anticipated that the incoming directors will be appointed to applicable vacant director seats of the combined company board of directors.

There are no family relationships among any of the proposed combined company directors and officers.

## **Director Independence**

Each of the MEI designees, other than \_\_\_\_\_, and each of the Infinity designees, other than \_\_\_\_\_, will meet the independence standards of Nasdaq with respect to the combined company as of the Effective Time.

## **Committees of the Board of Directors**

Presently, MEI's board of directors has the following standing committees: Audit Committee, Compensation Committee, and Nominating and Corporate Governance Committee. Each of the standing committees is composed solely of independent directors. Following the completion of the Merger the combined company will continue to have the following standing committees: Audit Committee, Compensation Committee, and Nominating and Corporate Governance Committee.

## **Audit Committee**

The Audit Committee of the MEI board of directors has been established in accordance with Section 3(a)(58)(A) of the Exchange Act. The Audit Committee's responsibilities include:

- overseeing financial and accounting activities;
- selecting and recommending the annual appointment of independent auditors;
- reviewing and approving the scope of audit and non-audit assignments and related fees;
- assessing annually MEI's major financial risks and exposures;
- evaluating the independence and performance of the independent auditors;
- reviewing the accounting principles used in financial reporting;
- reviewing and assessing our financial reporting activities and disclosures included in our periodic reports and the accounting standards and principles followed;
- reviewing the adequacy and effectiveness of our internal control over financial reporting; and
- reviewing and approving related party transactions.

The audit committee of the combined company is expected to retain these duties and responsibilities following the completion of the Merger.

Adelene Q. Perkins is expected to become the Chair of the combined company's audit committee. In connection with the closing of the Merger, the combined company's board of directors is expected to select the other members of the audit committee. To qualify as independent to serve on the combined company's audit committee, listing standards of Nasdaq and the applicable SEC rules require that a director not accept any consulting, advisory or other compensatory fee from the combined company, other than for service as a director, or be an affiliated person of the combined company. Infinity and MEI believe that, following the completion of the Merger, the composition of the audit committee will comply with the applicable requirements of the rules and regulations of Nasdaq and the SEC.

## **Compensation Committee**

MEI's Compensation Committee acts on behalf of the board of directors to fulfill the board's responsibilities to:

- oversee, review, modify and approve our compensation strategy and policies;
- assess the independence of compensation consultants and legal advisors prior to engagement;
- exercise sole power to retain compensation consultants and advisors and to determine the scope of the associated engagements;
- review and approve annual corporate performance goals;
- evaluate the chief executive officer's and executive officers' performance;
- review and determine the compensation to be paid to our executive officers, including the allocation of equity related grants;
- recommend the compensation and terms of appointment of non-executive directors to the Board of Directors for review and approval;
- ensure MEI meets the reporting requirements promulgated by the SEC regarding compensation and disclosure of compensation and compensation related practices;
- assess potential compensation related risks; and
- evaluate and ensure compliance with "Say-on-Pay" requirements.

The compensation committee of the combined company is expected to retain these duties and responsibilities following completion of the Merger.

### *Compensation Committee Interlocks and Insider Participation*

Thomas C. Reynolds is expected to become the Chair of the combined company's compensation committee. In connection with the closing of the Merger, the combined company's board of directors is expected to select the other members of the compensation committee. Each member of the combined company's compensation committee is expected to be a "non-employee" director within the meaning of Rule 16b-3 of the rules promulgated under the Exchange Act and independent within the meaning of the independent director guidelines of Nasdaq. MEI and Infinity believe that, following the completion of the Merger, the composition of the compensation committee will comply with the applicable requirements of the rules and regulations of Nasdaq.

## **Nominating and Corporate Governance Committee**

MEI's Nominating and Governance Committee is responsible for assisting the board of directors in:

- identifying qualified individuals who possess the desired experience and skills to serve on the Board;
- proposing chairpersons and members on committees to the Board;
- considering all qualified director candidates identified by the Nominating and Governance Committee, or by stockholders, in the event any member of the board of directors does not wish to continue in service or if the board of directors decides not to re-nominate a member for re-election;
- overseeing the Board evaluation process and evaluating the size and composition of the Board; and
- evaluating any stockholder proposal and whether to recommend to the board of directors and whether MEI shall support or oppose the proposal.

---

## [Table of Contents](#)

The nominating and corporate governance committee of the combined company is expected to retain these duties and responsibilities following completion of the Merger.

Charles V. Baltic III is expected to become the Chair of the combined company's nominating and corporate governance committee. In connection with the closing of the Merger, the combined company's board of directors is expected to select the other members of the nominating and corporate governance committee. MEI and Infinity believe that, after the completion of the Merger, the composition of the nominating and corporate governance committee will meet the requirements for independence under, and the functioning of such nominating and corporate governance committee will comply with, any applicable requirements of the rules and regulations of Nasdaq.

### **Non-Employee Director Compensation**

Please refer to "MEI's Director Compensation" above for a discussion of MEI's current policies with regard to the compensation of its non-employee directors. In connection with closing of the Merger, it is expected that the combined company will provide compensation to non-employee directors that is consistent with MEI's current practices; however, these director compensation policies may be re-evaluated by the combined company and the compensation committee following the completion of the Merger and may be subject to change. Non-employee directors are expected to receive an annual retainer fee and equity compensation in the form of a stock option grant.

## CERTAIN RELATIONSHIPS AND RELATED-PARTY TRANSACTIONS

In addition to the compensation arrangements, including employment, termination-of-employment and change-in-control arrangements, with MEI's and Infinity's directors and executive officers, including those discussed in the sections titled "*Management Following the Merger*," "*MEI Executive Compensation*" and "*Infinity Executive Compensation*," the following is a description of each transaction since January 1, 2022 with respect to Infinity and since January 1, 2022 with respect to MEI and each currently contemplated transaction in which:

- either MEI or Infinity has been or is a participant;
- the amounts involved exceeded or will exceed the lesser of \$120,000 and 1% of the average of MEI's or Infinity's total assets at year-end for the last two completed fiscal years, as applicable; and
- any of Infinity's directors, executive officers or holders of more than 5% of Infinity Common Stock, or any of the MEI directors who will be directors of the combined company, or an affiliate or immediate family member of the foregoing persons, had or will have a direct or indirect material interest.

### **Infinity Transactions**

Certain related party transactions involving Infinity's directors and executive officers are described in more detail in the section titled "*The Merger—Interests of Infinity Directors and Executive Officers in the Merger*" and "*The Merger—Compensation Payable to Infinity Named Executive Officers*" beginning on pages 167 and 172 of this joint proxy statement/prospectus.

### ***Employment, Retention and Severance Arrangements***

Infinity has entered into employment agreements with certain of its executive officers. For more information regarding these agreements, see the section titled "*Infinity Executive Compensation*."

Infinity has entered into Retention and Severance Protection Agreements with each of Infinity's named executive officers, each of whom is subject to the Infinity Severance Plan. For more information regarding these arrangements, see the section titled "*The Merger—Interests of Infinity Directors and Executive Officers in the Merger*" and "*The Merger—Compensation Payable to Infinity Named Executive Officers*."

### ***Limitation of Liability***

Infinity's restated certificate of incorporation (the "Infinity COI") provides that a member of Infinity's board of directors will not be personally liable to Infinity or its stockholders for monetary damages for breaches of their legal duties to Infinity or its stockholders as a director, except for liability:

- for any breach of the director's duty of loyalty to Infinity or its stockholders;
- for acts or omissions by the director not in good faith or which involve intentional misconduct or a knowing violation of the law;
- for declaring dividends or authorizing the purchase or redemption of shares in violation of Delaware law; or
- for transactions where the director derived any improper personal benefit.

The Infinity COI also allows Infinity to indemnify directors and officers to the fullest extent authorized by Delaware law.

The Infinity Bylaws, as amended, provide that Infinity shall, to the fullest extent authorized by the DGCL, indemnify its directors; provided, however, that Infinity may limit the extent of such indemnification by individual contracts with its directors; and, provided, further, that Infinity shall not be required to indemnify any



## [Table of Contents](#)

director in connection with any proceeding (or part thereof) initiated by such person or any proceeding by such person against Infinity or its directors, officers, employees or other agents unless (i) such indemnification is expressly required to be made by law, (ii) the proceeding was authorized by Infinity's board of directors, or (iii) such indemnification is provided by Infinity, in its board's sole discretion, pursuant to its powers under the DGCL.

### ***Policies and Procedures for Related Person Transactions***

Infinity's board of directors has adopted written policies and procedures for the review of any transaction, arrangement or relationship in which Infinity is a participant, the amount involved exceeds \$120,000, and one of Infinity's executive officers, directors, director nominees or 5% stockholders (or their immediate family members), or an entity under their direct or indirect control, each of whom Infinity refers to as a "related person," has a direct or indirect material interest.

If a related person proposes to enter into such a transaction, arrangement or relationship, which Infinity refers to as a "related person transaction," the related person must report the proposed related person transaction to Infinity's General Counsel. The policy calls for the proposed related person transaction to be reviewed and, if deemed appropriate, approved by Infinity's Audit Committee. Whenever practicable, the reporting, review and approval will occur prior to entry into the transaction. If advance review and approval is not practicable, Infinity's Audit Committee will review, and, in its discretion, may ratify the related person transaction. The policy also permits the chair of Infinity's Audit Committee to review and, if deemed appropriate, approve proposed related person transactions that arise between Infinity Audit Committee meetings, subject to ratification by Infinity's Audit Committee at its next meeting. Any related person transactions that are ongoing in nature will be reviewed annually.

A related person transaction reviewed under the policy will be considered approved or ratified if it is authorized by Infinity's Audit Committee after full disclosure of the related person's interest in the transaction. As appropriate for the circumstances, Infinity's Audit Committee will review and consider:

- the related person's interest in the related person transaction;
- the approximate dollar value of the amount involved in the related person transaction;
- the approximate dollar value of the amount of the related person's interest in the transaction without regard to the amount of profit or loss;
- whether the transaction was undertaken in the ordinary course of Infinity's business;
- whether the terms of the transaction are no less favorable to Infinity than terms that could have been reached with an unrelated party;
- the purpose of, and the potential benefits to Infinity of, the transaction; and
- any other information regarding the related person transaction or the related person in the context of the Contemplated Transaction that would be material to investors in light of the circumstances of the particular transaction.

Infinity's Audit Committee may approve or ratify the transaction only if Infinity's Audit Committee determines that, under all of the circumstances, the transaction is not inconsistent with Infinity's best interests. Infinity's Audit Committee may impose any conditions on the related person transaction that it deems appropriate.

In addition to the transactions that are excluded by the instructions to the SEC's related person transaction disclosure rule, Infinity's board of directors has determined that the following transactions do not create a material direct or indirect interest on behalf of related persons and, therefore, are not related person transactions for purposes of this policy:

- interests arising solely from the related person's position as an executive officer of another entity (whether or not the person is also a director of such entity), that is a participant in the transaction,

---

[Table of Contents](#)

where (a) the related person and all other related persons own in the aggregate less than a 10% equity interest in such entity, (b) the related person and his or her immediate family members are not involved in the negotiation of the terms of the transaction and do not receive any special benefits as a result of the transaction, and (c) the amount involved in the transaction equals less than the greater of \$200,000 or 5% of the annual consolidated gross revenues of the other entity that is a party to the transaction; and

- a transaction that is specifically contemplated by provisions of the Infinity COI or the Infinity Bylaws.

The policy provides that transactions involving compensation of executive officers shall be reviewed and approved by Infinity's Compensation Committee in the manner specified in its charter.

## ANTICIPATED ACCOUNTING TREATMENT

The Merger is expected to be accounted for as an asset acquisition pursuant to Accounting Standards Codification Topic 805 – *Business Combinations* (“ASC 805”). To determine the accounting for this transaction under U.S. GAAP, a company must assess whether an integrated set of assets and activities should be accounted for as an acquisition of a business or an asset acquisition. The guidance requires an initial screen test to determine if substantially all of the fair value of the gross assets acquired is concentrated in a single asset or group of similar assets. If that screen is met, the set is not a business. In connection with the acquisition of Infinity, substantially all the fair value is included in in-process research and development of eganelisib and, as such, the acquisition is expected to be treated as an asset acquisition. For accounting purposes, MEI is considered to be acquiring Infinity in the Merger.

The final allocation of the purchase price will be determined after the Merger is completed and after completion of an analysis to determine the allocation of the cost of the acquisition, including transaction costs, to the individual assets acquired and liabilities assumed of Infinity on a fair value basis. Accordingly, the final acquisition accounting adjustments may be materially different from the unaudited pro forma adjustments.

The financial condition and results of operations of MEI after completion of the Merger will reflect Infinity’s balances and results after completion of the Merger but will not be restated retroactively to reflect the historical financial condition or results of operations of Infinity. The earnings of MEI following completion of the Merger will reflect acquisition accounting adjustments, including the effect of changes in the carrying value of assets and liabilities.

## UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL STATEMENTS

### The Merger

On February 22, 2023, MEI Pharma, Inc, a Delaware corporation (“MEI”), Infinity Pharmaceuticals, Inc., a Delaware corporation (“Infinity”), and Meadow Merger Sub, Inc., a Delaware corporation and a wholly owned subsidiary of MEI (“Merger Sub,” and each of MEI, Merger Sub and Infinity are each sometimes referred to herein as a “Party” and collectively as the “Parties”), entered into an Agreement and Plan of Merger (the “Merger Agreement”).

The Merger Agreement provides, among other things, that on the terms and subject to the conditions set forth therein: (i) Merger Sub will merge with and into Infinity, with Infinity being the surviving entity as a wholly-owned subsidiary of MEI (the “Merger” and, collectively with the other transactions contemplated by the Merger Agreement, the “Transactions”), (ii) each share of the common stock, par value \$0.001 per share, of Infinity (the “Infinity Common Stock”) issued and outstanding immediately prior to the Merger (other than shares of Infinity Common Stock held in treasury, if any) shall be automatically converted into the right to receive 0.052245 shares (the “Exchange Ratio”) of the common stock, par value \$0.0000002 per share, of MEI (the “MEI Common Stock”), subject to customary equitable adjustment in the event of any recapitalization, stock split, reverse stock split or similar change and having been so adjusted from 1.0449 as provided in the Merger Agreement as a result of MEI’s reverse stock split which took effect on April 14, 2023, (iii) each outstanding option to purchase shares of the Infinity Common Stock (each, an “Infinity Stock Option”) will become fully vested in accordance with the terms of the underlying stock option agreement and will be assumed by MEI at the effective time of the Merger (the “Effective Time”) and converted into a stock option to purchase shares of MEI Common Stock, with (A) the number of shares of MEI Common Stock underlying each such assumed Infinity Stock Option equal to the product of the number of shares of Infinity Common Stock subject to such option immediately prior to the Effective Time multiplied by the Exchange Ratio and rounded down to the nearest whole share, and (B) the per share exercise price equal to the per share exercise price applicable to such Infinity Stock Option immediately prior to the Effective Time divided by the Exchange Ratio and rounded up to the nearest whole cent, and except as noted above, each assumed and converted Infinity Stock Option will continue to be governed by substantially the same terms and conditions (after giving effect to the full acceleration of vesting of such Infinity Stock Option in connection with the Merger) as were applicable to such Infinity Stock Option immediately prior to the Effective Time, (iv) before the Effective Time, each restricted stock unit of Infinity (each, an “Infinity RSU”) will become fully vested and the shares of Infinity Common Stock subject to by such Infinity RSUs will be distributed in accordance with the terms of the applicable restricted stock unit agreement, and the shares of Infinity Common Stock issued upon the vesting of Infinity RSUs will be treated as shares of Infinity Common Stock issued and outstanding immediately prior to the Effective Time in accordance with subpart (ii) hereof. Upon completion of the Merger, MEI’s stockholders will own approximately 58% of the combined company’s outstanding common stock and Infinity stockholders will own approximately 42%, subject to the terms of the Merger Agreement.

### Pro Forma Financial Information

The following unaudited pro forma condensed combined financial information is presented to illustrate the effect of the Merger of MEI and Infinity. The information under the “Unaudited Pro Forma Condensed Combined Balance Sheet” in the table below gives effect to the Merger as if it had taken place on December 31, 2022, the closing date of MEI’s latest period presented. The information under “Unaudited Pro Forma Condensed Combined Statement of Operations” for the six months ended December 31, 2022 and the twelve months ended June 30, 2022 give effect to the Merger as if it took place on July 1, 2021.

MEI and Infinity have different fiscal years. MEI’s fiscal year ends on June 30, whereas Infinity’s fiscal year ends on December 31. The unaudited pro forma condensed combined financial information is presented to

## [Table of Contents](#)

illustrate the estimated effects of the pending Merger between MEI and Infinity based on the historical financial position and results of operations of MEI and Infinity. It is presented as follows:

- The unaudited pro forma condensed combined balance sheet as of December 31, 2022, was prepared based on (i) the historical unaudited condensed balance sheet of MEI as of December 31, 2022, and (ii) the historical audited consolidated balance sheet of Infinity as of December 31, 2022.
- The unaudited pro forma condensed combined statement of operations for the six months ended December 31, 2022, combines the unaudited historical statements of operations of MEI and Infinity for the six months ended December 31, 2022.
- The unaudited pro forma condensed combined statement of operations for the twelve months ended June 30, 2022, combines the audited historical statements of operations of MEI and the unaudited historical statements of operations of Infinity for the twelve months ended June 30, 2022.
- The historical statement of operations of Infinity for the twelve months ended June 30, 2022, was derived from Infinity's unaudited condensed statement of operations for the six months ended June 30, 2022, and the unaudited condensed statement of operations for the six months ended December 31, 2021.

Assumptions underlying the pro forma adjustments are described in the accompanying notes, which should be read in conjunction with the unaudited pro forma condensed combined financial information. On April 14, 2023, MEI amended its certificate of incorporation to effect a combination of the outstanding MEI Common Stock at a ratio of one-for-twenty ("Reverse Stock Split"). The Reverse Stock Split was effective on April 14, 2023. All historical share and per share amounts have been adjusted to reflect the Reverse Stock Split. All stock options, restricted stock units and warrants outstanding were ratably adjusted to give effect to the Reverse Stock Split.

The adjustments presented to the unaudited pro forma condensed combined financial statements have been identified and presented to provide relevant information necessary for an accurate understanding of the combined company upon consummation of the Merger. The unaudited pro forma condensed combined financial information is based on assumptions and adjustments that are described in the accompanying notes. The unaudited pro forma condensed combined financial information is for illustrative purposes only. The financial results may have been different had the companies always been combined. The unaudited pro forma condensed combined financial information should not be relied upon as being indicative of the historical results that would have been achieved had the companies always been combined or the future results that the combined company will experience. The actual amounts recorded as of the completion of the Merger may differ materially from the information presented in these unaudited pro forma combined financial statements as a result of the amount of cash used by Infinity between the signing of the Merger Agreement and the closing of the Merger, the timing of the closing of the Merger, and other changes in the amounts or estimated fair value of Infinity's assets and liabilities prior to the completion of the Merger. The combined company believes that its assumptions and methodologies provide a reasonable basis for presenting all the significant effects of the transactions based on information available to management at this time and that the unaudited pro forma transaction accounting adjustments give appropriate effect to those assumptions and are properly applied in the unaudited pro forma condensed combined financial information.

The unaudited pro forma combined financial statements, including the notes thereto, should be read in conjunction with:

- The accompanying notes to the unaudited pro forma condensed combined financial information;
- The audited historical financial statements of MEI as of and for the fiscal years ended June 30, 2022 and 2021 and the related notes set forth in the Annual Report on Form 10-K filed by MEI with the SEC on September 8, 2022, included elsewhere in this joint proxy statement/prospectus;
- The unaudited historical financial statements of MEI as of and for the six months ended December 31, 2022 and 2021, and the related notes set forth in the Quarterly Report on Form 10-Q filed by MEI with the SEC on February 9, 2023, included elsewhere in this joint proxy statement/prospectus;

---

[Table of Contents](#)

- The audited historical consolidated financial statements of Infinity as of and for the years ended December 31, 2022 and 2021 and the related notes set forth in the Annual Report on Form 10-K filed by Infinity with the SEC on March 28, 2023, included elsewhere in this joint proxy statement/prospectus;
- The disclosures contained in the sections titled “MEI Management’s Discussion and Analysis of Financial Condition and Results of Operations,” and “Infinity Management’s Discussion and Analysis of Financial Condition and Results of Operations”, included elsewhere in this joint proxy statement/prospectus.

**Unaudited Pro Forma Condensed Combined Balance Sheet**  
**As of December 31, 2022**  
(in thousands)

	<u>Historical</u>		<u>Transaction Adjustments</u>	<u>Pro Forma Combined</u>
	<u>MEI</u>	<u>Infinity</u>		
<b>ASSETS</b>				
Current assets:				
Cash and cash equivalents	\$ 10,917	\$ 38,313		\$ 49,230
Short-term investments	113,256	—	—	113,256
Total cash, cash equivalents and short-term investments	124,173	38,313	—	162,486
Unbilled receivables	5,704	—	—	5,704
Prepaid expenses and other current assets	3,568	1,989	—	5,557
Total current assets	133,445	40,302	—	173,747
Operating lease right-of-use asset	12,698	697	—	13,395
Property and equipment, net	1,456	800	—	2,256
Restricted cash, less current portion	—	158	—	158
Other assets	—	194	—	194
Total assets	<u>\$ 147,599</u>	<u>\$ 42,151</u>	<u>\$ —</u>	<u>\$ 189,750</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)</b>				
Current liabilities:				
Accounts payable	\$ 4,067	\$ 4,405	\$ —	\$ 8,472
Accrued liabilities	14,346	9,223	6,060(d),(f),(h)	29,629
Deferred revenue	2,897	—	—	2,897
Operating lease liability	1,343	—	593(f)	1,936
Total current liabilities	22,653	13,628	6,653	42,934
Deferred revenue, long-term	64,545	—	—	64,545
Liabilities related to sale of future royalties, net, less current portion	—	47,213	—	47,213
Operating lease liability, long-term	12,027	324	—	12,351
Other liabilities	—	37	—	37
Total liabilities	<u>99,225</u>	<u>61,202</u>	<u>6,653</u>	<u>167,080</u>
Commitments and contingencies				
Stockholders' equity (deficit):				
Common stock	—	89	(89)(b)	—
Additional paid-in capital	428,904	836,812	(810,478)(b)	455,238
Accumulated deficit	(380,530)	(855,952)	803,914(c)	(432,568)
Total stockholders' equity (deficit)	48,374	(19,051)	(6,653)	22,670
Total liabilities and stockholders' equity	<u>\$ 147,599</u>	<u>\$ 42,151</u>	<u>\$ —</u>	<u>\$ 189,750</u>



**Unaudited Pro Forma Condensed Combined Statement of Operations**  
**For the six months ended December 31, 2022**  
(in thousands, except for per share amounts)

	<u>Historical</u>		<u>Transaction Adjustments</u>	<u>Pro Forma Combined</u>
	<u>MEI</u>	<u>Infinity</u>		
<b>Revenue:</b>				
Revenue	\$41,465	\$ —	\$ —	\$ 41,465
Royalty revenue	—	1,255	—	1,255
Total revenue	<u>41,465</u>	<u>1,255</u>	<u>—</u>	<u>42,720</u>
<b>Operating expenses:</b>				
Research and development	34,776	14,626	—	49,402
General and administrative	15,982	6,292	(1,093)(d)	21,181
Royalty expense	—	756	—	756
Total operating expenses	<u>50,758</u>	<u>21,674</u>	<u>(1,093)</u>	<u>71,339</u>
Loss from operations	(9,293)	(20,419)	1,093	(28,619)
<b>Other income:</b>				
Change in fair value of warrant liability	1,603	—	—	1,603
Interest and dividend income	1,325	—	—	1,325
Investment and other income (expense), net	(6)	562	—	556
Non-cash interest expense	—	(90)	—	(90)
Net loss	<u>\$ (6,371)</u>	<u>\$ (19,947)</u>	<u>\$ 1,093</u>	<u>\$ (25,225)</u>
<b>Net loss:</b>				
Basic	<u>\$ (6,371)</u>	<u>\$ (19,947)</u>	<u>\$ 1,093</u>	<u>\$ (25,225)</u>
Diluted	<u>\$ (6,371)</u>	<u>\$ (19,947)</u>	<u>\$ 1,093</u>	<u>\$ (25,225)</u>
<b>Net loss per share:</b>				
Basic	<u>\$ (0.96)</u>	<u>\$ (0.22)</u>	<u>\$ —</u>	<u>\$ (2.20)</u>
Diluted	<u>\$ (0.96)</u>	<u>\$ (0.22)</u>	<u>\$ —</u>	<u>\$ (2.20)</u>
<b>Shares used in computing net loss per share:</b>				
Basic	<u>6,663</u>	<u>89,285</u>	<u>4,825(g)</u>	<u>11,488</u>
Diluted	<u>6,663</u>	<u>89,285</u>	<u>4,825(g)</u>	<u>11,488</u>

**Unaudited Pro Forma Condensed Combined Statement of Operations**  
**Year ended June 30, 2022**

(in thousands, except for per share amounts)

	<u>Historical</u>		<u>Transaction Adjustments</u>	<u>Pro Forma Combined</u>
	<u>MEI</u>	<u>Infinity</u>		
<b>Revenue:</b>				
Revenue	\$ 40,697	\$ —	\$ —	\$ 40,697
Royalty revenue	—	2,217	—	2,217
Total revenue	<u>40,697</u>	<u>2,217</u>	<u>—</u>	<u>42,914</u>
<b>Operating expenses:</b>				
Research and development	85,641	33,274	463(e)	119,378
Acquired in-process research and development	—	—	49,938(a)	49,938
General and administrative	30,540	14,281	2,730(e),(h)	47,551
Royalty expense	—	1,337	—	1,337
Total operating expenses	<u>116,181</u>	<u>48,892</u>	<u>53,131</u>	<u>218,204</u>
Loss from operations	<u>(75,484)</u>	<u>(46,675)</u>	<u>(53,131)</u>	<u>(175,290)</u>
<b>Other income (loss):</b>				
Change in fair value of warrant liability	20,752	—	—	20,752
Interest and dividend income	284	—	—	284
Investment and other income (expense), net	(6)	69	—	63
Non-cash interest expense	—	(180)	—	(180)
Net loss	<u><u>\$ (54,454)</u></u>	<u><u>\$ (46,786)</u></u>	<u><u>\$ (53,131)</u></u>	<u><u>\$ (154,371)</u></u>
<b>Net loss:</b>				
Basic	<u><u>\$ (54,454)</u></u>	<u><u>\$ (46,786)</u></u>	<u><u>\$ (53,131)</u></u>	<u><u>\$ (154,371)</u></u>
Diluted	<u><u>\$ (62,500)</u></u>	<u><u>\$ (46,786)</u></u>	<u><u>\$ (53,131)</u></u>	<u><u>\$ (162,417)</u></u>
<b>Net loss per share:</b>				
Basic	<u><u>\$ (8.75)</u></u>	<u><u>\$ (0.53)</u></u>	<u><u>\$ —</u></u>	<u><u>\$ (13.97)</u></u>
Diluted	<u><u>\$ (9.99)</u></u>	<u><u>\$ (0.53)</u></u>	<u><u>\$ —</u></u>	<u><u>\$ (14.66)</u></u>
<b>Shares used in computing net loss per share:</b>				
Basic	<u><u>6,224</u></u>	<u><u>88,978</u></u>	<u><u>4,825(g)</u></u>	<u><u>11,049</u></u>
Diluted	<u><u>6,257</u></u>	<u><u>88,978</u></u>	<u><u>4,825(g)</u></u>	<u><u>11,082</u></u>

## NOTES TO UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL STATEMENTS

### 1. Basis of Presentation

The preceding unaudited pro forma condensed combined financial information has been prepared in accordance with U.S. GAAP and Article 11 of Regulation S-X as amended by the final rule, Release No. 33-10786 “Amendments to Financial Disclosures about Acquired and Disposed Businesses.” Release No. 33-10786 replaces the existing pro forma adjustment criteria with simplified requirements to depict the accounting for the transaction (“Transaction Accounting Adjustments”). Only Transaction Accounting Adjustments are presented in the following unaudited pro forma condensed combined financial information.

The Merger is expected to be accounted for as an asset acquisition as substantially all of the fair value of the gross assets acquired is concentrated in a group of similar identifiable assets, primarily in-process research and development. In accordance with ASC 805, asset acquisitions are accounted for by allocating the cost of the acquisition, including transaction costs, to the individual assets acquired and liabilities assumed on a fair value basis without the recognition of goodwill. MEI is considered to be the accounting acquirer based on the structure of the Merger, relative outstanding share ownership at closing and the composition of the combined company’s board of directors.

Fair value measurements can be highly subjective, and it is possible the application of reasonable judgment could develop different assumptions resulting in a range of alternative estimates using the same facts and circumstances.

Fair value estimates were determined based on preliminary discussions between MEI and Infinity management. The allocation of the aggregate Merger consideration used in the preliminary unaudited pro forma condensed combined financial information is based on preliminary estimates. The estimates and assumptions are subject to change as of the Effective Time. The final determination of the allocation of the aggregate Merger consideration will be based on the actual tangible and intangible assets and the liabilities of Infinity at the Effective Time. Refer to Note 2 for additional information.

For pro forma purposes, the valuation of consideration transferred is based on, among other things, the number of shares of Infinity Common Stock outstanding and the price per share and number of shares of MEI Common Stock as of the close of business on April 14, 2023. Refer to Note 2 for additional information. This is used for pro forma purposes only. The consideration transferred will ultimately be based on the number of shares of Infinity Common Stock outstanding and the number shares of MEI Common Stock as of immediately prior to the Effective Time, which could materially change from the assumptions included in this pro forma financial information.

The unaudited pro forma combined balance sheet data gives effect to the Merger as if it had occurred on December 31, 2022. The unaudited pro forma combined statement of operations data gives effect to the Merger as if it had occurred on July 1, 2021.

The unaudited pro forma condensed combined financial information is presented solely for informational purposes and is not necessarily indicative of the combined results of operations or financial position that might have been achieved for the period or date indicated, nor is it necessarily indicative of the future results of the combined company. The unaudited pro forma condensed combined financial information has not been adjusted to give effect to certain expected financial benefits of the Merger, such as cost synergies or the anticipated costs to achieve these benefits, including the cost of integration activities.

## 2. Shares of MEI Common Stock Issued to Infinity Stockholders upon Closing of the Merger and Purchase Price Allocation

### *Shares of MEI Common Stock Issued to Infinity Stockholders upon Closing of the Merger and Preliminary Purchase Price*

The number of shares of MEI Common Stock that MEI will issue to Infinity stockholders, for purposes of these pro forma combined financial statements as of December 31, 2022, is calculated pursuant to the terms of the Merger Agreement (in thousands, except share and per share amounts):

	<u>Amounts</u>
Number of shares of Infinity Common Stock outstanding as of April 14, 2023 (i)	92,351,287
Exchange Ratio - MEI shares to Infinity shares	0.052245
Equivalent MEI shares	<u>4,824,893</u>
MEI price per share as of April 14, 2023 (ii)	\$ 4.80
Fair value of the estimated number of shares of the combined company to be owned by Infinity's stockholders	<u>\$ 23,159</u>
Estimated fair value of vested Infinity Stock Options to be replaced by MEI (iii)	456
Infinity transaction costs (iv)	1,450
MEI estimated transaction costs (v)	<u>5,822</u>
Total preliminary purchase price	<u>\$ 30,887</u>

- (i) The number of shares of Infinity Common Stock outstanding of 92,351,287 includes 2,446,482 unvested Infinity RSUs all of which will be replaced in exchange for shares of MEI Common Stock and for purposes of these pro forma financial statements is calculated as of April 14, 2023. The 2,446,482 unvested Infinity RSUs outstanding immediately prior to the Effective Time will be distributed prior to the Effective Time and included in shares of Infinity Common Stock resulting therefrom.
- (ii) The closing price of MEI Common Stock was determined to be the most accurate measurement of the purchase consideration as the MEI Common Stock is traded on the Nasdaq Capital Market. The estimated value of the purchase consideration reflected in this pro forma condensed combined financial information does not purport to represent the actual value of the purchase consideration that will be deemed to be received by Infinity stockholders when the Merger is consummated. The final fair value of equity securities issued as part of the purchase consideration will be measured on the closing date at the then-current market price of MEI Common Stock. This requirement will likely result in a per share equity component different from the \$4.80 assumed in this pro forma condensed combined financial information and that difference may be material.
- (iii) Represents the fair value-based measure of the vested Infinity Stock Options to be assumed and replaced by MEI attributable to precombination service at the acquisition date of \$0.5 million. The fair value-based measure of these amounts will be determined based on the closing trading price of Infinity Common Stock on the Merger closing date, the number of Infinity equity awards outstanding on the Merger closing date, and the period of service provided by the holders of the awards prior to the Merger closing date.
- (iv) Represents Infinity transaction costs to be paid by MEI on behalf of Infinity upon the closing the Merger and included as consideration transferred in the acquisition.
- (v) Represents MEI transaction costs estimated to be approximately \$5.8 million which are capitalized as a component of the cost of the assets acquired.

## [Table of Contents](#)

### *Preliminary Purchase Price Allocation*

The following table provides an estimated, preliminary pro forma purchase price allocation, which is subject to change upon a completed valuation of the assets acquired and liabilities assumed as of the closing date. The preliminary purchase price allocation as of December 31, 2022, is as follows (in thousands):

	<u>Amounts</u>
<b>Assets acquired:</b>	
Cash and cash equivalents	\$ 38,313
Other current and non current assets	3,838
Total identifiable assets	<u>42,151</u>
<b>Liabilities to be assumed:</b>	
Accounts payable and other liabilities	(12,771)
Liabilities related to sale of future royalties (i)	(48,431)
Total identifiable liabilities	<u>(61,202)</u>
<b>In-process research and development</b>	<u>49,938</u>
Total preliminary purchase price	<u>\$ 30,887</u>

- (i) The valuation of the liabilities related to sale of future royalties is expected to materially change and will be based on the final purchase price allocation.

The guidance in ASC 805 requires an initial screen test to determine if substantially all of the fair value of the gross assets acquired is concentrated in a single asset or group of similar assets. If that screen is met, the set is not a business. The initial screen test was met as MEI determined that substantially all of the fair value was concentrated in the acquired in-process research and development.

In-process research and development represents the research and development assets of Infinity which were in-process, but not yet completed, and which MEI has the opportunity to advance. Current accounting standards require that the fair value of in-process research and development projects acquired in an asset acquisition with no alternative future use be allocated a portion of the consideration transferred and charged to expense at the acquisition date. The actual purchase price allocated to in-process research and development will fluctuate until the closing date of the Merger, and the final valuation of the in-process research and development consideration could differ significantly from the current estimate.

The purchase price allocation will remain preliminary until MEI management determines the fair values of assets acquired and liabilities assumed. The final determination of the purchase price allocation is anticipated to be completed as soon as practicable after completion of the transaction and will be based on the fair values of the assets acquired and liabilities assumed as of the transaction closing date. The final amounts allocated to assets acquired and liabilities assumed could differ significantly from the amounts presented in the unaudited pro forma condensed combined financial statements for the reasons described in Note 1.

### **3. Unaudited Pro Forma Adjustments**

The following provides explanations of the various adjustments to the unaudited pro forma combined financial statements:

- (a) Represents the recording of acquired in-process research and development in the unaudited pro forma condensed combined statement of operations for the year ended June 30, 2022 as if the Merger was completed on July 1, 2021 and the recording of acquired in-process research and development in the unaudited pro forma condensed combined balance sheet as of December 31, 2022 as if the Merger was completed on December 31, 2022 (see Note 2).

## [Table of Contents](#)

- (b) Represents the elimination of Infinity's historical common stock, additional paid-in capital and other adjustments (in thousands):

	<u>Amounts</u>
Elimination of Infinity additional paid-in capital	\$(836,812)
Estimated fair value of outstanding vested Infinity Stock Options (Note 2 (iii))	456
Estimated fair value of outstanding unvested Infinity Stock Options and Infinity RSUs (e)	1,269
Infinity transaction costs to be paid by MEI at close of Merger (Note 2 (iv))	1,450
Fair value of the estimated number of shares of the combined company to be owned by Infinity's stockholders (Note 2)	23,159
Total	<u>\$(810,478)</u>

- (c) Represents elimination of Infinity's accumulated deficit and other adjustments (in thousands):

	<u>Amounts</u>
Elimination of Infinity accumulated deficit	\$855,952
MEI incurred and accrued transaction fees as of December 31, 2022 (d)	1,093
Severance costs payable to Infinity executive officers (h)	(1,924)
Estimated fair value of outstanding unvested Infinity Stock Options and Infinity RSUs (e)	(1,269)
In-process research and development (a)	(49,938)
Total	<u>\$803,914</u>

- (d) Represents \$4.7 million of MEI's accrued transaction costs expected to be incurred in connection with the Merger and not yet reflected in the historical condensed balance sheet of MEI as of December 31, 2022. MEI's total estimated transaction costs of \$5.8 million are capitalized as a component of the cost of the assets acquired. Accrued transaction costs of \$1.1 million included as general and administrative expense in the condensed statement of operations of MEI for the six months ended December 31, 2022 are presented as a transaction adjustment as these costs are included in the allocation of acquired in-process research and development in the unaudited pro forma condensed combined statement of operations for the year ended June 30, 2022 as if the Merger was completed on July 1, 2021.
- (e) Represents the fair value-based measure of the unvested Infinity Stock Options and Infinity RSUs expected to fully vest on the closing of the Merger of \$1.3 million to be recognized immediately as compensation cost in the post-combination financial statements of the combined company. Total post-combination compensation cost is presented as \$0.8 million general and administrative expense and \$0.5 million research and development expense in the unaudited pro forma condensed combined statement of operations for the year ended June 30, 2022 as if the Merger was completed on July 1, 2021.
- (f) Represents reclassification of the current portion of Infinity's operating lease liability from accrued liabilities to operating lease liability to conform with MEI's condensed balance sheet presentation.
- (g) Represents the pro forma weighted average shares outstanding at the end of both the six months ended December 31, 2022, and year ended June 30, 2022, excluding any future or potential transactions or offerings, see Note 4.
- (h) Represents accrual of \$1.9 million in severance to be paid to executives of Infinity in connection with the Merger and presented as general and administrative in the unaudited pro forma condensed combined statement of operations for the year ended June 30, 2022 as if the Merger was completed on July 1, 2021.

[Table of Contents](#)**4. Loss per Share**

The unaudited pro forma weighted average number of basic and diluted shares outstanding and pro forma net loss per common share basic and diluted is calculated as follow (in thousands):

	<u>Six Months Ended December 31, 2022</u>	<u>Year Ended June 30, 2022</u>
MEI weighted average shares outstanding - basic	6,663	6,224
Estimated shares of common stock expected to be issued to Infinity shareholders upon consumation of the Merger (see Note 2)	4,825	4,825
Pro forma weighted average shares outstanding - basic	<u>11,488</u>	<u>11,049</u>
MEI weighted average shares outstanding - diluted	6,663	6,257
Estimated shares of common stock expected to be issued to Infinity shareholders upon consumation of the Merger (see Note 2)	4,825	4,825
Pro forma weighted average shares outstanding - diluted	<u>11,488</u>	<u>11,082</u>
Pro forma net loss attributable to common shareholders - basic	<u>\$ (25,225)</u>	<u>\$ (154,371)</u>
Pro forma net loss attributable to common shareholders - diluted	<u>\$ (25,225)</u>	<u>\$ (162,417)</u>
Pro forma net loss per common share - basic	<u>\$ (2.20)</u>	<u>\$ (13.97)</u>
Pro forma net loss per common share - diluted	<u>\$ (2.20)</u>	<u>\$ (14.66)</u>

## MARKET PRICE AND DIVIDEND INFORMATION

### MEI Common Stock

MEI Common Stock is listed on The Nasdaq Capital Market under the symbol “MEIP.”

The closing price of shares of MEI Common Stock on February 22, 2023, the trading day immediately prior to the public announcement of the Merger on February 23, 2023, as reported on The Nasdaq Capital Market, was \$4.80 per share.

As of March 31, 2023, there were 366 holders of record of MEI Common Stock. The actual number of stockholders of MEI’s Common Stock is greater than the number of record holders and includes stockholders whose MEI Common Stock are held in street name by brokers and other nominees.

### MEI Dividends

MEI has never declared or paid any cash dividends on its common stock. MEI currently intends to retain all available funds and future earnings, if any, for the operation and expansion of its business and does not anticipate declaring or paying any dividends in the foreseeable future.

The payment of dividends, if any, will be at the discretion of the combined company’s board of directors and will depend on its results of operations, capital requirements, financial condition, prospects, contractual arrangements, any limitations on payment of dividends present in its future debt agreements, and other factors that the board of directors of the combined company may deem relevant.

### Infinity Common Stock

The Infinity Common Stock is quoted on the Nasdaq Global Select Market under the symbol “INFI.”

The closing price of shares of the Infinity Common Stock on February 22, 2023, the trading day immediately prior to the public announcement of the Merger on February 23, 2023, as reported on the Nasdaq Global Select Market, was \$0.55 per share.

As of March 31, 2023 there were approximately 46 holders of record of Infinity Common Stock. The actual number of holders of Infinity Common Stock is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers or held by other nominees.

### Infinity Dividends

Infinity has never declared or paid cash dividends on its capital stock and does not anticipate paying any cash dividends in the foreseeable future if Infinity remains a standalone operating company. Notwithstanding the foregoing, any determination for Infinity to pay cash dividends following abandonment of the Merger would be at the discretion of Infinity’s board of directors and would depend upon a number of factors, including Infinity’s results of operations, financial condition, future prospects, contractual restrictions, restrictions imposed by applicable law and other factors Infinity’s board of directors deems relevant.



## DESCRIPTION OF MEI COMMON STOCK

The following description of MEI Common Stock, provisions of the MEI COI, and the MEI Bylaws are summaries and are qualified by reference to such MEI COI and MEI Bylaws and applicable provisions of Delaware corporate law. MEI has filed copies of these documents with the SEC as exhibits to its periodic filings.

### **Authorized Common Stock**

Under the MEI COI, MEI's total authorized share capital is 226,100,000 shares consisting of 226,000,000 shares of common stock, \$0.0000002 par value per share, and 100,000 shares of preferred stock, \$0.01 par value per share. As of April 23, 2023, 6,662,857 shares of MEI Common Stock and no shares of preferred stock are issued and outstanding.

### **Common Stock**

The holders of MEI Common Stock are entitled to one vote per share. In the event of a liquidation, dissolution or winding up of MEI's affairs, holders of the MEI Common Stock will be entitled to share ratably in all of MEI's assets that are remaining after payment of MEI's liabilities and the liquidation preference of any outstanding shares of preferred stock. All outstanding shares of MEI Common Stock are fully paid and non-assessable. The rights, preferences and privileges of holders of MEI Common Stock are subject to any series of preferred stock that we have issued or that we may issue in the future. The holders of MEI Common Stock have no preemptive rights and are not subject to future calls or assessments by MEI.

### **Preferred Stock**

The board has the authority to issue up to 100,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions in respect of that preferred stock, including dividend rights, dividend rates, conversion rights, voting rights, terms of redemption (including sinking fund provisions), redemption prices and liquidation preferences, and the number of shares constituting such series and the designation of any such series, without future vote or action by the shareholders. Therefore, the board of directors, without the approval of the shareholders, could authorize the issue of preferred stock with voting, conversion and other rights that could affect the voting power, dividend and other rights of the holders of shares or that could have the effect of delaying, deferring or preventing a change of control.

### **Anti-Takeover Effects of Amended and Restated Certificate of Incorporation and Fifth Amended and Restated Bylaws**

Certain provisions in the MEI COI and the MEI Bylaws as well as certain provision of the DGCL could discourage potential takeover attempts and make attempts by shareholders to change management more difficult. A description of these provisions is set forth below.

#### *Classified Board of Directors*

Under the MEI COI and the MEI Bylaws, directors are to be elected at each annual meeting of stockholders for a term of three years unless the director is removed, retires or the office is vacated earlier. The board is divided into three classes with respect to the term of office, with the terms of office of one class expiring each successive year. This classified board provision could discourage a third party from making a tender offer for MEI's shares or attempting to obtain control of MEI. It could also delay stockholders who do not agree with the policies of the board of directors from removing a majority of the board of directors for two years.

#### *Advance Notice Requirements for Shareholder Proposals and Nominations for Election as Directors*

Under the MEI Bylaws, stockholders seeking to bring business before an annual meeting of stockholders or to nominate candidates for election as directors at an annual meeting must provide timely notice thereof in writing to MEI.

To be timely, a shareholder's notice with respect to business to be brought before an annual meeting must be received at the principal executive office of MEI not later than ninety (90) days, nor earlier than 120 days, prior to an annual meeting. However, in the event that no annual meeting was held in the previous year or the date of the current year's annual meeting is more than thirty (30) days before or more than sixty (60) days after the anniversary date of the previous year's annual meeting, the notice by the stockholder must be received by the Secretary at the principal executive offices of MEI not earlier than one hundred and twenty (120) days prior to the current year's annual meeting and not later than the later of ninety (90) days prior to the current year's annual meeting and ten (10) days following the date on which public announcement of the date of such annual meeting is first made. Notwithstanding anything in the preceding sentence to the contrary, in the event that the number of directors to be elected to the board of directors at an annual meeting is increased and there is no public announcement by MEI naming all of the nominees for director or specifying the size of the increased board of directors at least ninety (90) days prior to the first anniversary of the preceding year's annual meeting, a stockholder's notice shall be considered timely, but only with respect to nominees for the new positions created by such increase, if it shall be delivered to the Secretary at the principal executive offices of MEI not later than ten (10) days following the day on which the increase in the number of directors to be elected is first announced to the public by MEI.

### ***Special Meetings of Stockholders***

Only such business shall be conducted at a special meeting of stockholders as shall have been brought before the meeting pursuant to MEI's notice of meeting. Directors may be elected at a special meeting of stockholders only in accordance with a determination of the board of directors that directors are to be elected at the special meetings. With respect to Special Meetings, nominations of persons for election as directors at that special meeting may be made (i) by the board of directors or (ii) by a stockholder who has given timely notice thereof in writing to the Secretary of MEI. This shall be the exclusive means for a stockholder to make nominations with regard to a special meeting of stockholders at which directors are to be elected. To be timely, a stockholder's notice must be received by the Secretary at the principal executive offices of MEI not earlier than one hundred and twenty (120) days prior to such special meeting and not later than the later of ninety (90) days prior to such special meeting or ten (10) days following the day on which public announcement of the date of the special meeting and of the nominees proposed by the board of directors to be elected at such meeting is first made. In no event shall the public announcement of an adjournment or postponement of a special meeting commence a new time period (or extend any time period) for the giving of a stockholder's notice as described above.

## COMPARISON OF RIGHTS OF HOLDERS OF MEI COMMON STOCK AND INFINITY COMMON STOCK

If the Merger is completed, Infinity stockholders will receive shares of MEI Common Stock, pursuant to the terms of the Merger Agreement. The following is a summary of certain differences between (i) the current rights of Infinity stockholders under the Infinity COI and the Infinity Bylaws, as amended, and (ii) the rights of MEI stockholders under the MEI COI and the MEI Bylaws. The summary set forth below is not intended to provide a comprehensive discussion of each company's governing documents or relevant corporate law. This summary is qualified in its entirety by reference to the full text of each company's governing documents and the DGCL. See "Where You Can Find More Information" beginning on page 338 of this joint proxy statement/prospectus for information on how to obtain a copy of these documents.

### General

MEI is incorporated under the laws of the State of Delaware and Infinity is incorporated under the laws of the State of Delaware. Accordingly, the rights of MEI stockholders and Infinity stockholders are governed by the DGCL. As a result of the Merger, Infinity stockholders who receive shares of MEI Common Stock will become MEI stockholders, and their rights as stockholders will be governed by the DGCL and the MEI organizational documents.

Following is a comparison of the rights of MEI stockholders and Infinity stockholders:

MEI

Infinity

#### Organizational Documents

The rights of MEI stockholders are governed by the MEI COI, the MEI Bylaws and the DGCL.

The rights of Infinity stockholders are governed by the Infinity COI, the Infinity Bylaws, as amended, and the DGCL.

#### Authorized Capital Stock

MEI is authorized to issue two classes of capital stock, which are designated, respectively, "common stock" and "preferred stock." The total number of shares that MEI is authorized to issue is 226,100,000, of which 226,000,000 shares are common stock, par value \$0.00000002 per share, and 100,000 shares are preferred stock, par value \$0.01 per share.

Infinity is authorized to issue two classes of capital stock, which are designated, respectively, "common stock" and "preferred stock." The total number of shares that Infinity is authorized to issue is 201,000,000, of which 200,000,000 shares are common stock, par value \$0.001 per share, and 1,000,000 shares are preferred stock, par value \$0.001 per share. The Infinity board of directors is authorized to increase or decrease the number of shares of any series of preferred stock subsequent to the issuance of shares of that series, but not below the number of shares of such series then outstanding. In case the number of shares of any series is decreased in accordance with the foregoing, the shares constituting such decrease shall resume the status that they had prior to the adoption of the resolution originally fixing the number of shares of such series.

#### Common Stock

The authorized MEI Common Stock consists of 226,000,000 shares of MEI Common Stock.

The authorized Infinity Common Stock consists of 200,000,000 shares of Infinity Common Stock.

Each holder of a share of MEI Common Stock is entitled to one vote per share.

Each holder of a share of Infinity Common Stock is entitled to one vote for each such share held of record on all matters to be voted upon by stockholders.

Preferred Stock

MEI's authorized preferred stock consists of 100,000 shares of preferred stock. No shares of MEI preferred stock are currently outstanding.

Infinity's authorized preferred stock consists of 1,000,000 shares of preferred stock. No shares of Infinity preferred stock are currently outstanding.

Number and Qualification of Directors

The MEI board of directors may consist of no less than two and no more than nine members. The number of directors is fixed from time to time by action of the MEI board of directors, and until so fixed, shall be seven. The MEI board of directors currently consists of seven members.

The number of directors which constitute the whole Infinity board of directors shall be established by the Infinity board of directors. The Infinity board of directors currently consists of eight members.

Structure of Board of Directors; Term of Directors; Election of Directors

Under the MEI COI and the MEI Bylaws, directors are to be elected at each annual meeting of stockholders for a term of three years to serve until their successors are elected and qualified or until their earlier death, resignation or removal. The MEI COI provides for a classified board of directors with three classes of directors, with the terms of office of one class expiring each successive year. In the election of directors, a plurality of the votes cast shall elect each director. MEI stockholders do not have cumulative voting rights.

Except as may be provided by applicable law, the Infinity COI or the Infinity Bylaws, as amended, each director is elected by the vote of the majority of the votes cast with respect to that director's election at any meeting for the election of directors at which a quorum is present, except in the case of contested elections, in which case directors shall be elected by a plurality of the votes cast. Each director is elected for a term of office to expire at the next annual meeting after their election, and until their successors are duly elected and qualified, subject to their earlier death, resignation or removal. Infinity stockholders do not have cumulative voting rights.

Quorum for a Board Meeting

Except as otherwise provided by law, a majority of the MEI board of directors shall constitute a quorum. A majority of the directors present, whether or not a quorum is present, may adjourn a meeting from time to time to another time and place without notice. The vote of the majority of the directors present at a meeting at which a quorum is present shall be the act of the MEI board of directors.

At all meetings of the Infinity board of directors, a majority of the directors shall constitute a quorum for the transaction of business and the act of a majority of the directors present at any meeting at which there is a quorum shall be the act of the Infinity board of directors, except as may be otherwise specifically provided by statute or by the Infinity COI. If a quorum shall not be present at any meeting of the Infinity Board, the directors present thereat may adjourn the meeting from time to time, without notice other than announcement at the meeting, until a quorum shall be present.

Removal of Directors

Any or all of the directors may be removed, with or without cause, by the holders of a majority of the shares of stock outstanding and entitled to vote for the election of directors. A vacancy on the MEI board of directors caused by any such removal may be filled as provided below.

Subject to any limitations imposed by law, the Infinity board of directors or any individual director may be removed from office at any time with or without cause by the affirmative vote of the holders of at least a majority of the voting power of all the then outstanding shares of capital stock entitled to vote generally in the election of directors. A vacancy

on the Infinity board of directors caused by any such removal may be filled as provided below.

*Vacancies on the Board of Directors*

Subject to the limitations prescribed by law, the MEI COI and the MEI Bylaws, all director vacancies, including vacancies created by newly created directorships resulting from an increase in the authorized number of directors, may be filled only by a vote of a majority of the directors then holding office, although less than a quorum, or by a sole remaining director; and any director so elected shall serve for the remainder of the full term of the class of directors in which the new directorship was created or the vacancy occurred and until such director's successor is duly elected and shall qualify or until such director's earlier resignation or removal.

In accordance with the Infinity Bylaws, as amended, and the Infinity COI, vacancies, including newly created directorships, may be filled only by a majority of the directors then in office, though less than a quorum, or by a sole remaining director. Each director so chosen shall hold office until a successor is duly elected and qualified or until his earlier death, resignation or removal.

*Stockholder Action by Written Consent*

The MEI Bylaws provide that MEI stockholders may act by written consent.

The Infinity COI provides that Infinity stockholders may not act by written consent and may only act at duly called meetings of stockholders.

*Special Meetings of Stockholders*

Special meetings of stockholders for the transaction of such business as may properly come before the meeting may be called by the MEI board of directors, the executive committee of the MEI board of directors or by stockholders holding together at least a majority of all the shares of the corporation entitled to vote at the meeting.

Special meetings of the stockholders, unless otherwise prescribed by statute or by the Infinity COI, may only be called, for any purpose or purposes, by the chief executive officer, the chairman of the Infinity board of directors or a majority of the Infinity board of directors.

Written notice must be given as provided below.

Written notice must be given as provided below.

*Notice of Stockholder Meetings*

Written notice of all meetings of stockholders shall be given to each stockholder of record who is entitled to vote at such meetings, stating the place, date, and time of the meeting, and, in the case of a special meeting, the purpose or purposes for which the meeting is called. Each notice of meeting must also include a proxy form and specify a place and fax number or electronic address for the receipt of proxy appointments. Except as otherwise provided by law, a copy of the notice of any meeting shall be given not less than ten days nor more than 60 days before the date of the meeting and directed to each stockholder of record at his record address.

Notice of an annual or special meeting stating the place, date and hour of the meeting must be given to each stockholder entitled to notice of such meeting not less than 10 nor more than 60 days before the date of the meeting as may be required by applicable law.

*Quorum for a Stockholder Meeting*

Except as otherwise provided by law, a quorum for the transaction of business at any meeting of MEI's

The holders of a majority of the Infinity stock issued and outstanding and entitled to vote thereat, present

stockholders shall consist of the stockholders holding at least one-third of the shares of MEI's capital stock issued and outstanding and entitled to vote at the meeting.

*Advance Notice Requirements for Stockholder Proposals*

The MEI Bylaws provide that, in addition to any other applicable requirements, for nominations or any other business to be brought before an annual or special meeting by a stockholder, the stockholder must have given timely notice in writing to the corporation. To be timely, stockholder's notice for an annual meeting must be received by the corporation not later than the 90th day, nor earlier than the 120th day, prior to the first anniversary of the preceding year's annual meeting (provided, however, that, in the event that no annual meeting was held in the previous year or the date of the current year's annual meeting is more than 30 days before or more than 60 days after the anniversary date of the previous year's annual meeting, the notice must be received not earlier than the 120th day prior to the current year's annual meeting and not later than the later of the 90th day prior to the current year's annual meeting and the 10th day following the date on which public announcement of the date of such annual meeting is first made). To be timely, a stockholder's notice for a special meeting must be received by the corporation not earlier than the 120th day prior to such special meeting and not later than the later of the 90th day prior to such special meeting or the 10th day following the day on which public announcement of the date of the special meeting and of the nominees proposed by the MEI board of directors to be elected at such meeting is first made. Unless otherwise required by law, if the stockholder proposing a nomination or other business does not appear at the meeting or any adjournment or postponement thereof to present the nomination or other proposed business, such nomination shall be disregarded and such other proposal shall not be considered.

*Exclusive Forum*

Unless MEI consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery of the State of Delaware does not have jurisdiction, the federal district court for the District of Delaware) shall, to the fullest extent permitted by law, be the sole and exclusive forum for (i) any derivative action or proceeding brought on behalf of MEI; (ii) any action asserting a claim of breach of a fiduciary duty owed by any director, officer,

in person or represented by proxy, shall constitute a quorum at all meetings of the Infinity stockholders for the transaction of business, except as otherwise provided by statute or by the Infinity COI.

The Infinity Bylaws, as amended, provide that for business to be properly brought before an annual meeting by a stockholder, a stockholder must notify Infinity in writing not earlier than the close of business on the 120th day and not later than the close of business on the 90th day, prior to the first anniversary of the preceding year's annual meeting; provided, that if the date of the annual meeting is more than 30 days before or more than 70 days after such anniversary date, notice by the stockholder to be timely must be so delivered not earlier than the close of business on the 120th day prior to the date of such annual meeting and not later than the close of business on the 10th day following the day on which public announcement of the date of such annual meeting is first made. The Infinity Bylaws, as amended, also provide that, subject to certain limitations, if a stockholder does not appear at a meeting of stockholders to present a nomination or proposed business, such nomination shall be disregarded and such proposed business shall not be transacted, notwithstanding that proxies in respect of such vote may have been received by Infinity.

Unless Infinity consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery of the State of Delaware does not have jurisdiction, the federal district court for the District of Delaware) shall, to the fullest extent permitted by law, be the sole and exclusive forum for (i) any derivative action or proceeding brought on behalf of Infinity; (ii) any action asserting a claim of breach of a fiduciary duty

other employee or stockholder of MEI to MEI or MEI's stockholders; (iii) any action asserting a claim arising pursuant to any provision of the DGCL or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware; or (iv) any action asserting a claim arising pursuant to any provision of the MEI COI or the MEI Bylaws (in each case, as they may be amended from time to time) or governed by the internal affairs doctrine.

*Amendment of Certificate of Incorporation*

MEI may amend the MEI COI in the manner prescribed by the DGCL. In addition to any such requirements of law, the affirmative vote of the holders of not less than 80% of the total number of votes eligible to be cast by the holders of all outstanding shares of capital stock entitled to vote thereon shall be required to amend, alter, rescind or repeal certain provisions of the MEI COI relating to the number of directors, classification of the MEI board of directors and filling vacancies on the MEI board of directors.

*Amendment of Bylaws*

The MEI board of directors is expressly authorized to adopt, amend or repeal the MEI Bylaws, subject to the reserved power of the stockholders to amend and repeal any bylaws adopted by the MEI board of directors.

owed by any director, officer, other employee or stockholder of Infinity to Infinity or Infinity's stockholders; (iii) any action asserting a claim arising pursuant to any provision of the DGCL or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware; or (iv) any action asserting a claim arising pursuant to any provision of the Infinity COI or Infinity Bylaws (in each case, as they may be amended from time to time) or governed by the internal affairs doctrine.

Infinity may repeal, alter, amend or rescind any provision contained in the Infinity COI in the manner prescribed by the DGCL.

The Infinity Bylaws, as amended, may be altered or amended or new bylaws adopted by the affirmative vote of a majority of the voting power of all of the then-outstanding shares of capital stock entitled to vote generally in the election of directors. The Infinity board of directors also has the power to adopt, amend or repeal bylaws by a vote of the majority of the Infinity board of directors, unless a greater or different vote is required pursuant to the provisions of the Infinity Bylaws, as amended, the Infinity COI or any applicable provision of law.

Notwithstanding the foregoing, and in addition to any affirmative vote required by law, the Infinity COI or any preferred stock designation, the affirmative vote of at least 66 2/3% of the directors or the affirmative vote of the holders of at least 66 2/3% of the voting power of all of the then-outstanding shares of the voting stock, voting together as a single class, shall be required to alter, amend or repeal certain provisions of the Infinity Bylaws, as amended, including provisions relating to annual meetings of stockholders, special meetings of stockholders and voting rights of stockholders.

Limitation on Director Liability

The MEI COI provides that a current or former director will not be personally liable to MEI or its stockholders for monetary damages for breach of fiduciary duty as a director unless, and only to the extent that such director is liable: (i) for any breach of the director's duty of loyalty to MEI or its stockholders; (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of the law; (iii) under Section 174 of the DGCL, or any amendment thereto or successor provision thereto; or (iv) for any transaction from which the director derived an improper personal benefit.

The Infinity COI provides that a member of the Infinity board of directors will not be personally liable to Infinity or its stockholders for monetary damages for breach of fiduciary duty as a director, except for liability: (i) for any breach of the director's duty of loyalty to Infinity or its stockholders; (ii) for acts or omissions by the director not in good faith or which involve intentional misconduct or a knowing violation of the law; (iii) under Section 174 of the DGCL; or (iv) for any transaction from which the director derived any improper personal benefit.

Indemnification

MEI is authorized to indemnify any former or current officer, director, employee or agent of the corporation, or any person who is or was serving at the request of the corporation as a director, officer, employee or agent of another enterprise, if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, such person had no reasonable cause to believe his conduct was unlawful; provided that no indemnification shall be made in respect of any claim, issue or matter as to which such person shall have been adjudged liable to MEI unless and only to the extent that the Court of Chancery or the court in which such action or suit was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.

To the fullest extent permitted by applicable law, Infinity is authorized to indemnify its directors and officers; provided, however, that, Infinity may limit the extent of such indemnification by individual contracts with its directors and executive officers; and, provided, further, that Infinity is not required to indemnify any director or executive officer in connection with any proceeding (or part thereof) initiated by such person or any proceeding by such person against Infinity or its directors, officers, employees or other agents unless (i) such indemnification is expressly required to be made by law, (ii) the proceeding was authorized by the Infinity board of directors, or (iii) such indemnification is provided by Infinity, in the Infinity board of directors' sole discretion, pursuant to Infinity's powers under the DGCL. Infinity has the power to indemnify its other officers, employees and other agents to the fullest extent permitted by the DGCL.

Conversion Rights

The shares of MEI Common Stock are not convertible into other securities.

The shares of Infinity Common Stock are not convertible into any other security.

Right of First Refusal

None of the outstanding shares of MEI Common Stock are subject to any right of first refusal in favor of MEI.

None of the outstanding shares of Infinity Common Stock are subject to any right of first refusal in favor of Infinity.

Right of Co-Sale

MEI does not have a right of co-sale in place with respect to MEI Common Stock.

Infinity does not have a right of co-sale in place with respect to Infinity Common Stock.



Preemptive Rights

None of the outstanding shares of MEI Common Stock are entitled or subject to any preemptive right, right of participation, right of maintenance or any similar right. Thus, if additional shares of MEI Common Stock are issued, the current holders of MEI Common Stock will own a proportionately smaller interest in a larger number of outstanding shares of MEI Common Stock to the extent that they do not participate in the additional issuance.

None of the outstanding shares of Infinity Common Stock are entitled or subject to any preemptive right, right of participation, right of maintenance or any similar right. Thus, if additional shares of Infinity Common Stock are issued, the current holders of Infinity Common Stock will own a proportionately smaller interest in a larger number of outstanding shares of Infinity Common Stock to the extent that they do not participate in the additional issuance.

Distributions to Stockholders

Subject to the provisions of the MEI COI, the MEI board of directors shall have power to declare and pay dividends upon shares of stock of the corporation, but only out of funds available for the payment of dividends as provided by law. In order to receive payment of any dividend or other distribution, the MEI board of directors may fix, in advance, a record date, which shall not be (i) more than 60 nor less than 10 days before the date of such meeting, or (ii) in the case of corporate action to be taken by consent in writing without a meeting, not more than 10 days after the date upon which the resolution fixing the record date is adopted by the MEI board of directors, or (iii) more than 60 days prior to any other action.

Dividends upon Infinity's capital stock, subject to the provisions of the Infinity COI, may be declared by the Infinity board of directors at any regular or special meeting, pursuant to law. Dividends may be paid in cash, in property, or in shares of the capital stock. Before payment of any dividend, there may be set aside out of any funds of Infinity available for dividends such sum or sums as the directors from time to time, in their absolute discretion, think proper as a reserve to meet contingencies, or for equalizing dividends, or for repairing or maintaining any property of Infinity, or for such other purposes as the directors think conducive to the interest of Infinity, and the directors may modify or abolish any such reserve in the manner in which it was created. In order to determine the stockholders entitled to receive payment of any dividend or other distribution, the Infinity board of directors may fix, in advance, a record date, which shall not be more than sixty nor less than ten days before the date of such meeting, nor more than 60 days prior to any other action.

Registration Rights

MEI does not have registration rights in place.

Infinity does not have registration rights in place.

Stock Transfer Restrictions Applicable to Stockholders

Shares of MEI are transferable in the manner prescribed by the law and in the MEI Bylaws.

Shares of Infinity capital stock are transferable in the manner prescribed by the law and in the Infinity Bylaws, as amended.

**PRINCIPAL STOCKHOLDERS OF MEI**

The following table and accompanying footnotes set forth certain information with respect to the beneficial ownership of MEI Common Stock as of March 31, 2023, which reflects the reverse split of MEI Common Stock effective on April 14, 2023 for:

- each person, or group of affiliated persons, who is known by MEI to beneficially own more than 5% of MEI's Common Stock;
- each of MEI's named executive officers and directors; and
- all of MEI's executive officers and directors as a group.

Beneficial ownership is reported below in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. In addition, these rules require that the table below include shares of MEI Common Stock issuable pursuant to the exercise of stock options and warrants that are either immediately exercisable or exercisable within 60 days of March 31, 2023. These shares are deemed to be outstanding and beneficially owned by the person holding those options or warrants for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to applicable community property laws.

Except as described above, beneficial ownership prior to the completion of the Merger is based on 6,662,857 shares of MEI Common Stock outstanding as of April 23, 2023. Unless otherwise indicated, the address of each beneficial owner listed below is c/o MEI Pharma, Inc., 11455 El Camino Real, Suite 250, San Diego, California 92130.

Name and Address of Beneficial Owner	Number of Shares of Common Stock Owned	+	Common Stock Underlying Options, Warrants and Other Rights Acquireable Within 60 Days	=	Total Beneficial Ownership	Percentage of Shares Beneficially Owned
<b>5% Stockholders</b>						
Anson Funds Management LP (2)	530,898		—		530,898	8.0%
Growth Equity Opportunities Fund V, LLC (1)	426,654		—		426,654	6.4%
The Vanguard Group (3)	383,551		—		383,551	5.7%
<b>Directors and Named Executive Officers</b>						
Daniel P. Gold, Ph.D.	20,866		161,785		182,651	2.7%
Brian G. Drazba	1,875		45,250		47,125	*
David M. Urso	2,464		85,990		88,454	1.3%
Richard G. Ghalie	1,447		39,208		40,655	*
Frederick W. Driscoll	1,875		14,313		16,188	*
Charles V. Baltic III (4)	5,555		17,646		23,201	*
Thomas C. Reynolds, M.D., Ph.D.	500		17,646		18,146	*
Nicholas R. Glover	—		17,646		17,646	*
Sujay R. Kango	—		5,938		5,938	*
Tamar D. Howson	—		11,646		11,646	*
<b>All Current Directors and Executive Officers as a Group (10 individuals)</b>						6.2%

\* Represents beneficial ownership of less than 1%.

## Table of Contents

- (1) Based upon information contained in Amendment No. 2 to the Statement on Schedule 13D filed by the stockholder on March 9, 2023, shares beneficially owned consists of 8,533,073 shares of common stock held directly. The shares are held of record by Growth Equity Opportunities Fund V, LLC. New Enterprise Associates 16, L.P. (“NEA 16”) is the sole member of GEO, NEA Partners 16, L.P. (“NEA Partners 16”), is the sole general partner of NEA 16 and NEA 16 GP, LLC (“NEA 16 LLC” and, together with NEA Partners 16, the “Control Entities”), is the sole general partner of NEA Partners. Forest Baskett, Anthony A. Florence, Jr., Mohamad H. Makhzoumi, Chetan Pettagunta, Jon M. Sakoda, Scott D. Sandell, Peter W. Sonsini and Ravi Viswanathan (together, the “Managers”) are the Managers of NEA 16 LLC. Each of the Control Entities and the Managers may be deemed to have beneficial ownership of the shares and warrants held of record by GEO. The principal address is c/o New Enterprise Associates, 1954 Greenspring Drive, Timonium, MD 21093.
- (2) Based upon information contained in the Statement on Schedule 13G filed by the stockholder on February 14, 2023, shares beneficially owned consists of 530,898 shares of common stock held directly. The shares are held of record by Anson Funds Management LP. The principal address is 16000 Dallas Parkway, Suite 800, Dallas, Texas 75248.
- (3) Based upon information contained in the Statement on Schedule 13G filed by the stockholder on February 9, 2023, aggregate shares beneficially owned are 383,551, including 381,749 shares where the stockholder has sole dispositive power and 1,802 shares where the stockholder has shared dispositive power. The principal address is 100 Vanguard Blvd., Malvern, Pennsylvania 19355.
- (4) Mr. Baltic exercises direct voting and investment control with respect to 5,288 shares of common stock and indirect voting and investment control with respect to 267 shares of common stock.

### PRINCIPAL STOCKHOLDERS OF INFINITY

The following table contains information regarding the beneficial ownership of Infinity Common Stock as of March 31, 2023 by:

- stockholders Infinity knows to beneficially own more than 5% of outstanding Infinity Common Stock;
- each of Infinity’s directors as of March 31, 2023;
- each of Infinity’s named executive officers for 2022; and
- all of Infinity’s current directors and executive officers as a group.

Name and Address of Beneficial Owner (1)	Number of Shares of Common Stock Owned	+	Common Stock Underlying Options, Warrants and Other Rights Acquirable Within 60 Days (2)	=	Total Beneficial Ownership (#)	Percentage of Common Stock Beneficially Owned (%) (3)
<b>5% Stockholders</b>						
Biotechnology Value Fund, L.P. (4)	6,353,645		—		6,353,645	7.11%
The Vanguard Group (5)	5,313,679		—		5,313,679	5.94%
<b>Directors</b>						
Adelene Q. Perkins (6)	833,801		3,675,762		4,509,563	4.84%
Samuel Agresta, M.D., M.P.H.	10,593		165,000		175,593	*
David Beier, J.D.	8,775		175,000		183,775	*
Anthony B. Evnin, Ph.D.	215,403		283,500		498,903	*
Richard Gaynor, M.D.	—		135,000		135,000	*
Sujay R. Kango	—		56,250		56,250	*
Brian Schwartz, M.D.	30,919		213,750		244,669	*
Norman C. Selby	15,000		387,000		402,000	*
<b>Other Named Executive Officers</b>						
Lawrence Bloch, M.D., J.D. (7)	772,223		2,175,221		2,947,444	3.22%

## Table of Contents

Name and Address of Beneficial Owner (1)	Number of Shares of Common Stock Owned	+	Common Stock Underlying Options, Warrants and Other Rights Acquirable Within 60 Days (2)	=	Total Beneficial Ownership (#)	Percentage of Common Stock Beneficially Owned (%) (3)
Robert Ilaria, Jr., M.D.	—		154,157		154,157	*
All directors and executive officers as a group (12 persons)	2,048,291		8,775,979		10,824,270	11.02%

\* Represents holdings of less than 1%.

- Unless otherwise indicated, the address for each person is to the care of Infinity Pharmaceuticals, Inc., 1100 Massachusetts Avenue, Floor 4, Cambridge, Massachusetts 02138.
- The number of shares of Infinity Common Stock owned by each person is determined under the rules of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under these rules, beneficial ownership includes any shares as to which the individual has sole or shared voting power or investment power and also any shares which the individual has the right to acquire on or before May 30, 2023, through the exercise of any stock option, warrant or other right. In connection with the Merger, and as previously announced, Infinity terminated Dr. Bloch's employment effective as of March 31, 2023. In connection with, Dr. Bloch's termination, (a) the 446,667 RSUs granted to Dr. Bloch on August 11, 2022 vested in their entirety; (b) 223,334 additional stock options vested under the accelerated vesting provisions of the Executive Severance Benefits Plan; and therefore (c) Dr. Bloch's beneficial ownership increased from 3.22% to 3.92%.
- Percentage of beneficial ownership is based on 89,422,138 shares of Infinity Common Stock outstanding as of March 31, 2023. In addition, shares of common stock subject to options or other rights currently exercisable, or exercisable within 60 days of March 31, 2023, are deemed outstanding and beneficially owned for the purpose of computing the percentage beneficially owned by (i) the individual holding such options, warrants or other rights (but not any other individual) and (ii) the directors and executive officers as a group.
- BVF Partners L.P. ("Partners"), BVF Inc., and Mark N. Lampert, as director and officer of BVF Inc., claim beneficial ownership, shared voting and shared dispositive power of 6,353,645 shares, of which: Biotechnology Value Fund, L.P. ("BVF"), claims beneficial ownership, shared voting and shared dispositive power of 3,430,822 shares, and BVF I GP LLC ("BVF GP"), as the general partner of BVF, may be deemed to beneficially own the 3,430,822 shares beneficially owned by BVF; Biotechnology Value Fund II, L.P. ("BVF2"), claims beneficial ownership, shared voting and shared dispositive power of 2,436,635 shares, and BVF II GP LLC ("BVF2 GP"), as the general partner of BVF2, may be deemed to beneficially own the 2,436,635 shares beneficially owned by BVF2; Biotechnology Value Trading Fund OS LP ("Trading Fund OS") and BVF Partners OS Ltd. ("Partners OS") each claim beneficial ownership, shared voting and shared dispositive power of 373,298 shares; BVF GP Holdings LLC ("BVF GPH"), as the sole member of each of BVF GP and BVF2 GP, may be deemed to beneficially own the 5,867,457 shares beneficially owned in the aggregate by BVF and BVF2. Partners, as the investment manager of BVF, BVF2 and Trading Fund OS, and the sole member of Partners OS, may be deemed to beneficially own the 6,353,645 shares beneficially owned in the aggregate by BVF, BVF2, Trading Fund OS, and a certain Partners managed account (the "Partners Managed Account"), including 112,890 shares held in the Partners Managed Account. The address of the principal business office of Partners, BVF Inc., Mr. Lampert, BVF, BVF GP, BVF2, BVF2 GP, and BVF GPH is 44 Montgomery St., 40th Floor, San Francisco, California 94104. The address of the principal business office of Trading Fund OS and Partners OS is PO Box 309 Uglan House, Grand Cayman, KY1-1104, Cayman Islands. For information regarding Partners, BVF Inc., Mr. Lampert, BVF, BVF2, Trading Fund OS, and Partners OS, and Partners Managed Account, Infinity has relied on the Schedule 13G filed jointly by Partners, BVF Inc., Mr. Lampert, BVF, BVF2, Trading Fund OS, and Partners OS on February 14, 2022.
- The Vanguard Group ("Vanguard") claims beneficial ownership of 5,313,679 shares, of which it claims shared voting power of 0 shares, sole dispositive power of 5,281,550 shares, and shared dispositive power of

---

[Table of Contents](#)

32,129 shares. The address of the principal business of Vanguard is 100 Vanguard Blvd., Malvern, PA 19355. For information regarding Vanguard, Infinity has relied on the Schedule 13G/A filed by Vanguard on February 9, 2023.

6. Includes approximately 16,447 shares of Infinity Common Stock held in Ms. Perkins' 401(k) Plan account.
7. Includes approximately 13,833 shares of Infinity Common Stock held in Dr. Bloch's 401(k) Plan account.

**PRINCIPAL STOCKHOLDERS OF PROPOSED COMBINED COMPANY**

The following table and accompanying footnotes set forth certain information with respect to the beneficial ownership of the common stock of the combined company, assuming the closing of the Merger will occur on March 31, 2023:

- each person, or group of affiliated persons, expected by MEI or Infinity to become the beneficial owner of more than 5% of the combined company’s common stock upon consummation of the Merger;
- each of the combined company’s named executive officers and directors; and
- all of the combined company’s executive officers and directors as a group.

Beneficial ownership is reported below in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. In addition, these rules require that the table below include shares of common stock issuable pursuant to the exercise of stock options and warrants that are either immediately exercisable or exercisable within 60 days of March 31, 2023. These shares are deemed to be outstanding and beneficially owned by the person holding those options or warrants for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to applicable community property laws.

Except as described above, beneficial ownership prior to the completion of the Merger is based on 11,487,985 shares of the common stock of the combined company outstanding as of March 31, 2023. Unless otherwise indicated, the address of each beneficial owner listed below is c/o MEI Pharma, Inc., 11455 El Camino Real, Suite 250, San Diego, California 92130.

<u>Name and Address of Beneficial Owner</u>	<u>Number of Shares of Common Stock Owned</u>	+	<u>Common Stock Underlying Options, Warrants and Other Rights Acquireable Within 60 Days</u>	=	<u>Total Beneficial Ownership</u>	<u>Percentage of Shares Beneficially Owned</u>
<b>5% Stockholders</b>						
The Vanguard Group (1)	661,163		—		661,163	5.8%
<b>Directors and Named Executive Officers</b>						
Daniel P. Gold, Ph.D.	20,866		161,785		182,651	1.6%
Brian G. Drazba	1,875		45,250		47,125	*
David M. Urso	2,464		85,990		88,454	*
Charles V. Baltic III (2)	5,555		17,646		23,201	*
Thomas C. Reynolds, M.D., Ph.D.	500		17,646		18,146	*
Sujay R. Kango	—		8,876		8,876	*
Norman C. Selby	783		20,218		21,001	*
Adelene Q. Perkins (3)	53,193		182,408		235,601	2.0%
Richard Gaynor, M.D.	—		7,053		7,053	*
Robert Ilaria, Jr., M.D.	4,473		3,580		8,053	*
<b>All Current Directors and Executive Officers as a Group (10 individuals)</b>	<b>89,709</b>		<b>544,514</b>		<b>640,161</b>	<b>5.3%</b>

\* Represents beneficial ownership of less than 1%.

(1) The Vanguard Group (“Vanguard”) claims beneficial ownership of 661,163 shares, of which it claims shared voting power of 0 shares, sole dispositive power of 657,683 shares, and shared dispositive power of

---

[Table of Contents](#)

3,480 shares. The address of the principal place of business of Vanguard is 100 Vanguard Blvd., Malvern, PA 19355. For information regarding Vanguard, the combined company has relied on Amendment No. 1 to the Schedule 13G filed by Vanguard on February 9, 2023, for Infinity, and the Schedule 13G filed by Vanguard on February 9, 2023, for MEI.

- (2) Mr. Baltic exercises direct voting and investment control with respect to 5,288 shares of common stock and indirect voting and investment control with respect to 267 shares of common stock.
- (3) Includes approximately 859 shares of common stock of the combined company held in Ms. Perkins' 401(k) Plan account.

## **LEGAL MATTERS**

Morgan, Lewis & Bockius LLP will pass upon the validity of MEI Common Stock offered by this joint proxy statement/prospectus.

## **EXPERTS**

The financial statements of MEI Pharma, Inc. as of June 30, 2022 and 2021, and for each of the three years in the period ended June 30, 2022, included in this joint proxy statement/prospectus have been so included in reliance on the report of BDO USA, LLP, an independent registered public accounting firm, given on the authority of such firm as experts in auditing and accounting.

The consolidated financial statements of Infinity Pharmaceuticals, Inc. at December 31, 2022 and 2021, and for each of the two years in the period ended December 31, 2022, included in this joint proxy statement/prospectus, have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their report appearing elsewhere herein (which contains an explanatory paragraph describing conditions that raise substantial doubt about Infinity's ability to continue as a going concern as described in Note 2 to Infinity's consolidated financial statements), and are included herein in reliance upon such report given on the authority of such firm as experts in accounting and auditing.



## WHERE YOU CAN FIND MORE INFORMATION

**This joint proxy statement/prospectus incorporates documents by reference which are not presented in or delivered with this joint proxy statement/prospectus. MEI stockholders and Infinity stockholders should rely only on the information contained in this joint proxy statement/prospectus and in the documents that MEI and Infinity have incorporated by reference into this joint proxy statement/prospectus. MEI and Infinity have not authorized anyone to provide MEI stockholders or Infinity stockholders with information that is different from or in addition to the information contained in this document or incorporated by reference into this joint proxy statement/prospectus.**

MEI and Infinity are subject to the informational requirements of the Exchange Act and in accordance therewith, file annual, quarterly and current reports, proxy statements and other information with the SEC electronically, and the SEC maintains a website that contains MEI's and Infinity's filings as well as reports, proxy and information statements, and other information issuers file electronically with the SEC at [www.sec.gov](http://www.sec.gov). In addition, you may obtain free copies of the documents MEI files with the SEC, including the Registration Statement on Form S-4, of which this joint proxy statement/prospectus forms a part, by going to MEI's Internet website at [www.meipharma.com](http://www.meipharma.com), and you may obtain free copies of the documents Infinity files with the SEC by going to Infinity's Internet website at [www.infi.com](http://www.infi.com). The Internet website addresses of MEI and Infinity are provided as inactive textual references only. The information provided on the Internet websites of MEI and Infinity, other than copies of the documents that have been filed with the SEC, is not part of this joint proxy statement/prospectus and, therefore, is not incorporated herein by reference.

MEI has supplied all the information contained in this joint proxy statement/prospectus relating to MEI, and Infinity has supplied all information contained in this joint proxy statement/prospectus relating to Infinity.

You may request a copy of this joint proxy statement/prospectus or any of the documents incorporated by reference into this joint proxy statement/prospectus without charge. If you would like to request documents from MEI or Infinity, please send a request in writing or by telephone to either MEI or Infinity at the following addresses:

MEI Pharma, Inc.  
11455 El Camino Real, Suite 250  
San Diego, California 92130  
Attention: Corporate Secretary  
Telephone: (858) 369-7100

Infinity Pharmaceuticals, Inc.  
1100 Massachusetts Avenue, Floor 4  
Cambridge, MA 02138  
Attention: Corporate Secretary  
Telephone: (617) 453-1000

## HOUSEHOLDING OF PROXY MATERIALS

The SEC has adopted rules that permit companies and intermediaries (e.g., brokers) to satisfy the delivery requirements for Notices of Internet Availability of Proxy Materials or other meeting materials with respect to two or more stockholders sharing the same address by delivering a single proxy materials or other meeting materials addressed to those stockholders. This process, which is commonly referred to as “householding,” potentially means extra convenience for stockholders and cost savings for companies. Some brokers household proxy materials, delivering a single proxy statement or notice to multiple stockholders sharing an address unless contrary instructions have been received from the affected stockholders. Once you have received notice from your broker that they will be householding materials to your address, householding will continue until you are notified otherwise or until you revoke your consent. If, at any time, you no longer wish to participate in householding and would prefer to receive a separate proxy statement or notice, or if your household is receiving multiple copies of these documents and you wish to request that future deliveries be limited to a single copy, please notify your broker.

Requests for additional copies of this joint proxy statement/prospectus should be directed to, as applicable:

MEI Pharma, Inc.  
11455 El Camino Real, Suite 250  
San Diego, California 92130  
Attention: Corporate Secretary  
Telephone: (858) 369-7100

Infinity Pharmaceuticals, Inc.  
1100 Massachusetts Avenue, Floor 4  
Cambridge, MA 02138  
Attention: Corporate Secretary  
Telephone: (617) 453-1000

## COMMUNICATIONS FROM MEI STOCKHOLDERS

The MEI board of directors will give appropriate attention to written communications that are submitted by stockholders, and will respond if and as appropriate. MEI’s Secretary is primarily responsible for monitoring communications from stockholders and for providing copies or summaries to MEI’s directors as he or she considers appropriate.

Communications are forwarded to all directors if they relate to important substantive matters and include suggestions or comments that MEI’s Secretary and Chair of the MEI board of directors consider to be important for the directors to know. In general, communications relating to corporate governance and long-term corporate strategy are more likely to be forwarded than communications relating to ordinary business affairs, personal grievances and matters as to which MEI tends to receive repetitive or duplicative communications. Stockholders who wish to send communications on any topic to the MEI board of directors should address such communications to the board of directors in writing: c/o Secretary, MEI Pharma, Inc., 11455 El Camino Real, Suite 250, San Diego, California 92130.

## COMMUNICATIONS FROM INFINITY STOCKHOLDERS

Infinity’s board of directors will give appropriate attention to written communications that are submitted by stockholders and other interested parties and will respond if and as appropriate. Mr. Selby, as Infinity’s current lead independent director, is primarily responsible for monitoring communications from stockholders and for providing copies or summaries to the other directors as he considers appropriate.

Communications are forwarded to all directors if they relate to important substantive matters and include suggestions or comments that the lead independent director considers to be important for the directors to know. In general, communications relating to corporate governance and corporate strategy are more likely to be forwarded than communications relating to ordinary business affairs, personal grievances, and matters as to which Infinity tends to receive repetitive or duplicative communications.

Stockholders who wish to send communications on any topic to Infinity’s board of directors should address such communications to board of directors, c/o Seth A. Tasker, Secretary, Infinity Pharmaceuticals, Inc., 1100 Massachusetts Avenue, Floor 4, Cambridge, MA 02138, or by email to [contactboard@infi.com](mailto:contactboard@infi.com).

## INDEX TO FINANCIAL STATEMENTS

Unaudited Condensed Financial Statements of MEI Pharma, Inc. for the Six Months Ended December 31, 2022:

<a href="#">Condensed Financial Statements (Unaudited)</a>	F-2
<a href="#">Condensed Balance Sheets as of December 31, 2022 and June 30, 2022</a>	F-2
<a href="#">Condensed Statements of Operations for the three and six months ended December 31, 2022 and 2021</a>	F-3
<a href="#">Condensed Statements of Stockholders' Equity for the three and six months ended December 31, 2022 and 2021</a>	F-4
<a href="#">Condensed Statements of Cash Flows for the six months ended December 31, 2022 and 2021</a>	F-5
<a href="#">Notes to Condensed Financial Statements</a>	F-6

Audited Financial Statements of MEI Pharma, Inc. for the Years Ended June 30, 2022, 2021 and 2020:

<a href="#">Report of Independent Registered Public Accounting Firm (BDO USA, LLP; San Diego, California; PCAOB ID# 243)</a>	F-22
<a href="#">Balance Sheets as of June 30, 2022 and 2021</a>	F-24
<a href="#">Statements of Operations for the years ended June 30, 2022, 2021 and 2020</a>	F-25
<a href="#">Statements of Stockholders' Equity for the years ended June 30, 2022, 2021 and 2020</a>	F-26
<a href="#">Statements of Cash Flows for the years ended June 30, 2022, 2021 and 2020</a>	F-27
<a href="#">Notes to Financial Statements</a>	F-28

Audited Consolidated Financial Statements of Infinity Pharmaceuticals, Inc. for the Years Ended December 31, 2022 and 2021:

<a href="#">Report of Independent Registered Public Accounting Firm (PCAOB ID: 42)</a>	F-48
<a href="#">Consolidated Balance Sheets at December 31, 2022 and 2021</a>	F-50
<a href="#">Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2022 and 2021</a>	F-51
<a href="#">Consolidated Statements of Cash Flows for the years ended December 31, 2022 and 2021</a>	F-52
<a href="#">Consolidated Statements of Stockholders' (Deficit) Equity for the years ended December 31, 2022 and 2021</a>	F-53
<a href="#">Notes to Consolidated Financial Statements</a>	F-54

**PART I FINANCIAL INFORMATION****Item 1. Condensed Financial Statements**

**MEI PHARMA, INC.**  
**CONDENSED BALANCE SHEETS**  
(In thousands, except par value data)

	December 31, 2022 (Unaudited)	June 30, 2022
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 10,917	\$ 15,740
Short-term investments	113,256	137,512
Total cash, cash equivalents and short-term investments	124,173	153,252
Unbilled receivables	5,704	10,044
Prepaid expenses and other current assets	3,568	3,830
Total current assets	133,445	167,126
Operating lease right-of-use asset	12,698	9,054
Property and equipment, net	1,456	1,660
Total assets	<u>\$ 147,599</u>	<u>\$ 177,840</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 4,067	\$ 7,918
Accrued liabilities	14,346	10,820
Deferred revenue	2,897	4,834
Operating lease liability	1,343	871
Total current liabilities	22,653	24,443
Deferred revenue, long-term	64,545	90,610
Operating lease liability, long-term	12,027	8,771
Warrant liability	—	1,603
Total liabilities	99,225	125,427
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, \$0.01 par value; 100 shares authorized; none outstanding	—	—
Common stock, \$0.00000002 par value; 226,000 shares authorized; 6,663 and 6,658 shares issued and outstanding at December 31, 2022 and June 30, 2022, respectively	—	—
Additional paid-in capital	428,904	426,572
Accumulated deficit	(380,530)	(374,159)
Total stockholders' equity	48,374	52,413
Total liabilities and stockholders' equity	<u>\$ 147,599</u>	<u>\$ 177,840</u>

*See accompanying notes to condensed financial statements.*

**MEI PHARMA, INC.**  
**CONDENSED STATEMENTS OF OPERATIONS**  
(In thousands, except per share amounts)  
(Unaudited)

	Three Months Ended		Six Months Ended	
	December 31,		December 31,	
	2022	2021	2022	2021
Revenue	\$32,735	\$ 11,832	\$41,465	\$ 19,589
Operating expenses:				
Research and development	15,313	21,531	34,776	41,484
General and administrative	8,496	7,926	15,982	15,835
Total operating expenses	<u>23,809</u>	<u>29,457</u>	<u>50,758</u>	<u>57,319</u>
Income (loss) from operations	8,926	(17,625)	(9,293)	(37,730)
Other income (expense):				
Change in fair value of warrant liability	486	5,458	1,603	8,046
Interest and dividend income	845	11	1,325	18
Other expense, net	(4)	—	(6)	—
Net income (loss)	<u>\$10,253</u>	<u>\$(12,156)</u>	<u>\$(6,371)</u>	<u>\$(29,666)</u>
Net income (loss):				
Basic	<u>\$10,253</u>	<u>\$(12,156)</u>	<u>\$(6,371)</u>	<u>\$(29,666)</u>
Diluted	<u>\$10,253</u>	<u>\$(17,614)</u>	<u>\$(6,371)</u>	<u>\$(37,712)</u>
Net income (loss) per share:				
Basic	<u>\$ 1.54</u>	<u>\$ (1.92)</u>	<u>\$ (0.96)</u>	<u>\$ (5.12)</u>
Diluted	<u>\$ 1.54</u>	<u>\$ (2.75)</u>	<u>\$ (0.96)</u>	<u>\$ (6.36)</u>
Shares used in computing net income (loss) per share:				
Basic	<u>6,663</u>	<u>6,336</u>	<u>6,663</u>	<u>5,799</u>
Diluted	<u>6,663</u>	<u>6,408</u>	<u>6,663</u>	<u>5,933</u>

*See accompanying notes to condensed financial statements.*

**MEI PHARMA, INC.**  
**CONDENSED STATEMENTS OF STOCKHOLDERS' EQUITY**  
(In thousands)  
(Unaudited)

	Common Shares	Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
<b>Balance at June 30, 2022</b>	6,658	\$426,572	\$ (374,159)	\$ 52,413
Net loss	—	—	(16,624)	(16,624)
Issuance of common stock for vested restricted stock units	5	(40)	—	(40)
Share-based compensation expense	—	1,559	—	1,559
<b>Balance at September 30, 2022</b>	6,663	428,091	(390,783)	37,308
Net income	—	—	10,253	10,253
Share-based compensation expense	—	813	—	813
<b>Balance at December 31, 2022</b>	<u>6,663</u>	<u>\$428,904</u>	<u>\$ (380,530)</u>	<u>\$ 48,374</u>
	Common Shares	Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
<b>Balance at June 30, 2021</b>	5,631	\$369,171	\$ (319,705)	\$ 49,466
Net loss	—	—	(17,510)	(17,510)
Issuance of common stock for vested restricted stock units	3	(194)	—	(194)
Share-based compensation expense	—	2,539	—	2,539
<b>Balance at September 30, 2021</b>	5,634	371,516	(337,215)	34,301
Net loss	—	—	(12,156)	(12,156)
Issuance of common stock, net of issuance costs of \$3,672	1,006	48,653	—	48,653
Exercise of stock options	5	212	—	212
Share-based compensation expense	—	2,324	—	2,324
<b>Balance at December 31, 2021</b>	<u>6,645</u>	<u>\$422,705</u>	<u>\$ (349,371)</u>	<u>\$ 73,334</u>

*See accompanying notes to condensed financial statements.*

**MEI PHARMA, INC.**  
**CONDENSED STATEMENTS OF CASH FLOWS**  
(In thousands)  
(Unaudited)

	Six Months Ended December 31,	
	2022	2021
<b>Cash flows from operating activities:</b>		
Net loss	\$ (6,371)	\$ (29,666)
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in fair value of warrant liability	(1,603)	(8,046)
Share-based compensation expense	2,372	4,863
Depreciation and amortization	191	152
Non-cash lease expense	703	449
Changes in operating assets and liabilities:		
Unbilled receivables	4,340	(2,569)
Prepaid expenses and other current assets	262	(1,014)
Accounts payable	(3,851)	(99)
Accrued liabilities	3,526	1,363
Deferred revenue	(28,002)	18,736
Operating lease liability	(619)	(456)
Net cash used in operating activities	<u>(29,052)</u>	<u>(16,287)</u>
<b>Cash flows from investing activities:</b>		
Purchases of short-term investments	(67,862)	(173,300)
Proceeds from maturity of short-term investments	92,118	144,983
Proceeds from (purchases) of property and equipment	13	(59)
Net cash provided by (used in) investing activities	<u>24,269</u>	<u>(28,376)</u>
<b>Cash flows from financing activities:</b>		
Payment of RSU tax withholdings in exchange for common shares surrendered by RSU holders	(40)	(194)
Proceeds from exercise of stock options	—	212
Proceeds from issuance of common stock, gross	—	52,325
Payment of issuance costs	—	(3,672)
Net cash (used in) provided by financing activities	<u>(40)</u>	<u>48,671</u>
Net (decrease) increase in cash and cash equivalents	(4,823)	4,008
Cash and cash equivalents at beginning of the period	15,740	8,543
Cash and cash equivalents at end of the period	<u>\$ 10,917</u>	<u>\$ 12,551</u>
<b>Supplemental disclosures:</b>		
Operating lease right-of-use assets obtained in exchange for operating lease liabilities	<u>\$ 4,347</u>	<u>\$ —</u>

*See accompanying notes to condensed financial statements.*

**MEI PHARMA, INC.**  
**NOTES TO CONDENSED FINANCIAL STATEMENTS**  
(Unaudited)

**Note 1. The Company and Summary of Significant Accounting Policies**

**The Company**

MEI Pharma, Inc. (Nasdaq: MEIP) is a clinical stage pharmaceutical company focused on developing potential new therapies for cancer. MEI Pharma's portfolio of drug candidates includes drug candidates with differentiated or novel mechanisms of action intended to address unmet medical needs and deliver improved benefit to patients, either as standalone treatments or in combination with other therapeutic options. Our common stock is listed on the Nasdaq Capital Market under the symbol "MEIP."

On April 14, 2023, we amended our Certificate of Incorporation to effect a combination of our issued and outstanding common stock at a ratio of one-for-twenty ("Reverse Stock Split"). The par value and authorized shares of our common stock was not adjusted as a result of the Reverse Stock Split. The Reverse Stock Split was effective on April 14, 2023. All historical share and per share amounts have been adjusted to reflect the Reverse Stock Split for all periods presented. All stock options, restricted stock units and warrants outstanding were ratably adjusted to give effect to the Reverse Stock Split.

**Clinical Development Programs**

We build our pipeline by licensing or acquiring promising cancer agents and creating value in programs through development, commercialization and strategic partnerships, as appropriate. Our objective is to leverage the mechanisms and properties of our pipeline drug candidates to optimize the balance between efficacy and tolerability to meet the needs of patients with cancer. Our drug candidate pipeline includes:

- Voruciclib, an oral cyclin-dependent kinase ("CDK") inhibitor;
- ME-344, an intravenous small molecule targeting the oxidative phosphorylation pathway; and
- Zandelisib, an oral phosphatidylinositol 3-kinase delta ("PI3Kd") inhibitor.

The results of pre-clinical studies and completed clinical trials are not necessarily predictive of future results, and our current drug candidates may not have favorable results in later studies or trials. The commercial opportunity will be reduced or eliminated if competitors develop and market products that are more effective, have fewer side effects or are less expensive than our drug candidates. We will need substantial additional funds to progress the clinical trial programs for the drug candidates voruciclib and ME-344 and to develop new compounds we might license or acquire. The actual amount of funds that will be needed are determined by a number of factors, some of which are beyond our control. Negative U.S. and global economic conditions may pose challenges to our business strategy, which relies on funding from the financial markets or collaborators.

**Reduction in Force and Current Events**

In November 2022, we and Kyowa Kirin Co., Ltd. ("KKC") met with the U.S. Food and Drug Administration ("FDA") in a follow-up meeting to the March 2022 end of Phase 2 meeting. At this meeting, the FDA provided further guidance regarding the design and statistical analysis for the COASTAL trial. Following the November meeting, the companies jointly concluded that a clinical trial consistent with the recent FDA guidance, including modification of the ongoing COASTAL trial, would likely not be feasible to complete within a time period that would support further investment or with sufficient certainty of the regulatory requirements for approval to justify continued global development efforts. As a result, we and KKC jointly decided to discontinue global development of zandelisib for indolent forms of non-Hodgkin lymphoma outside of Japan.

The discontinuation of zandelisib development outside of Japan was a business decision based on the most recent regulatory guidance from the FDA and is not related to the zandelisib clinical data generated to date.



## Table of Contents

KKC is continuing certain ongoing Japanese clinical trials, including the Phase 2 MIRAGE trial evaluating Japanese patients with relapsed or refractory indolent B-cell non-Hodgkin lymphomas, and will explore submitting the MIRAGE and TIDAL trials for marketing authorization in Japan. MIRAGE is a Phase 2 trial, similar in design to the global Phase 2, single-arm, TIDAL trial. In November 2022, we and KKC announced positive topline data from the Phase 2 MIRAGE trial.

We and KKC have begun closing all ongoing zandelisib clinical studies outside of Japan, including the Phase 3 COASTAL trial, the Phase 2 TIDAL trial, and the Phase 2 CORAL trial. Depending on the achievement of certain regulatory and commercial milestones in Japan, MEI may be eligible for additional payments from KKC under the current agreement. We are entitled to royalties on any sales of zandelisib in Japan.

In December 2022, we announced a plan to streamline our organization towards the continued clinical development of voruciclib and ME-344. As a result, we initiated a staggered workforce reduction, initially affecting 28 employees in December 2022 (representing approximately 27% of our workforce). In connection with the reduction in force, we incurred termination costs, which include severance, benefits, and related costs of approximately \$1.2 million, of which \$0.8 million was research and development expense and \$0.4 million was general and administrative expense. We have accrued these termination benefits as of December 31, 2022 and paid the associated benefits in January 2023.

### **Liquidity**

We have accumulated losses of \$380.5 million since inception and expect to incur operating losses and generate negative cash flows from operations for the foreseeable future. As of December 31, 2022, we had \$124.2 million in cash and cash equivalents and short-term investments. We believe that these resources will be sufficient to meet our obligations and fund our liquidity and capital expenditure requirements for at least the next 12 months from the issuance of these financial statements. Our current business operations are focused on continuing the clinical development of our drug candidates. Changes to our research and development plans or other changes affecting our operations and operating expenses may affect actual future use of existing cash resources. We cannot determine with certainty costs associated with ongoing and future clinical trials or the regulatory approval process. The duration, costs and timing associated with the development of our product candidates will depend on a variety of factors, including uncertainties associated with the results of our clinical trials.

To date, we have obtained cash and funded our operations primarily through equity financings and license agreements. In order to continue the development of our drug candidates, at some point in the future we expect to pursue one or more capital transactions, whether through the sale of equity securities, debt financing, license agreements or entry into strategic partnerships. There can be no assurance that we will be able to continue to raise additional capital in the future.

### **Basis of Presentation**

The accompanying unaudited financial statements have been prepared in accordance with accounting principles generally accepted in the U.S. (“U.S. GAAP”) for interim financial information and in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, the accompanying financial statements do not include all of the information and notes required by U.S. GAAP for complete financial statements. In the opinion of management, the accompanying financial statements reflect all adjustments (consisting of normal recurring adjustments) that are necessary for a fair statement of the financial position, results of operations and cash flows for the periods presented.

The accompanying unaudited financial statements for the quarterly period ended December 31, 2022 should be read in conjunction with the audited financial statements and notes thereto as of and for the fiscal year ended June 30, 2022, included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on September 8, 2022 (“2022 Annual Report”). Interim results are not necessarily indicative of results for a full year.

## [Table of Contents](#)

### **Use of Estimates**

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and disclosures made in the accompanying notes to the financial statements. We use estimates that affect the reported amounts (including assets, liabilities, revenues and expenses) and related disclosures. Actual results could materially differ from those estimates.

### **Fair Value Measurements**

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value is as follows:

- Level 1 – Observable inputs such as quoted prices in active markets for identical assets or liabilities.
- Level 2 – Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3 – Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

### **Revenue Recognition**

#### *Revenues from Customers*

In accordance with Accounting Standards Codification (“ASC”) Topic 606, *Revenue from Contracts with Customers* (“Topic 606”), we recognize revenue when control of the promised goods or services is transferred to our customers, in an amount that reflects the consideration we expect to be entitled to in exchange for those goods or services. For enforceable contracts with our customers, we first identify the distinct performance obligations – or accounting units – within the contract. Performance obligations are commitments in a contract to transfer a distinct good or service to the customer.

Payments received under commercial arrangements, such as licensing technology rights, may include non-refundable fees at the inception of the arrangements, milestone payments for specific achievements designated in the agreements, and royalties on the sale of products. At the inception of arrangements that include milestone payments, we use judgment to evaluate whether the milestones are probable of being achieved and we estimate the amount to include in the transaction price using the most likely method. If it is probable that a significant revenue reversal will not occur, the estimated amount is included in the transaction price. Milestone payments that are not within our or the licensee’s control, such as regulatory approvals, are not included in the transaction price until those approvals are received. At the end of each reporting period, we re-evaluate the probability of achievement of development milestones and any related constraint and, as necessary, we adjust our estimate of the overall transaction price.

We may enter into arrangements that consist of multiple performance obligations. Such arrangements may include any combination of our deliverables. To the extent a contract includes multiple promised deliverables, we apply judgment to determine whether promised deliverables are capable of being distinct and are distinct in the context of the contract. If these criteria are not met, the promised deliverables are accounted for as a combined performance obligation. For arrangements with multiple distinct performance obligations, we allocate variable

## Table of Contents

consideration related to our 50-50 cost share for development services directly to the associated performance obligation and then allocate the remaining consideration among the performance obligations based on their relative stand-alone selling price.

Stand-alone selling price is the price at which we would sell a promised good or service separately to the customer. When not directly observable, we typically estimate the stand-alone selling price for each distinct performance obligation. Variable consideration that relates specifically to our efforts to satisfy specific performance obligations is allocated entirely to those performance obligations. Other components of the transaction price are allocated based on the relative stand-alone selling price, over which management has applied significant judgment. We develop assumptions that require judgment to determine the stand-alone selling price for license-related performance obligations, which may include forecasted revenues, development timelines, reimbursement rates for personnel costs, discount rates and probabilities of technical, regulatory and commercial success. We estimate stand-alone selling price for research and development performance obligations by forecasting the expected costs of satisfying a performance obligation plus an appropriate margin.

In the case of a license that is a distinct performance obligation, we recognize revenue allocated to the license from non-refundable, up-front fees at the point in time when the license is transferred to the licensee and the licensee can use and benefit from the license. For licenses that are bundled with other distinct or combined obligations, we use judgment to assess the nature of the performance obligation to determine whether the performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. If the performance obligation is satisfied over time, we evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

The selection of the method to measure progress towards completion requires judgment and is based on the nature of the products or services to be provided. Revenue is recorded proportionally as costs are incurred. We generally use the cost-to-cost measure of progress because it best depicts the transfer of control to the customer which occurs as we incur costs. Under the cost-to-cost measure of progress, the extent of progress towards completion is measured based on the ratio of costs incurred to date to the total estimated costs at completion of the performance obligation (an “input method” under Topic 606). We use judgment to estimate the total cost expected to complete the research and development performance obligations, which include subcontractors’ costs, labor, materials, other direct costs and an allocation of indirect costs. We evaluate these cost estimates and the progress each reporting period and, as necessary, we adjust the measure of progress and related revenue recognition.

For arrangements that include sales-based or usage-based royalties, we recognize revenue at the later of (i) when the related sales occur or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied or partially satisfied. To date, we have not recognized any sales-based or usage-based royalty revenue from license agreements.

In connection with our License, Development and Commercialization Agreement (the “KKC Commercialization Agreement”) with KKC, we perform development services related to our 50-50 cost sharing arrangement for which revenue is recognized over time. Additionally, we perform services for KKC at their request, the costs of which are fully reimbursed to us. We record the reimbursement for such pass through services as revenue at 100% of reimbursed costs, as control of the additional services for KKC is transferred at the time we incur such costs. The costs of these services are recognized in the Condensed Statements of Operations as research and development expense.

[Table of Contents](#)

We recognized revenue associated with the KKC Commercialization Agreement for the periods presented (in thousands):

	Three Months Ended December 31,		Six Months Ended December 31,	
	2022	2021	2022	2021
Revenue	<u>\$32,735</u>	<u>\$11,832</u>	<u>\$41,465</u>	<u>\$19,589</u>
Timing of Revenue Recognition:				
Services performed over time	\$32,473	\$ 9,625	\$40,832	\$16,810
Pass through services at a point in time	262	2,207	633	2,779
	<u>\$32,735</u>	<u>\$11,832</u>	<u>\$41,465</u>	<u>\$19,589</u>

#### Contract Balances

Accounts receivable are included in “Prepaid expenses and other current assets”, and contract liabilities are included in “Deferred revenue” and “Deferred revenue, long-term” on our Condensed Balance Sheets. The following table presents changes in accounts receivable, unbilled receivables and contract liabilities accounted for under Topic 606 for the periods presented (in thousands):

	Six Months Ended December 31,	
	2022	2021
Accounts receivable		
Accounts receivable, beginning of period	\$ —	\$ —
Amounts billed	17,803	35,757
Payments received	(17,803)	(35,757)
Accounts receivable, end of period	<u>\$ —</u>	<u>\$ —</u>
Unbilled receivables		
Unbilled receivables, beginning of period	\$ 10,044	\$ 7,582
Billable amounts	13,463	38,326
Amounts billed	(17,803)	(35,757)
Unbilled receivables, end of period	<u>\$ 5,704</u>	<u>\$ 10,151</u>
Contract liabilities		
Contract liabilities, beginning of period	\$ 30,900	\$ 14,677
Payments received	—	20,000
Revenue recognized	(2,831)	(1,264)
Revenue recognized from change in estimate for performance obligations that are being closed	(16,565)	—
Revenue recognized for performance obligations that will no longer commence	(8,607)	—
Contract liabilities, end of period	<u>\$ 2,897</u>	<u>\$ 33,413</u>

The timing of revenue recognition, invoicing and cash collections results in billed accounts receivable and unbilled receivables and deferred revenue (contract liabilities). We invoice our customers in accordance with agreed-upon contractual terms, typically at periodic intervals or upon achievement of contractual milestones. Invoicing may occur subsequent to revenue recognition, resulting in unbilled receivables. We may receive advance payments from our customers before revenue is recognized, resulting in contract liabilities. The unbilled receivables and deferred revenue reported on the Condensed Balance Sheets relate to the KKC Commercialization Agreement.

## [Table of Contents](#)

As of December 31, 2022 and June 30, 2022, we had \$67.4 million and \$95.4 million, respectively, of deferred revenue associated with the KKC Commercialization Agreement, of which \$64.5 million relates to the U.S. license which is a unit of account under the scope of ASC Topic 808, *Collaborative Arrangements* (“Topic 808”) and is not a performance obligation under Topic 606. The remaining balance of deferred revenue as of December 31, 2022 and June 30, 2022 of \$2.9 million and \$30.9 million, respectively, relates to the development services performance obligations which are under the scope of Topic 606. The decrease in deferred revenue comes as a result of our beginning the close down of all zandelisib studies outside of Japan. We updated our estimated costs to complete each of the performance obligations, resulting in a higher progress towards completion based on the ratio of costs incurred to date to the total estimated costs. Additionally, we recognized revenue related to non-refundable payments for performance obligations that have not commenced and will no longer be initiated.

Our contract liabilities accounted for under Topic 606 relate to the amount of initial upfront consideration that was allocated to the development services performance obligations. Contract liabilities are recognized over the duration of the performance obligations based on the costs incurred relative to total expected costs.

### *Revenues from Collaborators*

At contract inception, we assess whether the collaboration arrangements are within the scope of Topic 808 to determine whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities. This assessment is performed based on the responsibilities of all parties in the arrangement. For collaboration arrangements within the scope of Topic 808 that contain multiple units of account, we first determine which units of account within the arrangement are within the scope of Topic 808 and which elements are within the scope of Topic 606. For units of account within collaboration arrangements that are accounted for pursuant to Topic 808, an appropriate recognition method is determined and applied consistently, by analogy to authoritative accounting literature. For elements of collaboration arrangements that are accounted for pursuant to Topic 606, we recognize revenue as discussed above. Consideration received that does not meet the requirements to satisfy Topic 606 revenue recognition criteria is recorded as deferred revenue in the accompanying Condensed Balance Sheets, classified as either short-term or long-term deferred revenue based on our best estimate of when such amounts will be recognized.

### **Research and Development Costs**

Research and development costs are expensed as incurred and include costs paid to third-party contractors to perform research, conduct clinical trials and develop and manufacture drug materials. Clinical trial costs, including costs associated with third-party contractors, are a significant component of research and development expenses. We expense research and development costs based on work performed. In determining the amount to expense, management relies on estimates of total costs based on contract components completed, the enrollment of subjects, the completion of trials, and other events. Costs incurred related to the purchase or licensing of in-process research and development for early-stage products or products that are not commercially viable and ready for use, or have no alternative future use, are charged to expense in the period incurred.

### **Leases**

We account for our leases under ASC Topic 842, *Leases* (“Topic 842”). Leases which are identified within the scope of Topic 842 and which have a term greater than one year are recognized on our Condensed Balance Sheets as right-of-use (“ROU”) assets and lease liabilities. Operating lease liabilities and their corresponding ROU assets are recorded based on the present value of lease payments over the expected remaining lease term. The lease term includes any renewal options and termination options that we are reasonably certain to exercise. Certain adjustments to the right-of-use asset may be required for items such as initial direct costs paid or incentives received. The present value of lease payments is determined by using the interest rate implicit in the

## [Table of Contents](#)

lease, if that rate is readily determinable; otherwise, we use our incremental borrowing rate. The incremental borrowing rate is determined based on the rate of interest that we would pay to borrow on a collateralized basis an amount equal to the lease payments for a similar term and in a similar economic environment. The interest rate implicit in lease contracts to calculate the present value is typically not readily determinable. As such, significant management judgment is required to estimate the incremental borrowing rate.

Rent expense for operating leases is recognized on a straight-line basis over the lease term based on the total lease payments. We have elected the practical expedient to not separate lease and non-lease components for our real estate leases. Our non-lease components are primarily related to property maintenance, which varies based on future outcomes, and thus is recognized in rent expense when incurred.

### **Share-Based Compensation**

Share-based compensation expense stock options and restricted stock units (“RSUs”) granted to employees and directors is recognized in the Condensed Statements of Operations based on estimated amounts. The cost of stock options is measured at the grant date, based on the estimated fair value of the stock option using the Black-Scholes valuation model, which incorporates various assumptions, including expected volatility, risk-free interest rate, the expected term of the award and the dividend yield on the underlying stock. Expected volatility is calculated based on the historical volatility of our stock over the expected option life and other appropriate factors. The expected option term is computed using the “simplified” method as permitted under the provisions of ASC Topic 718, *Compensation—Stock Compensation*. We use the simplified method to calculate the expected term of stock options and similar instruments, as we do not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. Risk-free interest rates are calculated based on continuously compounded risk-free rates for the appropriate term. The dividend yield is assumed to be zero as we have never paid or declared any cash dividends and do not intend to do so in the foreseeable future. For RSUs, we estimate the grant date fair value using our closing stock price on the date of grant. The estimated fair value of stock options and RSUs is amortized on a straight-line basis over the requisite service period, adjusted for actual forfeitures at the time they occur. The requisite service period is generally the time over which our share-based awards vest.

### **Income Taxes**

Our income tax expense consists of current and deferred income tax expense or benefit. Current income tax expense or benefit is the amount of income taxes expected to be payable or refundable for the current year. A deferred income tax asset or liability is recognized for the future tax consequences attributable to tax credits and loss carryforwards and to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized. As of December 31, 2022, we have established a valuation allowance to fully reserve our net deferred tax assets. Tax rate changes are reflected in income during the period such changes are enacted. Changes in our ownership may limit the amount of net operating loss carryforwards that can be utilized in the future to offset taxable income.

There have been no material changes in our unrecognized tax benefits since June 30, 2022, and, as such, the disclosures included in our 2022 Annual Report continue to be relevant for the six months ended December 31, 2022.

### **Recent Accounting Pronouncement**

In June 2016, the Financial Accounting Standards Board issued Accounting Standards Update 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* (“ASU 2016-13”), as amended. The amendments in ASU 2016-13 require, among other things, financial assets

## [Table of Contents](#)

measured at amortized cost basis to be presented at the net amount expected to be collected as compared to previous U.S. GAAP which delayed recognition until it was probable a loss had been incurred. The amendments in ASU 2016-13 are effective for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years, with early adoption permitted. We are currently evaluating the impact that adoption of ASU 2016-13 will have on our financial statements and related disclosures.

### Note 2. Fair Value Measurements

The carrying amounts of financial instruments such as cash equivalents, short-term investments and accounts payable approximate the related fair values due to the short-term maturities of these instruments. We invest our excess cash in financial instruments which are readily convertible into cash, such as money market funds and U.S. government securities. Cash equivalents and short-term investments are measured at fair value on a recurring basis and are classified as Level 1 as defined by the fair value hierarchy.

In May 2018, we issued warrants in connection with our private placement of shares of common stock. Pursuant to the terms of the warrants, we could be required to settle the warrants in cash in the event of an acquisition of the Company and, as a result, the warrants are required to be measured at fair value and reported as a liability in the Condensed Balance Sheet. We recorded the fair value of the warrants upon issuance using the Black-Scholes valuation model and are required to revalue the warrants at each reporting date with any changes in fair value recorded on our Condensed Statement of Operations. The valuation of the warrants is considered under Level 3 of the fair value hierarchy due to the need to use assumptions in the valuation that are both significant to the fair value measurement and unobservable. Inputs used to determine estimated fair value of the warrant liabilities include the estimated fair value of the underlying stock at the valuation date, the estimated term of the warrants, risk-free interest rates, expected dividends and the expected volatility of the underlying stock. The significant unobservable inputs used in the fair value measurement of the warrant liabilities were the volatility rate and the estimated term of the warrants. Generally, increases (decreases) in the fair value of the underlying stock and estimated term would result in a directionally similar impact to the fair value measurement. The change in the fair value of the Level 3 warrant liability is reflected in the Condensed Statements of Operations for the three and six months ended December 31, 2022 and 2021, respectively.

To calculate the fair value of the warrant liability, the following assumptions were used for the periods presented:

	December 31, 2022	June 30, 2022
Risk-free interest rate	4.7%	2.8%
Expected life (years)	0.4	0.9
Expected volatility	101.7%	139.4%
Dividend yield	0.0%	0.0%
Black-Scholes Fair Value	\$ —	\$ 2.00

The following table sets forth a summary of changes in the estimated fair value of our Level 3 warrant liability for the six months ended December 31, 2022 and 2021 (in thousands):

	Fair Value of Warrants Using Significant Unobservable Inputs (Level 3)	
	2022	2021
<b>Balance at July 1,</b>	\$ 1,603	\$ 22,355
Change in estimated fair value of liability classified warrants	(1,603)	(8,046)
<b>Balance at December 31,</b>	<u>\$ —</u>	<u>\$ 14,309</u>

### **Note 3. Short-Term Investments**

As of December 31, 2022, and June 30, 2022, our short-term investments consisted of \$113.3 million and \$137.5 million, respectively, in U.S. government securities. The short-term investments held as of December 31, 2022 and June 30, 2022 had maturity dates of less than one year, are considered to be “held to maturity” and are carried at amortized cost. As of December 31, 2022, and June 30, 2022, the gross holding gains and losses were immaterial.

### **Note 4. License Agreements**

#### *KKC License, Development and Commercialization Agreement*

In April 2020, we entered into the KKC Commercialization Agreement under which we granted to KKC a co-exclusive, sublicensable, payment-bearing license under certain patents and know-how controlled by us to develop and commercialize zandelisib and any pharmaceutical product containing zandelisib for all human indications in the U.S. (the “U.S. License”), and an exclusive (subject to certain retained rights to perform obligations under the KKC Commercialization Agreement), sublicensable, payment-bearing, license under certain patents and know-how controlled by us to develop and commercialize zandelisib and any pharmaceutical product containing zandelisib for all human indications in countries outside of the U.S. (the “Ex-U.S.” and the “Ex-U.S. License”). KKC granted to us a co-exclusive, sublicensable, license under certain patents and know-how controlled by KKC to develop and commercialize zandelisib for all human indications in the U.S., and a co-exclusive, sublicensable, royalty-free, fully paid license under certain patents and know-how controlled by KKC to perform our obligations in the Ex-U.S. under the KKC Commercialization Agreement. KKC paid us an initial payment of \$100.0 million. Additionally, in Japan, where development is now focused, the KKC Commercialization Agreement included potential regulatory and commercialization milestone payments plus royalties on net sales of zandelisib in Japan, which are tiered beginning in the teens.

KKC is responsible for the development and commercialization of zandelisib in the Ex-U.S. and, subject to certain exceptions, is solely responsible for all costs related thereto. We provide to KKC certain drug supplies necessary for the development and commercialization of zandelisib in the Ex-U.S., with the understanding that KKC will assume responsibility for manufacturing for the Ex-U.S. as soon as practicable.

We assessed the KKC Commercialization Agreement in accordance with Topic 808 and Topic 606 and determined that our obligations comprise the U.S. License, the Ex-U.S. License, and development services (the “Development Services”). We determined that the KKC Commercialization Agreement is a collaborative arrangement in accordance with Topic 808 that contains multiple units of account, as we and KKC are both active participants in the development and commercialization activities and are exposed to significant risks and rewards that are dependent on commercial success of the activities of the arrangement. The U.S. License is a unit of account under the scope of Topic 808 and is not a deliverable under Topic 606, while the Ex-U.S. License and Development Services performance obligations are under the scope of Topic 606.

As discussed in Note 1, we and KKC jointly decided to discontinue zandelisib development in the U.S. As of December 31, 2022, we updated our assessment of the total transaction price from the KKC Commercialization Agreement to be \$216.3 million, comprised of the upfront payment of \$100.0 million, milestone payments of \$20.0 million, estimated development cost-sharing of \$91.1 million, and deferred revenue of \$5.2 million. As of December 31, 2022, the updated assessment reflects a decrease in estimated variable consideration related to development cost sharing of \$143.8 million from June 30, 2022. We decreased our estimate for variable consideration related to development cost sharing primarily as a result of us discontinuing our zandelisib program. As a result, we recognized revenue of \$16.6 million from the change in estimate. Additionally, we recognized \$8.6 million of revenue related to non-refundable payments for performance obligations that have not commenced and will no longer be initiated. Any variable consideration related to sales-based royalties and commercial milestones related to licenses of intellectual property will be determined when the sale or usage occurs, and is therefore excluded from the transaction price. In addition, we are eligible to



receive future development and regulatory milestones upon the achievement of certain criteria; however, these amounts are excluded from variable consideration as the risk of significant revenue reversal will only be resolved depending on future research and development and/or regulatory approval outcomes. We re-evaluate the estimated variable consideration included in the transaction price and any related constraints at the end of each reporting period.

We allocated the transaction price of the Ex-U.S. License and Development Services performance obligations to each unit of account. Variable consideration that relates specifically to our efforts to satisfy specific performance obligations are allocated entirely to those performance obligations. Other components of the transaction price are allocated based on the relative stand-alone selling price, over which management has applied significant judgment. We developed the estimated stand-alone selling price for the licenses using the risk-adjusted net present values of estimated cash flows, and the estimated stand-alone selling price of the development services performance obligations by estimating costs to be incurred, and an appropriate margin, using an income approach.

We determined that control of the U.S. License and Ex-U.S. License were transferred to KKC during the year ended June 30, 2020, and recognized revenue of \$21.0 million related to the Ex-U.S. License. The \$64.5 million transaction price allocated to the U.S. License obligation accounted for under Topic 808 is included as non-current deferred revenue and will begin to be recognized upon completion of the collaborative arrangement as non-ASC 606 revenue. As of December 31, 2022 and June 30, 2022, we have deferred revenue of \$2.9 million and \$30.9 million, respectively, related to the transaction price allocated to the Development Services performance obligations and are recognizing this revenue based on the proportional performance of these development activities, which we expect to recognize through fiscal year 2024.

#### *Presage License Agreement*

In September 2017, we entered into a license agreement with Presage Biosciences, Inc. (“Presage”). Under the terms of such license agreement (the “Presage License Agreement”), Presage granted to us exclusive worldwide rights to develop, manufacture and commercialize voruciclib, a clinical-stage, oral and selective CDK inhibitor, and related compounds. In exchange, we paid \$2.9 million. With respect to the first indication, an incremental \$2.0 million payment, due upon dosing of the first subject in the first registration trial, will be owed to Presage, for total payments of \$4.9 million prior to receipt of marketing approval of the first indication in the U.S., E.U. or Japan. Additional potential payments of up to \$179 million will be due upon the achievement of certain development, regulatory and commercial milestones. We will also pay mid-single-digit tiered royalties on the net sales of any product successfully developed. As an alternative to milestone and royalty payments related to countries in which we sublicense product rights, we will pay to Presage a tiered percent (which decreases as product development progresses) of amounts received from such sublicensees.

#### **Note 5. BeiGene Collaboration**

In October 2018, we entered into a clinical collaboration with BeiGene, Ltd. (“BeiGene”) to evaluate the safety and efficacy of zandelisib in combination with BeiGene’s zanubrutinib (marketed as Brukinsa®), an inhibitor of Bruton’s tyrosine kinase, for the treatment of patients with B-cell malignancies. Under the terms of the clinical collaboration agreement, we amended our ongoing Phase 1b trial to include evaluation of zandelisib in combination with zanubrutinib in patients with B-cell malignancies. Study costs are being shared equally by the parties, and we agreed to supply zandelisib and BeiGene agreed to supply zanubrutinib. We record the costs reimbursed by BeiGene as a reduction of our research and development expenses. We retained full commercial rights for zandelisib and BeiGene retained full commercial rights for zanubrutinib. With the discontinuation of the zandelisib program outside of Japan, this clinical collaboration will be concluding with the discontinuation of the Phase 1b trial.

**Note 6. Net Income (Loss) Per Share**

Basic and diluted net income (loss) per share are computed using the weighted average number of shares of common stock outstanding during the period, less any shares subject to repurchase or forfeiture. There were no shares of common stock subject to repurchase or forfeiture for the three and six months ended December 31, 2022 and 2021. Diluted net income (loss) per share is computed based on the sum of the weighted average number of common shares and potentially dilutive common shares outstanding during the period.

The following table presents the calculation of net income (loss) used to calculate basic income (loss) and diluted income (loss) per share (in thousands):

	Three Months Ended December 31,		Six Months Ended December 31,	
	2022	2021	2022	2021
Net income (loss) – basic	\$10,253	\$(12,156)	\$(6,371)	\$(29,666)
Change in fair value of warrant liability	—	(5,458)	—	(8,046)
Net income (loss) – diluted	<u>\$10,253</u>	<u>\$(17,614)</u>	<u>\$(6,371)</u>	<u>\$(37,712)</u>

Share used in calculating net income (loss) per share was determined as follows (in thousands):

	Three Months Ended December 31,		Six Months Ended December 31,	
	2022	2021	2022	2021
Weighted average shares used in calculating basic net income (loss) per share	6,663	6,336	6,663	5,799
Effect of potentially dilutive common shares from equity awards and liability-classified warrants	—	72	—	134
Weighted average shares used in calculating diluted net income (loss) per share	<u>6,663</u>	<u>6,408</u>	<u>6,663</u>	<u>5,933</u>

Our potentially dilutive shares, which include outstanding stock options, restricted stock units and warrants, are considered to be common stock equivalents and are only included in the calculation of diluted net income (loss) per share when their effect is dilutive.

The following table presents weighted average potentially dilutive shares that have been excluded from the calculation of net income (loss) per share because of their anti-dilutive effect (in thousands):

	Three Months Ended December 31,		Six Months Ended December 31,	
	2022	2021	2022	2021
Stock options	1,373	1,023	1,380	1,034
Warrants	803	—	803	—
Restricted stock units	—	11	—	12
Total anti-dilutive shares	<u>2,176</u>	<u>1,034</u>	<u>2,183</u>	<u>1,046</u>

**Note 7. Commitments and Contingencies**

We have contracted with various consultants and third parties to assist us in pre-clinical research and development and clinical trials work for our leading drug compounds. The contracts are terminable at any time, but obligate us to reimburse the providers for any time or costs incurred through the date of termination. We also have employment agreements with certain of our current employees that provide for severance payments and accelerated vesting for share-based awards if their employment is terminated under specified circumstances.

## Table of Contents

### *Presage License Agreement*

As discussed in Note 4, we are party to a license agreement with Presage under which we may be required to make future payments upon the achievement of certain development, regulatory and commercial milestones, as well as potential future royalties based upon net sales. As of December 31, 2022, we had not accrued any amounts for potential future payments as achievement of the milestones had not been met.

### *COVID-19*

As a result of the ongoing COVID-19 pandemic, various public health orders and guidance measures have been implemented across much of the U.S., and across the globe, including in the locations of our office, clinical trial sites, key vendors and partners. Despite the relaxation of many governmental orders earlier this year, COVID-19 still impacts the normal conduct of business. While we continue to enroll and dose patients in our clinical trials, our clinical development program timelines may continue to be subject to potential negative impacts from the ongoing pandemic in the U.S. and globally.

We have experienced enrollment delays and suspensions, patient withdrawals, postponement of planned clinical or preclinical studies, redirection of site resources from studies, and study deviations or noncompliance. We may also need to maintain or implement study modifications, suspensions, or terminations, the introduction of additional remote study procedures and modified informed consent procedures, study site changes, direct delivery of investigational products to patient homes or alternative sites, which may require state licensing, and changes or delays in site monitoring. The foregoing may require that we consult with relevant review and ethics committees, Institutional Review Boards and the FDA. The foregoing may also impact the integrity of our study data. The ongoing COVID-19 pandemic may further increase the need for clinical trial patient monitoring and regulatory reporting of adverse effects, and may delay regulatory authority meetings, inspections, or the regulatory review of marketing or investigational applications or submissions.

Not only might the ongoing COVID-19 pandemic impact the conduct of our clinical trials, but it may also impact our ability to procure the necessary supply of our investigational drug products, as well as any ancillary supplies necessary for the conduct of our studies. Third party manufacturers may also need to implement measures and changes, or deviate from typical manufacturing requirements that may otherwise adversely impact our product candidates.

### *Nasdaq Bid Price Letter*

On May 9, 2022, we received a letter from Nasdaq indicating that, for the last thirty consecutive business days, the bid price for our common stock had closed below the minimum \$1.00 per share requirement for continued listing on the Nasdaq Capital Market.

In accordance with Nasdaq listing rules, we were provided an initial period of 180 calendar days, or until November 7, 2022, to regain compliance. On November 10, 2022, we received a letter from Nasdaq that we have been granted an additional 180 calendar day compliance period and that our compliance period now ends on May 8, 2023. The letter states that Nasdaq will provide written notification that we have achieved compliance with its rules if, at any time before May 8, 2023, the bid price of our common stock closes at \$1.00 per share or more for a minimum of ten consecutive business days. The Nasdaq letter had no immediate effect on the listing or trading of our common stock and our common stock continued to trade on the Nasdaq Capital Market.

We have not regained compliance with Nasdaq listing rules as of the date these financial statements were issued.

### *Torrey Partners*

In October 2022, we engaged Torrey Partners as a financial advisor to help explore additional strategic opportunities. As part of this engagement, we have agreed to issue warrants to acquire shares of our common

## [Table of Contents](#)

stock having a value equal to \$0.5 million at the time of issuance. To date these warrants have not been issued and have been accrued for as of December 31, 2022. We will also pay Torrey Partners a transaction fee equal to 20% of aggregate consideration, up to a maximum of \$2.0 million, in connection with a potential strategic transaction. As of December 31, 2022, we have not accrued any amount for potential future transaction fees.

### **Note 8. Leases**

In July 2020, we entered into a lease agreement (the “Initial Lease Agreement”) for approximately 32,800 square feet of office space in San Diego, California. The Initial Lease Agreement was extended to November 30, 2029, in accordance with the amended lease agreement that we entered into in January 2022 (the “Amended Lease Agreement”). The Amended Lease Agreement, which began on July 1, 2022 and expires on November 30, 2029, provides for an additional 12,300 square feet of office space adjacent to our current office in San Diego, for a total of approximately 45,100 square feet of office space. Upon taking control of the additional 12,300 square feet of office space adjacent to our current office in San Diego on July 1, 2022, we recognized operating lease ROU assets obtained in exchange for operating lease liabilities of \$4.3 million. The Initial Lease Agreement and Amended Lease Agreement are collectively referred to as the “Lease Agreements” and have been accounted for as operating leases.

The following is a schedule of the future minimum lease payments under the Lease Agreements, reconciled to the operating lease liability, as of December 31, 2022 (in thousands):

	<b>December 31, 2022</b>
Remainder of fiscal year ending June 30, 2023	\$ 1,133
Years ending June 30, 2024	2,335
2025	1,913
2026	2,477
2027	2,551
2028	2,715
Thereafter	4,386
Total lease payments	17,510
Less: Present value discount	(4,140)
Total operating lease liability	<u>\$ 13,370</u>
<b>Balance Sheet Classification – Operating Leases</b>	
Operating lease liability	\$ 1,343
Operating lease liability, long-term	12,027
Total operating lease liability	<u>\$ 13,370</u>
<b>Other Balance Sheet Information – Operating Leases</b>	
Weighted average remaining lease term (in years)	6.9
Weighted average discount rate	7.50%

The Lease Agreements include rent escalations over the lease terms. In addition, the Lease Agreements include renewal options which were not included in the determination of the ROU assets or lease liabilities as the renewals were not reasonably certain at the inception of the Lease Agreements. Under the terms of the Lease Agreements, we are subject to charges for variable non-lease components (e.g., common area maintenance, maintenance, etc.) that are not included in the ROU assets and operating lease liabilities and are recorded as an expense in the period incurred.

## [Table of Contents](#)

The total operating lease costs and supplemental cash flow information related to our operating leases were as follows (in thousands):

	Three Months Ended December 31,		Six Months Ended December 31,	
	2022	2021	2022	2021
Operating lease expense	\$ 608	\$ 377	\$ 1,217	\$ 753
Operating cash flows from operating leases	\$ 567	\$ 380	\$ 1,133	\$ 760

### **Note 9. Stockholders' Equity**

#### **Equity Transactions**

##### *Shelf Registration Statement*

We have a shelf registration statement that permits us to sell, from time to time, up to \$200.0 million of common stock, preferred stock and warrants. The shelf registration was filed and declared effective in May 2020, and carried forward approximately \$107.5 million of unsold securities registered under the prior shelf registration statement. As of December 31, 2022, there was \$123.4 million aggregate value of securities available under the shelf registration statement, including \$60.0 million remaining available under the 2020 ATM Sales Agreement described below.

##### *At-The-Market Equity Offering*

On November 10, 2020, we entered into an At-The-Market Equity Offering Sales Agreement (the "2020 ATM Sales Agreement"), pursuant to which we may sell an aggregate of up to \$60.0 million of our common stock pursuant to the shelf registration statement. As of December 31, 2022, there was \$60.0 million remaining available under the 2020 ATM Sales Agreement.

##### *Warrants*

As of December 31, 2022, we have outstanding warrants to purchase 802,949 shares of our common stock related to a private placement equity financing that we closed in May 2018. The warrants are fully vested, exercisable at a price of \$50.80 per share and expire in May 2023. Pursuant to the terms of the warrants, we could be required to settle the warrants in cash in the event of an acquisition of the Company and, as a result, the warrants are required to be measured at fair value and reported as a liability in the Condensed Balance Sheets. The warrants were revalued as of December 31, 2022 and June 30, 2022 at zero and \$1.6 million, respectively. The change in fair value of \$0.5 million and \$1.6 million was recorded on the Condensed Statement of Operations for the three and six months ended December 31, 2022.

### **Note 10. Share-based Compensation**

We use equity-based compensation programs to provide long-term performance incentives for our employees. These incentives consist primarily of stock options and RSUs. In December 2008, we adopted the MEI Pharma, Inc. 2008 Stock Omnibus Equity Compensation Plan ("Omnibus Plan"), as amended and restated from time-to-time, under which 1,450,740 shares of common stock are authorized for issuance. The Omnibus Plan provides for the grant of options and/or other stock-based or stock-denominated awards to our non-employee directors, officers, and employees. As of December 31, 2022, there were 166,771 shares available for future grant under the Omnibus Plan. In January 2023, our stockholders approved the increase of 400,000 additional shares available for future grant under the Omnibus Plan.

In May 2021, we adopted the 2021 Inducement Plan ("Inducement Plan"), under which 125,000 shares of common stock are authorized for issuance. The Inducement Plan is intended to assist us in attracting and

## [Table of Contents](#)

retaining selected individuals to serve as employees who are expected to contribute to our success, by providing an inducement for such individuals to enter into employment with us, and to achieve long-term objectives that will benefit stockholders of the Company. As of December 31, 2022, there were 24,570 shares available for future grant under the Inducement Plan.

Total share-based compensation expense for all stock awards consisted of the following for the periods presented (in thousands):

	Three Months Ended December 31,		Six Months Ended December 31,	
	2022	2021	2022	2021
Research and development	\$ 201	\$ 658	\$ 850	\$1,280
General and administrative	612	1,666	1,522	3,583
Total share-based compensation expense	<u>\$ 813</u>	<u>\$ 2,324</u>	<u>\$2,372</u>	<u>\$4,863</u>

### *Stock Options*

Stock options granted to employees vest 25% one year from the date of grant and ratably each month thereafter for a period of 36 months and expire ten years from the date of grant. Stock options granted to directors vest ratably each month for a period of 12 months from the date of grant and expire ten years from the date of grant. Of the total options outstanding of 1,270,243 as of December 31, 2022, 1,169,813 were granted under the Omnibus Plan and 100,430 were granted under the Inducement Plan.

A summary of our stock option activity and related data follows:

	Number of Options	Weighted- Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at June 30, 2022	996,700	\$ 57.00		
Granted	461,021	10.60		
Expired	(7,833)	52.60		
Forfeited/Cancelled	(179,645)	41.00		
Outstanding at December 31, 2022	<u>1,270,243</u>	42.40	7.7	\$ —
Vested and exercisable at December 31, 2022	<u>612,103</u>	57.80	6.3	\$ —

As of December 31, 2022, the aggregate intrinsic value of outstanding options was calculated as the difference between the exercise price of the underlying options and the closing price of our common stock of \$4.80 on that date.

Unrecognized compensation expense related to non-vested stock options totaled \$5.2 million as of December 31, 2022. Such compensation expense is expected to be recognized over a weighted average period of 1.6 years. As of December 31, 2022, we expect all options to vest.

[Table of Contents](#)

We use the Black-Scholes valuation model to estimate the grant date fair value of stock options. To calculate these fair values, the following weighted average assumptions were used for the periods presented:

	Six Months Ended December 31,	
	2022	2021
Risk-free interest rate	2.9%	1.1%
Expected life (years)	6.0	6.0
Expected volatility	84.1%	68.0%
Dividend yield	0.0%	0.0%
Weighted average grant date fair value	\$7.80	\$35.60

*Restricted Stock Units*

A summary of our RSU activity and related data for the six months ended December 31, 2022 was as follows:

	Number of RSUs	Weighted Average Grant Date Fair Value
Non-vested at June 30, 2022	9,220	\$ 69.80
Vested	(9,220)	\$ 69.80
Non-vested at December 31, 2022	<u>—</u>	\$ —

## [Table of Contents](#)

### REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Stockholders and Board of Directors  
MEI Pharma, Inc.  
San Diego, California

#### **Opinion on the Financial Statements**

We have audited the accompanying balance sheets of MEI Pharma, Inc. (the “Company”) as of June 30, 2022 and 2021, the related statements of operations, stockholders’ equity, and cash flows for each of the three years in the period ended June 30, 2022 and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at June 30, 2022 and 2021, and the results of its operations and its cash flows for each of the three years in the period ended June 30, 2022, in conformity with accounting principles generally accepted in the United States of America.

#### **Basis for Opinion**

These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (“PCAOB”) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

#### **Critical Audit Matters**

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

#### ***Estimation of accrued pre-clinical and clinical trial expenses***

As described in Note 7 of the financial statements, the Company had accrued pre-clinical and clinical trial expenses of \$5.3 million as of June 30, 2022. Clinical trial costs, including costs associated with third-party contractors, are a



## Table of Contents

significant component of research and development expenses. In determining the amount of accrued pre-clinical and clinical trial expenses incurred, management relies on estimates of work completed to date for various components of contracted services, the enrollment of subjects, the completion of trials, and other events.

We identified the estimation of accrued pre-clinical and clinical trial expenses as a critical audit matter. Evaluating the progress or stage of completion of the activities under the Company's research and development agreements is dependent upon multiple points of data from third-party service providers and internal clinical personnel. Additionally, due to the duration of clinical-related development activities, the estimate of accrued pre-clinical and clinical trial expenses incurred requires judgment based on the nature and amounts of ongoing activities, the status of each activity, and the estimated progress for each key activity. Auditing these elements involved especially challenging and subjective auditor judgment due to the nature and extent of auditor effort required to address the matter.

The primary procedures we performed to address this critical audit matter included:

- Assessing the nature and extent of progress of clinical trial activities based on inquiries of the Company's research and development personnel, which were corroborated through inspection of meeting minutes maintained by the Company related to clinical trial and project status meetings held with various third parties.
- Developing independent estimates of the costs incurred for certain activities performed by third parties utilizing information from internal and external sources and comparing expected amounts to the amounts recorded by the Company.
- Evaluating the completeness of the accrued clinical trial expenses by comparing invoices received by the Company subsequent to June 30, 2022 to the amounts accrued by the Company.

### ***Revenue recognition for the KKC License, Development and Commercialization Agreement***

As described in Notes 1 and 2 of the financial statements, the Company recognizes revenue under the KKC Commercialization Agreement when control of the promised goods or services are transferred to the customer in an amount that reflects the consideration to which the company expects to be entitled to in exchange for those goods or services. For development services satisfied over time, the Company uses the cost-to-cost measure of progress whereby progress is measured based on the ratio of costs incurred to date compared to the total estimated costs.

We have identified the accounting for revenue recognition under the KKC Commercialization agreement as a critical audit matter. The Company identified certain errors in the revenue recognition model, constituting a material weakness, related to the manner in which revenue related to development services was recognized under the KKC Commercialization Agreement. Auditing the Company's revised revenue recognition model was especially challenging due to the increased auditor effort required.

The primary procedures we performed to address this critical audit matter included:

- Evaluating the logic and key assumptions used in the Company's revised revenue recognition model to determine that errors identified were corrected and revenue recognition was accurately calculated.
- Recalculating current year revenue and deferred revenue balances based on the terms of the KKC Commercialization Agreement as well as management estimates with respect to the progress towards completion of development services.

/s/ BDO USA, LLP

We have served as the Company's auditor since 2011.

San Diego, California

September 8, 2022, except for the impact of the reverse stock split as described in Note 1, as to which the date is April 27, 2023

**MEI PHARMA, INC.**  
**BALANCE SHEETS**  
(In thousands, except per share amounts)

	June 30,	
	2022	2021
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 15,740	\$ 8,543
Short-term investments	137,512	144,883
Total cash, cash equivalents and short-term investments	153,252	153,426
Unbilled receivables	10,044	7,582
Prepaid expenses and other current assets	3,830	3,809
Total current assets	167,126	164,817
Operating lease right-of-use asset	9,054	7,774
Property and equipment, net	1,660	1,507
Total assets	\$ 177,840	\$ 174,098
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 7,918	\$ 6,355
Accrued liabilities	10,820	8,402
Deferred revenue	4,834	4,526
Operating lease liability	871	928
Total current liabilities	24,443	20,211
Deferred revenue, long-term	90,610	74,696
Operating lease liability, long-term	8,771	7,370
Warrant liability	1,603	22,355
Total liabilities	125,427	124,632
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Preferred stock, \$0.01 par value; 100 shares authorized; none outstanding	—	—
Common stock, \$0.00000002 par value; 226,000 shares authorized; 6,658 and 5,631 shares issued and outstanding at June 30, 2022 and 2021, respectively.	—	—
Additional paid-in capital	426,572	369,171
Accumulated deficit	(374,159)	(319,705)
Total stockholders' equity	52,413	49,466
Total liabilities and stockholders' equity	\$ 177,840	\$ 174,098

*See accompanying notes to financial statements.*

**MEI PHARMA, INC.**  
**STATEMENTS OF OPERATIONS**  
(In thousands, except per share amounts)

	<b>Years Ended June 30,</b>		
	<u>2022</u>	<u>2021</u>	<u>2020</u>
Revenue	\$ 40,697	\$ 34,796	\$ 27,756
Operating expenses:			
Cost of revenue	—	1,408	2,671
Research and development	85,641	69,398	34,065
General and administrative	30,540	24,414	16,717
Total operating expenses	<u>116,181</u>	<u>95,220</u>	<u>53,453</u>
Loss from operations	<u>(75,484)</u>	<u>(60,424)</u>	<u>(25,697)</u>
Other income (expense):			
Change in fair value of warrant liability	20,752	18,122	(22,870)
Interest and dividend income	284	510	1,395
Other (expense) income, net	(6)	486	—
Income tax expense	—	(8)	(1)
Total other income (expense), net	<u>21,030</u>	<u>19,110</u>	<u>(21,476)</u>
Net loss	<u>\$ (54,454)</u>	<u>\$ (41,314)</u>	<u>\$ (47,173)</u>
Net loss:			
Basic	<u>\$ (54,454)</u>	<u>\$ (41,314)</u>	<u>\$ (47,173)</u>
Diluted	<u>\$ (62,500)</u>	<u>\$ (68,708)</u>	<u>\$ (47,173)</u>
Net loss per share:			
Basic	<u>\$ (8.75)</u>	<u>\$ (7.34)</u>	<u>\$ (10.36)</u>
Diluted	<u>\$ (9.99)</u>	<u>\$ (12.00)</u>	<u>\$ (10.36)</u>
Shares used in computing net loss per share:			
Basic	<u>6,224</u>	<u>5,626</u>	<u>4,554</u>
Diluted	<u>6,257</u>	<u>5,724</u>	<u>4,554</u>

*See accompanying notes to financial statements.*

**MEI PHARMA, INC.**  
**STATEMENTS OF STOCKHOLDERS' EQUITY**  
(In thousands)

	<u>Common Shares</u>	<u>Additional Paid-In Capital</u>	<u>Accumulated Deficit</u>	<u>Total Stockholders' Equity</u>
<b>Balance at June 30, 2019</b>	3,677	\$279,148	\$ (231,218)	\$ 47,930
Net loss	—	—	(47,173)	(47,173)
Issuance of common stock, net of issuance costs of \$3,731	1,891	69,231	—	69,231
Exercise of stock options	8	272	—	272
Share-based compensation expense	—	6,801	—	6,801
<b>Balance at June 30, 2020</b>	<u>5,576</u>	<u>355,452</u>	<u>(278,391)</u>	<u>77,061</u>
Net loss	—	—	(41,314)	(41,314)
Issuance of common stock, net of issuance costs of \$64	48	3,136	—	3,136
Exercise of warrants	—	6	—	6
Exercise of stock options	7	332	—	332
Share-based compensation expense	—	10,245	—	10,245
<b>Balance at June 30, 2021</b>	<u>5,631</u>	<u>369,171</u>	<u>(319,705)</u>	<u>49,466</u>
Net loss	—	—	(54,454)	(54,454)
Issuance of common stock, net of issuance costs of \$3,652	1,006	48,673	—	48,673
Issuance of common stock for vested restricted stock units	3	(194)	—	(194)
Exercise of stock options	18	572	—	572
Share-based compensation expense	—	8,350	—	8,350
<b>Balance at June 30, 2022</b>	<u><u>6,658</u></u>	<u><u>\$426,572</u></u>	<u><u>\$ (374,159)</u></u>	<u><u>\$ 52,413</u></u>

*See accompanying notes to financial statements.*

**MEI PHARMA, INC.**  
**STATEMENTS OF CASH FLOWS**  
(In thousands)

	Years Ended June 30,		
	2022	2021	2020
<b>Cash flows from operating activities:</b>			
Net loss	\$ (54,454)	\$ (41,314)	\$ (47,173)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:			
Change in fair value of warrant liability	(20,752)	(18,122)	22,870
Share-based compensation	8,350	10,245	6,801
Non-cash lease expense	909	—	—
Depreciation and amortization	326	285	109
Impairment of intangible assets	—	—	227
Changes in operating assets and liabilities:			
Unbilled receivables	(2,462)	(4,724)	(2,347)
Receivable for foreign tax withholding	—	20,420	(20,420)
Prepaid expenses and other current assets	(21)	(1,073)	(812)
Accounts payable	1,563	3,918	(2,350)
Accrued liabilities	2,418	2,312	1,470
Deferred revenue	16,222	(4,435)	75,883
Operating lease liability	(845)	524	—
Net cash (used in) provided by operating activities	<u>(48,746)</u>	<u>(31,964)</u>	<u>34,258</u>
<b>Cash flows from investing activities:</b>			
Purchases of property and equipment	(479)	(708)	(894)
Purchases of short-term investments	(272,652)	(420,153)	(190,279)
Proceeds from maturity of short-term investments	280,023	445,569	84,879
Net cash provided by (used in) investing activities	<u>6,892</u>	<u>24,708</u>	<u>(106,294)</u>
<b>Cash flows from financing activities:</b>			
Proceeds from issuance of common stock, gross	52,325	3,200	72,962
Payment of issuance costs	(3,652)	(64)	(3,731)
Proceeds from exercise of stock options	572	332	272
Payment of RSU tax withholdings in exchange for common shares surrendered by RSU holders	(194)	—	—
Collection of common stock proceeds receivable	—	—	5,274
Net cash provided by financing activities	<u>49,051</u>	<u>3,468</u>	<u>74,777</u>
Net increase (decrease) in cash and cash equivalents	7,197	(3,788)	2,741
Cash and cash equivalents at beginning of the year	8,543	12,331	9,590
Cash and cash equivalents at end of the year	<u>\$ 15,740</u>	<u>\$ 8,543</u>	<u>\$ 12,331</u>
<b>Supplemental cash flow information:</b>			
Income taxes paid	\$ —	\$ (8)	\$ (1)
Operating lease right-of-use assets obtained in exchange for operating lease liabilities	\$ 2,189	\$ 8,689	\$ —
<b>Non-cash financing activities:</b>			
Warrants issued pursuant to cashless exercise	\$ —	\$ 6	\$ —

*See accompanying notes to financial statements.*

**MEI PHARMA, INC.**  
**NOTES TO FINANCIAL STATEMENTS**

**Note 1. The Company and Summary of Significant Accounting Policies**

**The Company**

MEI Pharma, Inc. is a late-stage pharmaceutical company committed to the development and commercialization of novel cancer therapies intended to improve outcomes for patients. Our portfolio of drug candidates includes three clinical-stage assets, including zandelisib (f/k/a ME-401), currently in multiple ongoing clinical studies intended to support marketing applications with the U.S. Food and Drug Administration (“FDA”) and other regulatory authorities globally. Our common stock is listed on the Nasdaq Capital Market under the symbol “MEIP.”

On April 14, 2023, we amended our Certificate of Incorporation to effect a combination of our issued and outstanding common stock at a ratio of one-for-twenty (“Reverse Stock Split”). The par value and authorized shares of our common stock were not adjusted as a result of the Reverse Stock Split. The Reverse Stock Split was effective on April 14, 2023. All historical share and per share amounts have been adjusted to reflect the Reverse Stock Split for all periods presented. All stock options, restricted stock units and warrants outstanding were ratably adjusted to give effect to the Reverse Stock Split.

**Clinical Development Programs**

We build our pipeline by licensing or acquiring promising cancer agents and creating value in programs through development, commercialization and strategic partnerships, as appropriate. Our objective is to leverage the mechanisms and properties of our pipeline drug candidates to optimize the balance between efficacy and tolerability to meet the needs of patients with cancer. Our drug candidate pipeline includes:

- zandelisib (f/k/a ME-401), an oral phosphatidylinositol 3-kinase (“PI3K”) delta inhibitor;
- voruciclib, an oral cyclin-dependent kinase (“CDK”) 9 inhibitor; and
- ME-344, a mitochondrial inhibitor targeting the oxidative phosphorylation (“OXPHOS”) complex.

**Use of Estimates**

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America (“U.S. GAAP”) requires management to make estimates and assumptions that affect the amounts reported in the financial statements and disclosures made in the accompanying notes to the financial statements. We use estimates that affect the reported amounts (including assets, liabilities, revenues and expenses) and related disclosures. Actual results could materially differ from those estimates.

**Liquidity**

We have accumulated losses of \$374.2 million since inception and expect to incur operating losses and generate negative cash flows from operations for the foreseeable future. As of June 30, 2022, we had \$153.3 million in cash, cash equivalents and short-term investments. We believe that these resources will be sufficient to meet our obligations and fund our liquidity and capital expenditure requirements for at least the next 12 months from the issuance of these financial statements. Our current business operations are focused on continuing the clinical development of our drug candidates. Changes to our research and development plans or other changes affecting our operating expenses may affect actual future use of existing cash resources. Our research and development expenses are expected to increase in the foreseeable future. We cannot determine with certainty costs associated with ongoing and future clinical trials or the regulatory approval process. The duration, costs and timing associated with the development of our product candidates will depend on a variety of factors, including uncertainties associated with the results of our clinical trials.

## [Table of Contents](#)

To date, we have obtained cash and funded our operations primarily through equity financings and license agreements. In order to continue the development of our drug candidates, at some point in the future we expect to pursue one or more capital transactions, whether through the sale of equity securities, debt financing, license agreements or entry into strategic partnerships. There can be no assurance that we will be able to continue to raise additional capital in the future.

### **Reclassifications**

Proceeds from issuance of common stock and payment of issuance costs have been reclassified in the prior year financial statements to conform to the current year financial statement presentation. These changes did not impact previously reported net loss, loss per share, stockholders' equity, total assets or total cash flows.

### **Cash and Cash Equivalents**

Cash and cash equivalents consist of cash and highly liquid investments with original maturities of three months or less when purchased. Cash is maintained at financial institutions and, at times, balances may exceed federally insured limits. We have not experienced any losses related to these balances.

### **Short-Term Investments**

Short-term investments are marketable securities with maturities greater than three months but less than one year from date of purchase. As of June 30, 2022 and 2021, our short-term investments consisted of \$137.5 million and \$144.9 million, respectively, in United States, "U.S.", government securities. The short-term investments held as of June 30, 2022 and 2021 are considered to be "held to maturity" and are carried at amortized cost. As of June 30, 2022 and 2021, the gross unrealized gains and losses were immaterial.

### **Fair Value Measurements**

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value is as follows:

- Level 1 — Observable inputs such as quoted prices in active markets for identical assets or liabilities.
- Level 2 — Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

### **Property and Equipment**

Property and equipment are stated at cost and depreciated over the estimated useful lives of the assets (generally three to seven years) using the straight-line method. Leasehold improvements are stated at cost and are amortized over the shorter of the estimated useful lives of the assets or the lease term.

### **Leases**

Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 842, *Leases* ("Topic 842") establishes a right-of-use ("ROU") model that requires a lessee to record a ROU asset and

## [Table of Contents](#)

a lease liability on the Balance Sheets for all leases with terms longer than 12 months. Leases are classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. We elected the following as practical expedients: 1) an entity need not reassess whether any expired or existing contracts are or contain leases, 2) an entity need not reassess the lease classification for any expired or existing leases, and 3) an entity need not reassess initial direct costs for any existing leases.

Rent expense for operating leases is recognized on a straight-line basis over the lease term based on the total lease payments. We have elected the practical expedient to not separate lease and non-lease components for our real estate leases. Our non-lease components are primarily related to property maintenance, which varies based on future outcomes, and thus is recognized in rent expense when incurred.

### **Revenue Recognition**

#### *Revenue from Customers*

In accordance with ASC Topic 606, *Revenue from Contracts with Customers* (“Topic 606”), we recognize revenue when control of the promised goods or services is transferred to our customers, in an amount that reflects the consideration we expect to be entitled to in exchange for those goods or services. For enforceable contracts with our customers, we first identify the distinct performance obligations – or accounting units – within the contract. Performance obligations are commitments in a contract to transfer a distinct good or service to the customer.

Payments received under commercial arrangements, such as licensing technology rights, may include non-refundable fees at the inception of the arrangements, milestone payments for specific achievements designated in the agreements, and royalties on the sale of products. At the inception of arrangements that include milestone payments, we use judgment to evaluate whether the milestones are probable of being achieved, and we estimate the amount to include in the transaction price using the most likely method. If it is probable that a significant revenue reversal will not occur, the estimated amount is included in the transaction price. Milestone payments that are not within our or the licensee’s control, such as regulatory approvals, are not included in the transaction price until those approvals are received. At the end of each reporting period, we re-evaluate the probability of achievement of development milestones and any related constraint and, as necessary, we adjust our estimate of the overall transaction price.

We may enter into arrangements that consist of multiple performance obligations. Such arrangements may include any combination of our deliverables. To the extent a contract includes multiple promised deliverables, we apply judgment to determine whether promised deliverables are capable of being distinct and are distinct in the context of the contract. If these criteria are not met, the promised deliverables are accounted for as a combined performance obligation. For arrangements with multiple distinct performance obligations, we allocate variable consideration related to our 50-50 cost share for development services directly to the associated performance obligation and then allocate the remaining consideration among the performance obligations based on their relative stand-alone selling price. Stand-alone selling price is the price at which we would sell a promised good or service separately to the customer. When not directly observable, we typically estimate the stand-alone selling price for each distinct performance obligation. Variable consideration that relates specifically to our efforts to satisfy specific performance obligations is allocated entirely to those performance obligations. Other components of the transaction price are allocated based on the relative stand-alone selling price, over which management has applied significant judgment. We develop assumptions that require judgment to determine the stand-alone selling price for license-related performance obligations, which may include forecasted revenues, development timelines, reimbursement rates for personnel costs, discount rates and probabilities of technical, regulatory and commercial success. We estimate stand-alone selling price for research and development performance obligations by forecasting the expected costs of satisfying a performance obligation plus an appropriate margin.

In the case of a license that is a distinct performance obligation, we recognize revenue allocated to the license from non-refundable, up-front fees at the point in time when the license is transferred to the licensee and



## [Table of Contents](#)

the licensee can use and benefit from the license. For licenses that are bundled with other distinct or combined obligations, we use judgment to assess the nature of the performance obligation to determine whether the performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. If the performance obligation is satisfied over time, we evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition. From time to time, we perform additional services for Kyowa Kirin Co., Ltd. (“KKC”) at their request, the costs of which are fully reimbursed to us. The cost of these services is recognized in the Statements of Operations as research and development expense.

The selection of the method to measure progress towards completion requires judgment and is based on the nature of the products or services to be provided. Revenue is recorded proportionally as costs are incurred. We generally use the cost-to-cost measure of progress because it best depicts the transfer of control to the customer which occurs as we incur costs. Under the cost-to-cost measure of progress, the extent of progress towards completion is measured based on the ratio of costs incurred to date to the total estimated costs at completion of the performance obligation (an “input method” under Topic 606). We use judgment to estimate the total cost expected to complete the research and development performance obligations, which include subcontractors’ costs, labor, materials, other direct costs and an allocation of indirect costs. We evaluate these cost estimates and the progress each reporting period and, as necessary, we adjust the measure of progress and related revenue recognition.

For arrangements that include sales-based or usage-based royalties, we recognize revenue at the later of (i) when the related sales occur or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied or partially satisfied. To date, we have not recognized any sales-based or usage-based royalty revenue from license agreements.

We recognized revenue associated with the following license agreements for the periods presented (in thousands):

	Years Ended June 30,		
	2022	2021	2020
<b>License Agreement:</b>			
KKC Commercialization Agreement	\$40,697	\$34,356	\$26,386
Helsinn License Agreement	—	440	1,370
	<u>\$40,697</u>	<u>\$34,796</u>	<u>\$27,756</u>
<b>Timing of Revenue Recognition:</b>			
Development services performed over time	\$37,304	\$31,302	\$ 6,768
Pass through services at a point in time	3,393	3,494	—
License transferred at a point in time	—	—	20,988
	<u>\$40,697</u>	<u>\$34,796</u>	<u>\$27,756</u>

Based on the characteristics of the Helsinn License Agreement, we recognized revenue based on the extent of progress towards completion of the performance obligations. The performance obligations under the Helsinn License Agreement were completed in June 2021, and the Helsinn License Agreement was terminated in November 2021.

## [Table of Contents](#)

### *Contract Balances*

Accounts receivable are included on our Balance Sheets in “Prepaid expenses and other current assets”, and contract liabilities are included in “Deferred revenue” and “Deferred revenue, long-term” in our Balance Sheets. The following table presents changes in accounts receivable, unbilled receivables and contract liabilities accounted for under Topic 606 for the periods presented (in thousands):

	Years Ended June 30,	
	2022	2021
<b>Accounts receivable</b>		
Accounts receivable, beginning of year	\$ —	\$ 83
Amounts billed	54,611	25,682
Payments received	(54,611)	(25,765)
Accounts receivable, end of year	<u>\$ —</u>	<u>\$ —</u>
<b>Unbilled receivables</b>		
Unbilled receivables, beginning of year	\$ 7,582	\$ 2,858
Billable amounts	56,816	30,406
Amounts billed	(54,354)	(25,682)
Unbilled receivables, end of year	<u>\$ 10,044</u>	<u>\$ 7,582</u>
<b>Contract liabilities</b>		
Contract liabilities, beginning of year	\$ 14,677	\$ 19,108
Revenue recognized	(3,777)	(4,798)
Payments received	20,000	367
Contract liabilities, end of year	<u>\$ 30,900</u>	<u>\$ 14,677</u>

The timing of revenue recognition, invoicing and cash collections results in billed accounts receivable and unbilled receivables (contract assets) and deferred revenue (contract liabilities). We invoice our customers in accordance with agreed-upon contractual terms, typically at periodic intervals or upon achievement of contractual milestones. Invoicing may occur subsequent to revenue recognition, resulting in unbilled receivables. We may receive advance payments from our customers before revenue is recognized, resulting in contract liabilities. The unbilled receivables and deferred revenue reported on the Balance Sheets relate to the KKC Commercialization Agreement.

As of June 30, 2022 and 2021, we had unbilled receivables of \$10.0 million and \$7.6 million, respectively, related to our remaining performance obligations under the KKC Commercialization Agreement. Our unbilled receivables are comprised of amounts that are billable based on the contractual provisions of the license agreement but not yet billed.

As of June 30, 2022 and 2021, we had \$95.4 million and \$79.2 million, respectively, of deferred revenue associated with the KKC Commercialization Agreement, of which \$64.5 million relates to the U.S. license which is a unit of account under the scope of ASC Topic 808, *Collaborative Arrangements* (“Topic 808”) and is not a performance obligation under Topic 606. The remaining balance of deferred revenue as of June 30, 2022 and 2021 of \$30.9 million and \$14.7 million, respectively, relates to the development services performance obligations which are under the scope of Topic 606.

Our contract liabilities accounted for under Topic 606 relate to the amount of initial upfront consideration that was allocated to the development services performance obligations. Contract liabilities are recognized over the duration of the performance obligations based on the costs incurred relative to total expected costs.

### *Revenue from Collaborators*

At contract inception, we assess whether the collaboration arrangements are within the scope of Topic 808, to determine whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities. This assessment is performed based on the responsibilities of all parties in the arrangement. For collaboration arrangements within the scope of Topic 808 that contain multiple units of account, we first determine which units of account within the arrangement are within the scope of Topic 808 and which elements are within the scope of Topic 606. For units of account within collaboration arrangements that are accounted for pursuant to Topic 808, an appropriate recognition method is determined and applied consistently, by analogy to authoritative accounting literature. For elements of collaboration arrangements that are accounted for pursuant to Topic 606, we recognize revenue as discussed above. Consideration received that does not meet the requirements to satisfy Topic 606 revenue recognition criteria is recorded as deferred revenue in the accompanying Balance Sheets, classified as either current or long-term deferred revenue based on our best estimate of when such amounts will be recognized.

### **Cost of Revenue**

Cost of revenue primarily includes external costs paid to third party contractors to perform research, conduct clinical trials and develop and manufacture drug materials, and internal compensation and related personnel expenses to support our research and development performance obligations associated with the Helsinn License Agreement which was terminated in November 2021.

### **Research and Development**

Research and development costs are expensed as incurred and include costs paid to third party contractors to perform research, conduct clinical trials and develop and manufacture drug materials. Clinical trial costs, including costs associated with third party contractors, are a significant component of research and development expenses. We expense research and development costs based on work performed. In determining the amount to expense, management relies on estimates of total costs based on contract components completed, the enrollment of subjects, the completion of trials, and other events. Costs incurred related to the purchase or licensing of in-process research and development for early-stage products or products that are not commercially viable and ready for use, or have no alternative future use, are charged to expense in the period incurred.

### **Share-Based Compensation**

Share-based compensation expense for stock options and restricted stock units ("RSUs") granted to employees and directors is recognized in the Statements of Operations based on estimated amounts. The cost of stock options is measured at the grant date, based on the estimated fair value of the stock option using the Black-Scholes valuation model, which incorporates various assumptions including expected volatility, risk-free interest rate, the expected term of the award and the dividend yield on the underlying stock. Expected volatility is calculated based on the historical volatility of our stock over the expected option life and other appropriate factors. The expected option term is computed using the "simplified" method as permitted under the provisions of ASC 718-10-S99. We use the simplified method to calculate the expected term of share options and similar instruments as we do not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. Risk-free interest rates are calculated based on continuously compounded risk-free rates for the appropriate term. The dividend yield is assumed to be zero as we have never paid or declared any cash dividends and does not intend to do so in the foreseeable future. For RSUs, we estimate the grant date fair value using our closing stock price on the date of grant. The estimated fair value of stock options and RSUs is amortized on a straight-line basis over the requisite service period, adjusted for actual forfeitures at the time they occur. The requisite service period is generally the time over which our share-based awards vest.

### Interest and Dividend Income

Interest on cash balances is recognized when earned. Dividend income is recognized when the right to receive the payment is established.

### Income Taxes

Our income tax expense consists of current and deferred income tax expense or benefit. Current income tax expense or benefit is the amount of income taxes expected to be payable or refundable for the current year. A deferred income tax asset or liability is recognized for the future tax consequences attributable to tax credits and loss carryforwards and to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized. As of June 30, 2022 and 2021, we have established a valuation allowance to fully reserve our net deferred tax assets. Tax rate changes are reflected in income during the period such changes are enacted. Changes in our ownership may limit the amount of net operating loss carryforwards that can be utilized in the future to offset taxable income.

The FASB Topic on income taxes prescribes a recognition threshold and measurement attribute criteria for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more-likely-than-not to be sustained upon examination by taxing authorities. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. There were no unrecognized tax benefits as of June 30, 2022 and 2021.

### Net Loss Per Share

Basic and diluted net loss per share are computed using the weighted-average number of shares of common stock outstanding during the period, less any shares subject to repurchase or forfeiture. There were no shares of common stock subject to repurchase or forfeiture for the years ended June 30, 2022, 2021 and 2020. Our potentially dilutive shares, which include outstanding stock options, restricted stock units, and warrants, are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive. The assessment of dilution is made on a quarterly basis and therefore the annual determination of diluted net loss per share only includes those quarters in which the potential common stock equivalents were determined to be dilutive.

The following table presents the calculation of net loss used to calculate basic and diluted loss per share for the periods presented (in thousands):

	Years Ended June 30,		
	2022	2021	2020
Net loss—basic	<u>\$ (54,454)</u>	<u>\$ (41,314)</u>	<u>\$ (47,173)</u>
Change in fair value of warrant liability	<u>(8,046)</u>	<u>(27,394)</u>	<u>—</u>
Net loss—diluted	<u>\$ (62,500)</u>	<u>\$ (68,708)</u>	<u>\$ (47,173)</u>

## [Table of Contents](#)

Shares used in calculating net loss per share for the periods presented was determined as follows (in thousands):

	Years Ended June 30,		
	2022	2021	2020
Weighted average shares used in calculating basic net loss per share	6,224	5,626	4,554
Effect of potentially dilutive common shares from equity awards and liability-classified warrants	33	98	—
Weighted average shares used in calculating diluted net loss per share	<u>6,257</u>	<u>5,724</u>	<u>4,554</u>

The following potentially dilutive shares have been excluded from the calculation of net loss per share for the periods presented because of their anti-dilutive effect (in thousands):

	Years Ended June 30,		
	2022	2021	2020
Stock options	1,024	794	552
Warrants	402	201	803
Restricted stock units	11	21	—
Total anti-dilutive shares	<u>1,437</u>	<u>1,016</u>	<u>1,355</u>

### Recent Account Pronouncement

In June 2016, the FASB issued ASU 2016-13, as amended. The amendments in ASU 2016-13 require, among other things, financial assets measured at amortized cost basis to be presented at the net amount expected to be collected as compared to previous U.S. GAAP which delayed recognition until it was probable a loss had been incurred. The amendments in this standard are effective for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years, with early adoption permitted. We are currently evaluating the impact that adoption of ASU 2016-13 will have on our financial statements and related disclosures.

### Note 2. KKC License, Development and Commercialization Agreement

In April 2020, we entered into the License, Development and Commercialization Agreement (the “KKC Commercialization Agreement”) with Kyowa Kirin Company (“KKC”). Under the KKC Commercialization Agreement, we granted to KKC a co-exclusive, sublicensable, payment-bearing license under certain patents and know-how controlled by us to develop and commercialize zandelisib and any pharmaceutical product containing zandelisib for all human indications in the U.S. (the “U.S. License”), and an exclusive (subject to certain retained rights to perform obligations under the KKC Commercialization Agreement), sublicensable, payment-bearing, license under certain patents and know-how controlled by us to develop and commercialize zandelisib and any pharmaceutical product containing zandelisib for all human indications in countries outside of the U.S. (the “Ex-U.S.” or the “Ex-U.S. License”). KKC granted to us a co-exclusive, sublicensable, license under certain patents and know-how controlled by KKC to develop and commercialize zandelisib for all human indications in the U.S., and a co-exclusive, sublicensable, royalty-free, fully paid license under certain patents and know-how controlled by KKC to perform our obligations in the Ex-U.S. under the KKC Commercialization Agreement. KKC paid us an initial payment of \$100 million in May 2020. Additionally, we may earn up to approximately \$582.5 million in potential development, regulatory and commercialization milestone payments, plus royalties on net sales of zandelisib in the Ex-U.S., which are tiered beginning in the teens.

KKC will be responsible for the development and commercialization of zandelisib in the Ex-U.S. and, subject to certain exceptions, will be solely responsible for all costs related thereto. We will co-develop and

## Table of Contents

co-promote zandelisib with KKC in the U.S., with the Company recording all revenue from U.S. sales. We will share U.S. profits and costs (including development costs) on a 50-50 basis with KKC. We will also provide to KKC certain drug supplies necessary for the development and commercialization of zandelisib in the Ex-U.S., with the understanding that KKC will assume responsibility for manufacturing for the Ex-U.S. as soon as practicable.

We assessed the KKC Commercialization Agreement in accordance with Topic 808 and Topic 606 and determined that our obligations comprise the U.S. License, the Ex-U.S. License, and development services (the “Development Services”). We determined that the KKC Commercialization Agreement is a collaborative arrangement in accordance with Topic 808 that contains multiple units of account, as we and KKC are both active participants in the development and commercialization activities and are exposed to significant risks and rewards that are dependent on commercial success of the activities of the arrangement. The U.S. License is a unit of account under the scope of Topic 808 and is not a deliverable under Topic 606, while the Ex-U.S. License and Development Services performance obligations are under the scope of Topic 606.

We determined, at the time of our initial assessment, that the total transaction price of \$191.5 million is comprised of the upfront payment of \$100.0 million, expected milestone payments of \$20.0 million, estimated variable consideration related to development cost-sharing of \$66.3 million, and deferred revenue of \$5.2 million from the KKC Commercialization Agreement. During the year ended June 30, 2022, we updated our estimate of variable consideration related to development cost sharing to \$234.9 million. We increased our estimate primarily as a result of further visibility into total expected costs for these development estimates. Any variable consideration related to sales-based royalties and commercial milestones related to licenses of intellectual property will be determined when the sale or usage occurs and is, therefore, excluded from the transaction price. In addition, we are eligible to receive future development and regulatory milestones upon the achievement of certain criteria; however, these amounts are excluded from variable consideration as the risk of significant revenue reversal will only be resolved depending on future research and development and/or regulatory approval outcomes. We re-evaluate the estimated variable consideration included in the transaction price and any related constraints at the end of each reporting period.

We allocated the transaction price to each unit of account. Variable consideration that relates specifically to our efforts to satisfy specific performance obligations are allocated entirely to those performance obligations. Other components of the transaction price are allocated based on the relative stand-alone selling price, over which management has applied significant judgment. We developed the estimated stand-alone selling price for the licenses using the risk-adjusted net present values of estimated cash flows, and the estimated stand-alone selling price of the development services performance obligations by estimating costs to be incurred, and an appropriate margin, using an income approach.

We determined that control of the U.S. License and Ex-U.S. License were transferred to KKC during the year ended June 30, 2020, and recognized revenue of \$21.0 million related to the Ex-U.S. License. The \$64.5 million transaction price allocated to the U.S. License obligation accounted for under Topic 808 is recorded as non-current deferred revenue and will begin to be recognized upon future commercialization as non-ASC 606 revenue. As of June 30, 2022 and 2021, we recorded deferred revenue of \$30.9 million and \$14.7 million, respectively, for the transaction price allocated to the Development Services performance obligations, and we are recognizing this revenue based on the proportional performance of these development activities which we expect to recognize through fiscal year 2030.

### **Note 3. BeiGene Collaboration**

In October 2018, we entered into a clinical collaboration with BeiGene, Ltd. (“BeiGene”) to evaluate the safety and efficacy of zandelisib in combination with BeiGene’s zanubrutinib (marketed as Brukinsa), an investigational inhibitor of Bruton’s tyrosine kinase (“BTK”), for the treatment of patients with B-cell malignancies. Under the terms of the clinical collaboration agreement with BeiGene, we amended our ongoing

## [Table of Contents](#)

Phase 1b trial to include evaluation of zandelisib in combination with zanubrutinib in patients with B-cell malignancies. Study costs are being shared equally by the parties, and we agreed to supply zandelisib and BeiGene agreed to supply zanubrutinib. We record the costs reimbursed by BeiGene as a reduction of our research and development expenses. We retained full commercial rights for zandelisib, and BeiGene retained full commercial rights for zanubrutinib.

### **Note 4. Other License Agreements**

#### *Presage License Agreement*

In September 2017, we, as licensee, entered into a license agreement with Presage Biosciences, Inc. (“Presage”). Under the terms of the license agreement, Presage granted to us exclusive worldwide rights to develop, manufacture and commercialize voruciclib, a clinical-stage, oral and selective CDK inhibitor, and related compounds. In exchange, we paid \$2.9 million to Presage. With respect to the first indication, an incremental \$2.0 million payment, due upon dosing of the first subject in the first registration trial, will be owed to Presage, for total payments of \$4.9 million prior to receipt of marketing approval of the first indication in the U.S., EU or Japan. Additional potential payments of up to \$179 million will be due upon the achievement of certain development, regulatory and commercial milestones. We will also pay mid-single digit tiered royalties on the net sales of any product successfully developed. As an alternative to milestone and royalty payments related to countries in which we sublicense product rights, we will pay to Presage a tiered percentage (which decreases as product development progresses) of amounts received from such sublicensees.

#### *Helsinn License Agreement*

In August 2016, we entered into an exclusive worldwide license, development, manufacturing and commercialization agreement with Helsinn Healthcare SA, a Swiss pharmaceutical corporation, for pracinostat in acute myeloid leukemia, myelodysplastic syndrome and other potential indications (the “Helsinn License Agreement”). As of June 30, 2021, our performance obligations related to the Helsinn License Agreement had been met, and the Helsinn License Agreement was terminated in November 2021.

### **Note 5. Fair Value Measurements**

The carrying amounts of financial instruments such as cash equivalents, short-term investments and accounts payable approximate the related fair values due to the short-term maturities of these instruments. We invest our excess cash in financial instruments which are readily convertible into cash, such as money market funds and U.S. government securities. Cash equivalents and short-term investments are classified as Level 1 as defined by the fair value hierarchy.

In May 2018, we issued warrants in connection with our private placement of shares of common stock. Pursuant to the terms of the warrants, we could be required to settle the warrants in cash in the event of an acquisition of the Company and, as a result, the warrants are required to be measured at fair value and reported as a liability in the Balance Sheets. We recorded the fair value of the warrants upon issuance using the Black-Scholes valuation model and are required to revalue the warrants at each reporting date with any changes in fair value recorded on our Statements of Operations. The valuation of the warrants is considered under Level 3 of the fair value hierarchy due to the need to use assumptions in the valuation that are both significant to the fair value measurement and unobservable. Inputs used to determine the estimated fair value of the warrant liabilities include the estimated fair value of the underlying stock at the valuation date, the estimated term of the warrants, risk-free interest rates, expected dividends and the expected volatility of the underlying stock. The significant unobservable inputs used in the fair value measurement of the warrant liabilities were the volatility rate and the estimated term of the warrants. Generally, increases or decreases in the fair value of the underlying stock and estimated term would result in a directionally similar impact to the fair value measurement. The changes in the fair value of the Level 3 warrant liability are reflected on the Statements of Operations for the years ended June 30, 2022, 2021 and 2020.

## [Table of Contents](#)

To calculate the fair value of the warrant liability, the following assumptions were used for the periods presented:

	June 30,	
	2022	2021
Risk-free interest rate	2.8%	0.2%
Expected life (years)	0.9	1.9
Expected volatility	139.4%	88.5%
Dividend yield	0.0%	0.0%
Black-Scholes fair value	\$ 2.00	\$27.80

The following table sets forth a summary of changes in the estimated fair value of our Level 3 warrant liability for the years ended June 30, 2022 and 2021 (in thousands):

	Fair Value of Warrants Using Significant Unobservable Inputs (Level 3)	
	2022	2021
<b>Balance at July 1,</b>	\$ 22,355	\$ 40,483
Reclassification of warrant liability to equity upon exercise of warrants	—	(6)
Change in estimated fair value of liability classified warrants	(20,752)	(18,122)
<b>Balance at June 30,</b>	<u>\$ 1,603</u>	<u>\$ 22,355</u>

## Note 6. Property and Equipment

Property and equipment consisted of the following, in thousands:

	June 30,	
	2022	2021
Furniture and equipment	\$1,254	\$ 896
Leasehold improvements	1,054	941
	2,308	1,837
Less: accumulated depreciation	(648)	(330)
Property and equipment, net	<u>\$1,660</u>	<u>\$1,507</u>

Depreciation expense of property and equipment for the years ended June 30, 2022, 2021 and 2020 was approximately \$326,000, \$285,000 and \$75,000, respectively.



**Note 7. Accrued Liabilities**

Accrued liabilities consisted of the following, in thousands:

	June 30,	
	2022	2021
Accrued pre-clinical and clinical trial expenses	\$ 5,264	\$4,004
Accrued compensation and benefits	4,346	3,513
Accrued legal and professional services expenses	1,036	813
Other	174	72
Total accrued liabilities	<u>\$10,820</u>	<u>\$8,402</u>

**Note 8. Stockholders' Equity****Equity Transactions***Underwritten Registered Offering*

During the year ended June 30, 2022, we completed an underwritten registered offering of 1,006,250 shares of common stock at a price per share of \$52.00 for net cash proceeds of \$48.7 million, after offering costs of \$3.7 million. During the year ended June 30, 2020, we completed an underwritten registered offering of 1,617,188 shares of common stock at a price per share of \$32.00 for net cash proceeds of \$48.5 million, after offering costs of \$3.3 million.

*Shelf Registration Statement*

We have a shelf registration statement that permits us to sell, from time to time, up to \$200.0 million of common stock, preferred stock and warrants. The shelf registration was filed and declared effective in May 2020, replacing our prior shelf registration statement that was filed and declared effective in May 2017, and carrying forward approximately \$107.5 million of unsold securities registered under the prior shelf registration statement. As of June 30, 2022, there was \$123.4 million aggregate value of securities available under the shelf registration statement.

*At-The-Market Equity Offering*

On November 10, 2020, we entered into an At-The-Market Equity Offering Sales Agreement (the "2020 ATM Sales Agreement"), pursuant to which we may sell an aggregate of up to \$60.0 million of our common stock pursuant to the shelf registration statement. We had previously entered into an At-The-Market Equity Offering Sales Agreement in November 2017 (the "2017 ATM Sales Agreement"), pursuant to which we could sell an aggregate of up to \$30.0 million of our common stock pursuant to the shelf registration statement. The 2017 ATM Sales Agreement expired on November 8, 2020. During the year ended June 30, 2020, we sold 273,584 shares under the 2017 ATM Sales Agreement for net proceeds of \$20.7 million, after costs of \$0.4 million. During the year ended June 30, 2021, we sold 47,904 shares under the 2017 ATM Sales Agreement for net proceeds of \$3.1 million, after costs of \$0.1 million. As of June 30, 2022, there was \$60.0 million available under the 2020 ATM Sales Agreement.

*Warrants*

As of June 30, 2022, we have outstanding warrants to purchase 802,949 shares of our common stock. The warrants are fully vested, exercisable at a price of \$50.80 per share and expire in May 2023. Pursuant to the terms of the warrants, we could be required to settle the warrants in cash in the event of an acquisition of the Company and, as a result, the warrants are required to be measured at fair value and reported as a liability in the Balance Sheets. The warrants were revalued as of June 30, 2022, 2021 and 2020 at \$1.6 million, \$22.4 million and

## [Table of Contents](#)

\$40.5 million, respectively. The changes in fair value were recorded on our Statements of Operations for the years ended June 30, 2022, 2021 and 2020. During the year ended June 30, 2021, a warrant holder completed a cashless exercise of 131 warrants for 48 shares of common stock. No warrants were exercised during the years ended June 30, 2022 and 2020.

### **Description of Capital Stock**

Our total authorized share capital is 226,100,000 shares consisting of 226,000,000 shares of common stock, \$0.00000002 par value per share, and 100,000 shares of preferred stock, \$0.01 par value per share.

#### *Common Stock*

The holders of common stock are entitled to one vote per share. In the event of a liquidation, dissolution or winding up of our affairs, holders of the common stock will be entitled to share ratably in all our assets that are remaining after payment of our liabilities and the liquidation preference of any outstanding shares of preferred stock. All outstanding shares of common stock are fully paid and non-assessable. The rights, preferences and privileges of holders of common stock are subject to any series of preferred stock that we have issued or that we may issue in the future. The holders of common stock have no pre-emptive rights and are not subject to future calls or assessments by us.

#### *Preferred Stock*

Our board of directors has the authority to issue up to 100,000 shares of preferred stock with a par value of \$.01 per share in one or more series and to fix the rights, preferences, privileges and restrictions in respect of that preferred stock, including dividend rights, dividend rates, conversion rights, voting rights, terms of redemption (including sinking fund provisions), redemption prices and liquidation preferences, and the number of shares constituting such series and the designation of any such series, without future vote or action by the stockholders. Therefore, the board of directors, without the approval of the stockholders, could authorize the issue of preferred stock with voting, conversion and other rights that could affect the voting power, dividend and other rights of the holders of shares or that could have the effect of delaying, deferring or preventing a change of control. There were no shares of preferred stock outstanding as of June 30, 2022 or 2021.

### **Note 9. Share-Based Compensation**

We use equity-based compensation programs to provide long-term performance incentives for our employees. These incentives consist primarily of stock options and RSUs. In December 2008, we adopted the MEI Pharma, Inc. 2008 Stock Omnibus Equity Compensation Plan (the "Omnibus Plan"), as amended and restated from time to time, under which 1,450,740 shares of common stock are authorized for issuance. The Omnibus Plan provides for the grant of options and/or other stock-based or stock-denominated awards to our non-employee directors, officers, employees and advisors. As of June 30, 2022, there were 457,733 shares available for future grant under the Omnibus Plan.

In May 2021, we adopted the 2021 Inducement Plan ("Inducement Plan"), under which 125,000 shares of common stock are authorized for issuance. The Inducement Plan is intended to assist us in attracting and retaining selected individuals to serve as employees who are expected to contribute to our success, by providing an inducement for such individuals to enter into employment with us, and to achieve long-term objectives that will benefit stockholders of the Company. As of June 30, 2022, there were 7,150 shares available for future grant under the Inducement Plan.

## [Table of Contents](#)

Total share-based compensation expense for all stock awards consists of the following, in thousands:

	Years Ended June 30,		
	2022	2021	2020
Research and development	\$2,610	\$ 4,144	\$2,777
General and administrative	5,740	6,101	4,024
Total share-based compensation	<u>\$8,350</u>	<u>\$10,245</u>	<u>\$6,801</u>

### *Stock Options*

Stock options granted to employees vest 25% one year from the date of grant and ratably each month thereafter for a period of 36 months and expire ten years from the date of grant. Stock options granted to directors vest ratably each month for a period of 12 months from the date of grant and expire ten years from the date of grant. As of June 30, 2022, there were a total of 996,700 options outstanding. Of the total outstanding options, 878,850 were granted under the Omnibus Plan and 117,850 were granted under the Inducement Plan.

A summary of our stock option activity and related data follows:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at June 30, 2021	833,427	\$ 60.20		
Granted	356,237	\$ 51.40		
Exercised	(17,428)	\$ 32.80		
Forfeited	(175,536)	\$ 63.00		
Outstanding at June 30, 2022	<u>996,700</u>	\$ 57.00	7.4	\$ 50,600
Vested and exercisable at June 30, 2022	<u>542,232</u>	\$ 59.00	6.2	\$ —

As of June 30, 2022, the aggregate intrinsic value of outstanding options is calculated as the difference between the exercise price of the underlying options and the closing price of our common stock of \$12.20 on that date. The total fair value of options that vested during the years ended June 30, 2022, 2021 and 2020 was \$9.0 million, \$6.4 million and \$5.4 million, respectively.

Unrecognized compensation expense related to non-vested stock options totaled \$6.6 million as of June 30, 2022. Such compensation expense is expected to be recognized over a weighted-average period of 1.7 years. As of June 30, 2022, we expect all outstanding options to vest.

We use a Black-Scholes valuation model to estimate the grant date fair value of stock options. To calculate these fair values, the following weighted-average assumptions were used:

	Years Ended June 30,		
	2022	2021	2020
Risk-free interest rate	1.3%	0.5%	1.7%
Expected life (years)	6.0	6.0	6.0
Expected volatility	69.6%	80.1%	74.1%
Dividend yield	0.0%	0.0%	0.0%
Weighted-average grant date fair value	\$31.40	\$46.00	\$32.80

## [Table of Contents](#)

### *Restricted Stock Units*

A summary of our RSU activity and related data follows:

	Number of RSUs	Weighted-Average Grant Date Fair Value
Non-vested at June 30, 2021	20,033	\$ 69.80
Vested	(6,500)	\$ 69.80
Forfeited	(4,313)	\$ 69.80
Non-vested at June 30, 2022	<u>9,220</u>	\$ 69.80

Each RSU represents the contingent right to receive one share of our common stock. Under the terms of the Omnibus Plan, each of the RSUs is calculated as 1.25 shares of common stock for purposes of determining the number of shares available for future grant. As of June 30, 2022, unrecognized compensation expense related to the unvested portion of our RSUs was *de minimis*.

### **Note 10. Commitments and Contingencies**

We have contracted with various consultants and third parties to assist us in pre-clinical research and development and clinical trials work for our leading drug compounds. The contracts are terminable at any time, but obligate us to reimburse the providers for any time or costs incurred through the date of termination. We also have employment agreements with certain of our current employees that provide for severance payments and accelerated vesting for share-based awards if their employment is terminated under specified circumstances.

#### *Presage License Agreement*

As discussed in Note 4. Other License Agreements, we are party to a license agreement with Presage under which we may be required to make future payments upon the achievement of certain development, regulatory and commercial milestones, as well as potential future royalties based upon net sales. As of June 30, 2022, we had not accrued any amounts for potential future payments as achievement of the milestones had not been met.

#### *COVID-19*

As a result of the ongoing COVID-19 pandemic, various public health orders and guidance measures have been implemented across much of the U.S., and across the globe, including in the locations of our office, clinical trial sites, key vendors and partners. Despite the relaxation of many governmental orders earlier this year, the ongoing COVID-19 pandemic still impacts the normal conduct of business. While we continue to enroll and dose patients in our clinical trials, our clinical development program timelines may continue to be subject to potential negative impacts from the ongoing pandemic in the U.S. and globally.

We may experience enrollment delays and suspensions, patient withdrawals, postponement of planned clinical or preclinical studies, redirection of site resources from studies, and study deviations or noncompliance. We may also need to maintain or implement study modifications, suspensions, or terminations, the introduction of additional remote study procedures and modified informed consent procedures, study site changes, direct delivery of investigational products to patient homes or alternative sites, which may require state licensing, and changes or delays in site monitoring. The foregoing may require that we consult with relevant review and ethics committees, Institutional Review Boards and the FDA. The foregoing may also impact the integrity of our study data. The ongoing COVID-19 pandemic may further increase the need for clinical trial patient monitoring and regulatory reporting of adverse effects, and may delay regulatory authority meetings, inspections, assessments, or the regulatory review of marketing or investigational applications or submissions.

## [Table of Contents](#)

Not only might the ongoing COVID-19 pandemic impact the conduct of our clinical trials, but it may also impact our ability to procure the necessary supply of our investigational drug products, as well as any ancillary supplies necessary for the conduct of our studies. Third party manufacturers may also need to implement measures and changes, or deviate from typical manufacturing requirements that may otherwise adversely impact our product candidates.

Government stimulus programs enacted in response to the ongoing COVID-19 pandemic have not had a material impact on our financial condition, results of operations, or liquidity.

### *Nasdaq Bid Price Letter*

On May 9, 2022, we received a letter from Nasdaq indicating that, for the last thirty consecutive business days, the bid price for our common stock had closed below the minimum \$1.00 per share requirement for continued listing on the Nasdaq Capital Market.

In accordance with Nasdaq listing rules, we were provided an initial period of 180 calendar days, or until November 7, 2022, to regain compliance. The letter states that Nasdaq will provide written notification that we have achieved compliance with its rules if at any time before November 7, 2022, the bid price of our common stock closes at \$1.00 per share or more for a minimum of ten consecutive business days. The Nasdaq letter had no immediate effect on the listing or trading of our common stock and the common stock continued to trade on The Nasdaq Capital Market.

If we do not regain compliance with Nasdaq listing rules by November 7, 2022, we may be eligible for an additional 180 calendar day compliance period. To qualify, we would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for the Nasdaq Capital Market, with the exception of the bid price requirement, and would need to provide written notice of our intention to cure the deficiency during the second compliance period, by effecting a reverse stock split, if necessary. However, if it appears to Nasdaq that we will not be able to cure the deficiency, or if we are otherwise not eligible, Nasdaq would notify us that our securities would be subject to delisting. In the event of such a notification, we may appeal Nasdaq's determination to delist our securities, but there can be no assurance Nasdaq would grant our request for continued listing.

We have not regained compliance with Nasdaq listing rules as of September 8, 2022.

### **Note 11. Leases**

In July 2020, we entered into a lease agreement (the "Initial Lease Agreement") for approximately 32,800 square feet of office space in San Diego, California. The Lease Agreement was scheduled to expire in March 2028 but was extended by 20 months to November 2029 in accordance with the amended lease agreement we entered into in January 2022 (the "Amended Lease Agreement"). The Initial and Amended Lease Agreements are collectively referred to as the lease agreements. The lease agreements contain rent escalations over the lease term. We have accounted for the lease agreements as operating leases. The lease agreements contain an option to renew and extend the lease term, which is not included in the determination of the ROU asset and operating lease liability, as it was not reasonably certain to be exercised. Upon commencement of the Amended Lease Agreement, to extend the lease term, we recognized an additional operating lease ROU asset and a corresponding operating lease liability. The lease agreements include variable non-lease components (e.g., common area maintenance, maintenance, etc.) that are not included in the ROU asset and operating lease liability and are reflected as an expense in the period incurred.

The Amended Lease Agreement also provides for an additional 12,300 square feet of office space adjacent to our current office in San Diego, beginning on July 1, 2022, for approximately 45,100 square feet of office space, which will be accounted for as an additional ROU asset and operating lease liability once we obtain control of the additional lease space. Our total contractual obligation for the additional lease space is \$5.7 million.

## [Table of Contents](#)

The total operating lease costs for the Lease Agreement were as follows for the periods presented (in thousands):

	Years Ended June 30,		
	2022	2021	2020
Operating lease cost	\$1,583	\$1,507	\$692

Supplemental cash flow information related to our operating leases was as follows for the periods presented (in thousands):

	Years Ended June 30,		
	2022	2021	2020
Cash paid for amounts included in the measurement of lease liabilities:			
Operating cash flows from operating leases	\$1,519	\$ 983	\$—
Right-of-use assets obtained in exchange for operating lease obligations:	\$2,189	\$8,689	\$—

The following is a schedule of the future minimum rental payments for our operating leases, reconciled to the lease liability as of June 30, 2022 (in thousands):

	June 30, 2022
Years ending June 30,	
2023	\$ 1,565
2024	1,612
2025	1,168
2026	1,710
2027	1,761
Thereafter	5,090
Total lease payments	12,906
Less: Present value discount	(3,264)
Total operating lease liability	<u>\$ 9,642</u>
<b>Balance Sheet Classification—Operating Leases</b>	
Operating lease liability	\$ 871
Operating lease liability, long-term	8,771
Total operating lease liability	<u>\$ 9,642</u>
<b>Other Balance Sheet Information—Operating Leases</b>	
Weighted average remaining lease term (in years)	7.4
Weighted average discount rate	7.50%

### Note 12. Segment Information

We have one operating segment which is the development of pharmaceutical compounds. All of our assets and liabilities were located in the U.S. as of June 30, 2022 and 2021.

**Note 13. Income Taxes**

Pre-tax loss consists of the following jurisdictions (in thousands):

	Years Ended June 30,		
	2022	2021	2020
Domestic	\$ (54,454)	\$ (41,306)	\$ (47,172)
Foreign	—	—	—
Pre-tax loss	<u>\$ (54,454)</u>	<u>\$ (41,306)</u>	<u>\$ (47,172)</u>

The reconciliation of income tax computed at the U.S. federal statutory tax rates to income tax expense is as follows (in thousands):

	Years Ended June 30,					
	2022		2021		2020	
	\$	%	\$	%	\$	%
Tax benefit at U.S. statutory rates	\$ 11,435	21%	\$ 8,674	21%	\$ 9,906	21%
State tax	191	0%	(99)	0%	9	0%
Warrant liability costs	4,358	8%	3,806	9%	(4,803)	(10)%
Equity compensation	(71)	0%	(6)	0%	(2)	0%
Increase in valuation allowance	(15,473)	(28)%	(10,536)	(26)%	(4,473)	(10)%
Other	(440)	(1)%	(1,847)	(4)%	(638)	(1)%
	<u>\$ 0</u>	<u>0%</u>	<u>\$ (8)</u>	<u>0%</u>	<u>\$ (1)</u>	<u>0%</u>

Deferred tax liabilities and assets are comprised of the following (in thousands):

	June 30,	
	2022	2021
Deferred tax assets (liabilities):		
Deferred revenue	\$ 20,362	\$ 16,637
Fixed and intangible assets	13,283	15,924
Share-based payments	4,869	4,182
Tax losses carried forward	29,581	16,104
Compensation accruals	927	727
Consultant and other accruals	25	22
Right-of-use assets	(1,932)	(1,633)
Lease liabilities	2,057	1,742
Charitable contributions	7	1
Total deferred tax assets (liabilities)	<u>69,179</u>	<u>53,706</u>
Valuation allowance for deferred tax assets	<u>(69,179)</u>	<u>(53,706)</u>
Net deferred tax assets and liabilities	<u>\$ —</u>	<u>\$ —</u>

We evaluate the recoverability of the deferred tax assets and the amount of the required valuation allowance. Due to the uncertainty surrounding the realization of the tax deductions in future tax returns, we have recorded a valuation allowance against our net deferred tax assets as of June 30, 2022 and 2021. At such time as it is determined that it is more likely than not that the deferred tax assets will be realized, the valuation allowance would be reduced.

We had federal and state net operating loss carryforwards of approximately \$133.9 million and \$23.8 million as of June 30, 2022. The federal net operating loss will carry forward indefinitely subject to an 80% taxable income limitation. The state net operating loss carryforwards will begin to expire in 2030 unless previously utilized.

---

## [Table of Contents](#)

Our ability to utilize our net operating loss carryforwards may be substantially limited due to ownership changes that have occurred or that could occur in the future under Section 382 of the Internal Revenue Code and similar state laws. During 2022, we completed a study to analyze whether one or more ownership changes had occurred and determined that two such ownership changes did occur. While the ownership changes do limit the amount of net operating loss we are able to use each year, all of our net operating losses are expected to be available for utilization prior to expiring.

None of our prior income tax returns have been selected for examination by a major taxing jurisdiction; however, the statutes of limitations for various filings remain open. The oldest filings subject to potential examination for federal and state purposes are 2019 and 2018, respectively. If we utilize a net operating loss related to a closed tax year, the tax year in which the loss was incurred is subject to adjustment up to the amount of the net operating loss.

We have not reduced any tax benefit on our financial statements due to uncertain tax positions as of June 30, 2022 and we are not aware of any circumstance that would significantly change this result through the end of fiscal year 2022. To the extent we incur income-tax related penalties or interest, we will recognize them as additional income tax expense.



[Table of Contents](#)

**Index to Financial Statements of Infinity Pharmaceuticals, Inc.**

<a href="#">Report of Independent Registered Public Accounting Firm (PCAOB ID: 42)</a>	F-48
<a href="#">Consolidated Balance Sheets at December 31, 2022 and 2021</a>	F-50
<a href="#">Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2022 and 2021</a>	F-51
<a href="#">Consolidated Statements of Cash Flows for the years ended December 31, 2022 and 2021</a>	F-52
<a href="#">Consolidated Statements of Stockholders' (Deficit) Equity for the years ended December 31, 2022 and 2021</a>	F-53
<a href="#">Notes to Consolidated Financial Statements</a>	F-54

## [Table of Contents](#)

### Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Infinity Pharmaceuticals, Inc.

### Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Infinity Pharmaceuticals, Inc. (the Company) as of December 31, 2022 and 2021, the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows for each of the two years in the period ended December 31, 2022, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2022, in conformity with U.S. generally accepted accounting principles.

### The Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has suffered recurring losses from operations, has limited financial resources, and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

### Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

### Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially

## Table of Contents

challenging, subjective or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the account or disclosure to which it relates.

### Accrued Clinical Expenses

#### *Description of the Matter*

The Company's accrual for clinical expenses totaled \$4.3 million as of December 31, 2022. As discussed in Note 2 to the consolidated financial statements, the Company is required to estimate accruals for clinical expenses using judgment based on certain information, including actual costs incurred or level of effort expended, as provided by its vendors. Payments for such activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred.

Auditing the Company's accrual for clinical expenses was complex and judgmental, as the amounts are based on various estimates from third-party vendors, including patient enrollment. Furthermore, due to the duration of the Company's ongoing clinical activities and the timing of invoicing received from third parties, the actual amounts incurred are not typically known by the date the financial statements are issued.

#### *How We Addressed the Matter in Our Audit*

To evaluate the accruals for clinical expenses, our audit procedures included, among others, testing the accuracy and completeness of the underlying data used in the estimates and evaluating the significant judgments and estimates noted above that are used by management to estimate the amounts recorded. We corroborated the progress of clinical activities through discussion with the Company's research and development personnel that oversee the clinical projects. We also inspected the Company's contracts with third parties and any pending change orders to assess the impact on amounts recorded. Additionally, we reviewed information received by the Company directly from certain sites and other third parties, which included third parties' estimates of costs incurred to date. We also performed analytical procedures over fluctuations in accruals by vendor, study, or other significant work orders throughout the period subject to audit and inspected subsequent invoices received from third parties to assess the impact to the accrual.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2001.

Boston, Massachusetts

March 28, 2023

## INFINITY PHARMACEUTICALS, INC.

## Consolidated Balance Sheets

(in thousands, except share and per share amounts)

	December 31,	
	2022	2021
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 38,313	\$ 80,726
Prepaid expenses and other current assets	1,989	1,542
<b>Total current assets</b>	<b>40,302</b>	<b>82,268</b>
Property and equipment, net	800	1,241
Restricted cash, less current portion	158	158
Operating lease right-of-use assets	697	1,064
Other assets	194	54
<b>Total assets</b>	<b>\$ 42,151</b>	<b>\$ 84,785</b>
<b>Liabilities and stockholders' (deficit) equity</b>		
Current liabilities:		
Accounts payable	\$ 4,405	\$ 2,320
Accrued expenses and other current liabilities	9,223	10,980
<b>Total current liabilities</b>	<b>13,628</b>	<b>13,300</b>
Liabilities related to sale of future royalties, net, less current portion (Note 9)	47,213	48,727
Operating lease liability, less current portion	324	917
Other liabilities	37	270
<b>Total liabilities</b>	<b>61,202</b>	<b>63,214</b>
Commitments and contingencies		
Stockholders' (deficit) equity:		
Preferred Stock, \$0.001 par value; 1,000,000 shares authorized, no shares issued and outstanding at December 31, 2022 and 2021	—	—
Common Stock, \$0.001 par value; 200,000,000 shares authorized; 89,411,471 and 89,155,311 shares issued and outstanding at December 31, 2022 and 2021, respectively	89	89
Additional paid-in capital	836,812	833,065
Accumulated deficit	(855,952)	(811,583)
<b>Total stockholders' (deficit) equity</b>	<b>(19,051)</b>	<b>21,571</b>
<b>Total liabilities and stockholders' (deficit) equity</b>	<b>\$ 42,151</b>	<b>\$ 84,785</b>

*The accompanying notes are an integral part of these consolidated financial statements.*

## INFINITY PHARMACEUTICALS, INC.

## Consolidated Statements of Operations and Comprehensive Loss

(in thousands, except share and per share amounts)

	Years Ended December 31,	
	2022	2021
Royalty revenue	\$ 2,593	\$ 1,858
Operating expenses:		
Research and development	32,411	31,647
General and administrative	13,463	14,174
Royalty expense (Note 11)	1,563	1,120
Total operating expenses	47,437	46,941
Loss from operations	(44,844)	(45,083)
Other income (expense):		
Investment and other income	655	1
Non-cash interest expense (Note 9)	(180)	(180)
Total other income (expense)	475	(179)
Net loss	\$ (44,369)	\$ (45,262)
Basic and diluted loss per common share	\$ (0.50)	\$ (0.53)
Basic and diluted weighted average number of common shares outstanding	89,247,785	85,597,264
Other comprehensive loss:		
Net unrealized holding gains on available-for-sale securities arising during the period	\$ —	\$ 1
Comprehensive loss	\$ (44,369)	\$ (45,261)

*The accompanying notes are an integral part of these consolidated financial statements.*

## INFINITY PHARMACEUTICALS, INC.

## Consolidated Statements of Cash Flows

(in thousands)

	Years Ended December 31,	
	2022	2021
Operating activities		
Net loss	\$ (44,369)	\$ (45,262)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	458	480
Stock-based compensation	3,621	2,695
Non-cash royalty revenue	(1,373)	(984)
Non-cash interest expense	180	180
Other, net	91	59
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(587)	171
Operating lease right-of-use asset	367	355
Accounts payable, accrued expenses and other liabilities	(300)	2,177
Operating lease liability	(519)	(489)
Net cash used in operating activities	(42,431)	(40,618)
Investing activities		
Purchases of property and equipment	(17)	(11)
Purchases of available-for-sale securities	(16,038)	—
Proceeds from maturities of available-for-sale securities	16,000	5,500
Net cash (used in) provided by investing activities	(55)	5,489
Financing activities		
Proceeds from public offering, net	—	85,838
Proceeds from common stock sales facility, net of issuance costs	—	336
Proceeds from issuances of common stock, net	73	931
Net cash provided by financing activities	73	87,105
Net (decrease) increase in cash, cash equivalents and restricted cash	(42,413)	51,976
Cash, cash equivalents and restricted cash at beginning of period	80,884	28,908
Cash, cash equivalents and restricted cash at end of period	<u>\$ 38,471</u>	<u>\$ 80,884</u>
Reconciliation of cash, cash equivalents, and restricted cash to the consolidated balance sheets		
Cash and cash equivalents	\$ 38,313	\$ 80,726
Restricted cash, less current portion	158	158
Total cash, cash equivalents and restricted cash	<u>\$ 38,471</u>	<u>\$ 80,884</u>

*The accompanying notes are an integral part of these consolidated financial statements.*

## INFINITY PHARMACEUTICALS, INC.

## Consolidated Statements of Stockholders' (Deficit) Equity

(in thousands, except share amounts)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive (Loss) Income	Total Stockholders' (Deficit) Equity
	Shares	Amount				
Balance at December 31, 2020	64,320,244	\$ 64	\$743,269	\$ (766,321)	\$ (1)	\$ (22,989)
Exercise of stock options	531,864	1	859			860
Stock-based compensation expense			2,695			2,695
Issuance of common stock related to public offering, net of issuance costs	24,150,000	24	85,814			85,838
Issuance of common stock related to sales facility, net of issuance costs	89,520	—	336			336
Issuance of common stock, net	63,683	—	92			92
Unrealized gain on marketable securities					1	1
Net loss				(45,262)		(45,262)
Balance at December 31, 2021	89,155,311	\$ 89	\$833,065	\$ (811,583)	\$ —	\$ 21,571
Exercise of stock options	17,708	—	15			15
Stock-based compensation expense			3,621			3,621
Issuance of common stock, net	238,452	—	111			111
Net loss				(44,369)		(44,369)
Balance at December 31, 2022	89,411,471	\$ 89	\$836,812	\$ (855,952)	\$ —	\$ (19,051)

The accompanying notes are an integral part of these consolidated financial statements.

INFINITY PHARMACEUTICALS, INC.

Notes to Consolidated Financial Statements

1. Organization

Infinity Pharmaceuticals, Inc., is a clinical-stage innovative biopharmaceutical company dedicated to developing novel medicines for people with cancer. As used throughout these audited, consolidated financial statements, the terms “Infinity,” “we,” “us,” and “our” refer to the business of Infinity Pharmaceuticals, Inc., and its wholly owned subsidiaries.

On February 22, 2023, we, MEI Pharma, Inc., a Delaware corporation, or MEI, and Merger Sub, Inc., a Delaware corporation and a wholly owned subsidiary of MEI, or the Merger Sub, entered into an Agreement and Plan of Merger, or the Merger Agreement, pursuant to which, among other matters, and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into Infinity, with Infinity continuing as a wholly owned subsidiary of MEI and the surviving corporation of the merger, which transaction is referred to herein as the Merger. If the Merger is completed, the combined company will combine the expertise and resources of MEI and Infinity to advance a pipeline of three clinical-stage oncology drug candidates.

2. Summary of Significant Accounting Policies

*Basis of Presentation*

These consolidated financial statements include the accounts of Infinity and its wholly-owned subsidiaries. We have eliminated all significant intercompany accounts and transactions in consolidation.

The preparation of consolidated financial statements in accordance with generally accepted accounting principles requires our management to make estimates and judgments that may affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates and judgments. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates under different assumptions or conditions.

*Segment Information*

We operate in one business segment, which focuses on drug development. We make operating decisions based upon the performance of the enterprise as a whole and utilize our consolidated financial statements for decision making.

*Cash Equivalents and Available-For-Sale Securities*

Cash equivalents consist of money market funds. We consider all highly liquid investments with maturities of three months or less at the time of purchase to be cash equivalents. Cash equivalents are stated at fair value. They are also readily convertible to known amounts of cash and have such short-term maturities that each presents insignificant risk of change in value due to changes in interest rates. Our classification of cash equivalents is consistent with prior periods.

From time to time we invest our cash in short-term marketable securities. We determine the appropriate classification of marketable securities at the time of purchase and re-evaluate such designation at each balance sheet date, if applicable. Typically, the marketable securities in which we invest have been classified as “available-for-sale.” We carry available-for-sale securities at fair value. Unrealized gains and losses on



## [Table of Contents](#)

available-for-sale debt securities are reported in accumulated other comprehensive (loss) income, which is a separate component of stockholders' equity. At various points during the years ended December 31, 2022 and 2021, we owned marketable securities that were classified as available-for-sale. We did not own any such securities as of December 31, 2022 or 2021.

We adjust the cost of available-for-sale debt securities for amortization of premiums and accretion of discounts to maturity. We include such amortization and accretion in investment and other income. The cost of securities sold is based on the specific identification method. We include in investment income interest and dividends on securities classified as available-for-sale.

We conduct periodic reviews to identify and evaluate each available-for-sale debt security that is in an unrealized loss position in order to determine whether an other-than-temporary impairment exists. An unrealized loss exists when the current fair value of an individual security is less than its amortized cost basis. For available-for-sale debt securities in an unrealized loss position, we perform an analysis to assess whether we intend to sell or whether we would more likely than not be required to sell the security before the expected recovery of the amortized cost basis. Where we intend to sell a security, or may be required to do so, the security's decline in fair value is deemed to be other-than-temporary, and the full amount of the unrealized loss is recorded within earnings as an impairment loss. Unrealized losses on available-for-sale debt securities that are determined to be temporary, and not related to credit loss, are recorded, net of tax, in accumulated other comprehensive loss.

Regardless of our intent to sell a security, we perform additional analysis on all securities in an unrealized loss position to evaluate losses associated with the creditworthiness of the security. Credit losses are identified where we do not expect to receive cash flows sufficient to recover the amortized cost basis of a security and are recorded within earnings as an impairment loss.

### *Liquidity and Going Concern*

As of December 31, 2022, we had cash and cash equivalents of \$38.3 million. We have primarily incurred operating losses since inception and have relied on our ability to fund our operations through collaboration and license arrangements, or other strategic arrangements, and through the sale of our common stock.

We expect to continue to spend significant resources to fund the development and potential commercialization of eganelisib, also known as IPI-549, an orally administered immuno-oncology product candidate that selectively inhibits the enzyme phosphoinositide-3-kinase gamma, or PI3K-gamma, and to incur significant operating losses for the foreseeable future.

As of December 31, 2022, we had an accumulated deficit of \$856.0 million and during the year ended December 31, 2022 used \$42.4 million in cash and cash equivalents to fund operating activities. We expect to continue to incur substantial operating losses and negative cash flows from operations for the foreseeable future. These conditions raise substantial doubt about our ability to continue as a going concern for at least twelve months from the date these consolidated financial statements are issued on March 28, 2023.

If the Merger is not completed, we will need to raise additional capital in order to successfully execute on our current operating plans to further the development of eganelisib. If the Merger is not completed, we will explore other plans to mitigate the conditions which raise substantial doubt about our ability to continue as a going concern. We consider one of the following courses of action to be the most likely alternatives if the Merger is not completed:

- *Pursue another strategic transaction.* We may resume the process of evaluating a potential strategic transaction, including the sale of the company or its assets. Based on our prior assessment, we do not expect that we would have the necessary time or financial resources to pursue another strategic transaction like the proposed Merger.

## Table of Contents

- *Wind down the company.* If the Merger does not close and we are unable to enter into another strategic transaction, our board of directors may conclude that it is in the best interest of stockholders to cease normal operations and wind down the company through bankruptcy or dissolution proceedings. In such case, there would be no assurances as to the amount or timing of available cash remaining, if any, to distribute to stockholders after paying our obligations and setting aside funds for reserves.

Our consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and settlement of liabilities and commitments in the ordinary course of business. The consolidated financial statements do not include any adjustments that might result from the outcome of the conditions described above.

### *Concentration of Credit Risk*

Cash and cash equivalents are primarily maintained with two major financial institutions in the United States. Deposits at banks may exceed the insurance provided on such deposits. Generally, these deposits may be redeemed upon demand and, therefore, bear minimal risk. From time to time the Company invests its cash in other financial instruments that potentially subject us to concentration of credit risk, primarily consisting of available-for-sale securities. Our investment policy, which has been approved by our board of directors, limits the amount that we may invest in any one issuer of investments, thereby reducing credit risk concentrations. As of December 31, 2022 and 2021, the Company did not have any cash or cash equivalents invested in available-for-sale securities.

### *Property and Equipment*

Property and equipment are stated at cost. Depreciation is recorded using the straight-line method over the estimated useful lives of the applicable assets. Application development costs incurred for computer software developed or obtained for internal use are capitalized. Upon sale or retirement, the cost and related accumulated depreciation are eliminated from the respective account, and the resulting gain or loss, if any, is included in current operations. Amortization of leasehold improvements, building improvements and finance leases is recorded as depreciation expense and included in research and development and general and administrative expense, as applicable. Repairs and maintenance charges that do not increase the useful life of the assets are charged to operations as incurred. Property and equipment are depreciated over the following periods:

Computer equipment and software	3 to 5 years
Leasehold improvements	Shorter of lease term or useful life of asset
Furniture and fixtures	7 to 10 years

### *Impairment of Long-Lived Assets*

We evaluate our long-lived assets for potential impairment. Potential impairment is assessed when there is evidence that events or changes in circumstances have occurred that indicate that the carrying amount of a long-lived asset may not be recovered. Recoverability of these assets is assessed based on undiscounted expected future cash flows from the assets, considering a number of factors, including past operating results, budgets and economic projections, market trends and product development cycles. An impairment in the carrying value of each asset is assessed when the undiscounted expected future cash flows, including its eventual residual value, derived from the asset are less than its carrying value. Impairments, if any, are recognized in earnings. An impairment loss would be recognized in an amount equal to the excess of the carrying amount over the undiscounted expected future cash flows.

### *Fair Value Measurements*

We define fair value as the price that we would receive to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. We determine fair value based on the

## [Table of Contents](#)

assumptions market participants use when pricing the asset or liability. We use a valuation hierarchy for disclosure of the inputs used to measure fair value. This hierarchy prioritizes the inputs into three broad levels. Level 1 inputs, which we consider the highest level inputs, are quoted prices (unadjusted) in active markets for identical assets or liabilities. Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument. Level 3 inputs are unobservable inputs based on our own assumptions used to measure assets and liabilities at fair value. The classification of a financial asset or liability within the hierarchy is determined based on the lowest level input that is significant to the fair value measurement.

### *Liabilities Related to Sale of Future Royalties*

We treat the liabilities related to sale of future royalties (see Note 9) as debt financings, amortized under the effective interest rate method over the estimated life of the related expected royalty stream. The liabilities related to sale of future royalties and the debt amortization are based on our current estimates of future royalties expected to be paid over the life of the arrangement. We will periodically assess the expected royalty payments using projections from external sources. To the extent our estimates of future royalty payments are greater or less than previous estimates or the estimated timing of such payments is materially different than previous estimates, we will adjust the effective interest rate and recognize related non-cash interest expense on a prospective basis. Non-cash royalty revenue is reflected as royalty revenue, and non-cash amortization of debt is reflected as non-cash interest expense in the Consolidated Statements of Operations and Comprehensive Loss.

### *Leases*

We have entered into leases for office space and a data center. As of January 1, 2019, we adopted the provisions of Accounting Standards Codification, or ASC, Topic 842, Leases, or ASC 842. Accordingly, we recorded a right-of-use asset and a corresponding lease liability related to our leases. Rights and obligations related to our leases are included within operating lease right-of-use assets, accrued expenses and other current liabilities, and operating lease liability, less current portion in the Consolidated Balance Sheets.

We recognize a right-of-use asset and a lease liability upon the commencement of a lease that has a term of more than twelve months. We combine lease and nonlease components for our leases. Lease payments included in determining the right-of-use asset and lease liability recognized include fixed payments to be paid over the term of the lease, less any lease incentives to be paid or payable to us by the lessor. Variable lease payments are included if they are based on an index or rate. Variable lease payments that are not based on an index or rate are recognized as expense in the period incurred. The lease term is determined at lease commencement, and includes the noncancellable period during which we have the right to use the underlying asset. Any period covered by an option to extend or terminate a lease is also included in the lease term if we are reasonably certain that the option to extend will be exercised or the option to terminate will not be exercised.

Our leases do not provide an implicit rate; therefore, we use an estimate of our incremental borrowing rate based on the information available at the adoption date or lease commencement date in determining the present value of lease payments.

### *Revenue Recognition*

To date, all our revenue has been generated under collaboration agreements, including payments to us of upfront license fees, funding or reimbursement of research and development efforts, milestone payments, if specified objectives are achieved, and royalties on product sales.

We recognize revenue when we transfer goods or services to customers in an amount that reflects the consideration that we expect to receive for those goods or services. These principles are applied using a five-step

## Table of Contents

model: 1) identify the customer contract; 2) identify the contract's performance obligations; 3) determine the transaction price; 4) allocate the transaction price to the performance obligations; and 5) recognize revenue when or as a performance obligation is satisfied. We evaluate all promised goods and services within a customer contract and determine which of those are separate performance obligations. This evaluation includes an assessment of whether the good or service is capable of being distinct and whether the good or service is separable from other promises in the contract. When a performance obligation is satisfied, we recognize as revenue the amount of the transaction price, excluding estimates of variable consideration that are constrained, that is allocated to that performance obligation. For contracts that contain variable consideration, such as milestone payments, we estimate the amount of variable consideration by using either the expected value method or the most likely amount method. In making this assessment, we evaluate factors such as the clinical, regulatory, commercial and other risks that must be overcome to achieve the milestone. Each reporting period we re-evaluate the probability of achievement of such milestones and any related constraints. We will include variable consideration, without constraint, in the transaction price to the extent it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

We recognize sales-based milestones and royalty revenue based upon net sales by the licensee of licensed products in licensed territories, and in the period the sales occur under the sales- and usage-based royalty exception when the sole or predominate item to which the royalty relates is a license to intellectual property.

In the event of an early termination of a collaboration agreement, any contract liabilities would be recognized in the period in which all our obligations under the agreement have been fulfilled.

### *Research and Development Expense*

Research and development expense consists of expenses incurred in performing research and development activities, including salaries and benefits, overhead expenses including facilities expenses, materials and supplies, preclinical expenses, clinical trial and related clinical manufacturing expenses, comparator and combination drug expenses, stock-based compensation expense, depreciation of property and equipment, contract services, and other outside expenses. We also include as research and development expense upfront license payments related to acquired technologies which have not yet reached technological feasibility and have no alternative use. We expense research and development costs as they are incurred. Prepaid comparator and combination drug expenses are capitalized and then recognized as expense when title transfers to us. We have been a party to collaboration agreements in which we were reimbursed for work performed on behalf of the collaborator, as well as one in which we reimbursed the collaborator for work it had performed. We record all appropriate expenses under our collaborations as research and development expense. If the arrangement provides for reimbursement of research and development expenses incurred by us, we evaluate the terms of the arrangement to determine whether the reimbursement should be recorded as revenue or as an offset to research and development expense. If the arrangement provides for us to reimburse the collaborator for research and development expenses or for the achievement of a development milestone for which a payment is due, we record the reimbursement or the achievement of the development milestone as research and development expense.

### *Stock-based Compensation Expense*

We issue stock-based awards to employees, directors, and non-employees, generally in the form of stock options, restricted stock units, or RSUs, or as awards under our 2013 Employee Stock Purchase Plan, or ESPP. We measure stock-based compensation cost at the grant date based on the estimated fair value of the award and recognize it as expense over the requisite service period on a straight-line basis. Stock-based compensation costs for non-employees are recognized as expense over the vesting period on a ratable basis. The grant date fair value of stock options and awards under our ESPP is measured using the Black-Scholes valuation model, which requires us to make assumptions about the fair value of our common stock on the date of grant. The grant date fair value of RSUs is estimated to be equal to the closing price of our common stock on the date of grant. For

## [Table of Contents](#)

awards with performance conditions, we estimate the likelihood of satisfaction of the performance conditions, which affects the period over which the expense is recognized. When the likelihood of satisfying the performance conditions related to these awards is determined to be probable, we recognize the expense over the requisite service period. We have no awards with market conditions. We recognize forfeitures related to share-based payments as they occur.

### *Royalty Expense*

Royalty expense is recorded when incurred and represents the expense associated with amounts owed to third parties as a result of royalty revenue recognized and the amounts owed by us to Takeda Pharmaceutical Company Limited, or Takeda, in relation to the sale of future royalties (see Note 11).

### *Income Taxes*

We use the liability method to account for income taxes. Deferred tax assets and liabilities are determined based on differences between financial reporting and income tax basis of assets and liabilities, as well as net operating loss and tax credit carryforwards, and are measured using the enacted tax rates and laws that will be in effect when the differences reverse. Deferred tax assets are reduced by a valuation allowance to reflect the uncertainty associated with their ultimate realization. The effect of a change in tax rate on deferred taxes is recognized in income or loss in the period that includes the enactment date.

We use our judgment for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. We recognize any material interest and penalties related to unrecognized tax benefits in income tax expense.

Due to the uncertainty surrounding the realization of the net deferred tax assets in future periods, we have recorded a full valuation allowance against our otherwise recognizable net deferred tax assets as of December 31, 2022 and 2021.

### *Basic and Diluted Net Loss per Common Share*

Basic net loss per share is based upon the weighted average number of common shares outstanding during the period, excluding restricted stock units that have been issued but have not yet vested. Diluted net loss per share is based upon the weighted average number of common shares outstanding during the period plus the effect of additional weighted average common equivalent shares outstanding during the period when the effect of adding such shares is dilutive. Common equivalent shares result from the assumed exercise of outstanding stock options and the exercise of outstanding warrants (the proceeds of which are then assumed to have been used to repurchase outstanding stock using the treasury stock method) and the vesting of restricted shares of common stock. In addition, the assumed proceeds under the treasury stock method include the average unrecognized compensation expense of stock options that are in-the-money. This results in the “assumed” buyback of additional shares, thereby reducing the dilutive impact of stock options. The two-class method is used for outstanding warrants as such warrants are considered to be participating securities, and this method is more dilutive than the treasury stock method. The following outstanding shares of common stock equivalents were excluded from the computation of net loss per share attributable to common stockholders for the periods presented because including them would have been antidilutive:

	At December 31,	
	2022	2021
Stock options	14,663,697	12,689,439
Non-vested restricted stock	2,939,816	50,000

### *Comprehensive Loss*

Comprehensive loss is comprised of net loss and other comprehensive loss. Other comprehensive loss is comprised of unrealized holding gains arising during the period on available-for-sale securities that are not other-than-temporarily impaired. During the year ended December 31, 2022, there were no material reclassifications out of accumulated other comprehensive (loss) income.

### *New Accounting Pronouncements*

In June 2016, the Financial Accounting Standards Board, or FASB, issued Accounting Standard Update, or ASU, No. 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Statements*, or ASU No. 2016-13, which requires that credit losses be reported using an expected losses model rather than the incurred losses model that is currently used, and it establishes additional disclosure requirements related to credit risks. For available-for-sale debt securities with expected credit losses, this standard now requires allowances to be recorded instead of reducing the amortized cost of the investment. In November 2019, the FASB subsequently issued ASU 2019-10, *Financial Instruments—Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842): Effective Dates*, whereby the effective date of this standard for smaller reporting companies was deferred to annual reporting periods beginning after December 15, 2022, including interim periods within those annual reporting periods, and early adoption is still permitted. We adopted this standard effective January 1, 2023 on a prospective basis. The adoption of this standard has not had a material impact on our consolidated financial statements and related disclosures.

In August 2020, the FASB issued ASU No. 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity’s Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity’s Own Equity*, or ASU No. 2020-06, which simplifies the guidance on an issuer’s accounting for convertible instruments and contracts in its own equity. The provisions of ASU No. 2020-06 are applicable for fiscal years beginning after December 15, 2023, with early adoption permitted no earlier than fiscal years beginning after December 15, 2020. We are currently evaluating the impact of ASU No. 2020-06 on our consolidated financial statements and related disclosures.

In November 2021, the FASB issued ASU No. 2021-10, *Government Assistance (Topic 832): Disclosures by Business Entities about Government Assistance*, or ASU No. 2021-10, which requires additional annual disclosures about transactions with a government that are accounted for by applying a grant or contribution accounting model by analogy. The additional disclosures required by this standard include 1) information about the nature of the transactions and the related accounting policy used to account for the transactions, 2) the financial statement line items that are impacted by the transactions and the amounts applicable to each financial statement line item and 3) significant terms and conditions of the transactions, including commitments and contingencies. We adopted this standard effective January 1, 2022 on a prospective basis. The adoption of the standard has not had a material impact on our consolidated financial statements.

### 3. Stock-Based Compensation

Under each of the stock incentive plans described below, stock option awards made to new employees upon commencement of employment typically provide for vesting of 25% of the shares underlying the award at the end of the first year of service with the remaining 75% of the shares underlying the award vesting ratably on a monthly basis over the following three-year period subject to continued service. Annual grants to existing employees typically provide for ratable vesting over specified periods determined by the board of directors. In addition, under each plan, all options granted expire no later than ten years after the date of grant.

#### *2019 Equity Incentive Plan*

Our 2019 Equity Incentive Plan, or the 2019 Plan, was approved by our stockholders in June 2019. The 2019 Plan provides for the grant of incentive stock options intended to qualify under Section 422 of the Internal

## [Table of Contents](#)

Revenue Code of 1986, as amended, or IRC, as well as nonstatutory stock options, stock appreciation rights, restricted stock, restricted stock units and other stock-based and cash-based awards. Up to 12,531,009 shares of our common stock may be issued pursuant to awards granted under the 2019 Plan, plus an additional amount of our common stock underlying awards issued under the 2010 Stock Incentive Plan, or the 2010 Plan, that expire or are canceled without the holders receiving any shares under those awards. As of December 31, 2022, an aggregate of 7,744,676 shares of our common stock were reserved for issuance upon the vesting or exercise of outstanding awards, and up to 2,564,077 shares of common stock may be issued pursuant to awards granted under the 2019 Plan.

### *2010 Stock Incentive Plan*

The 2010 Plan provided for the grant of incentive stock options under the IRC, as well as nonstatutory stock options, stock appreciation rights, restricted stock, restricted stock units and other stock-based and cash-based awards. As of December 31, 2022, an aggregate of 6,309,021 shares of our common stock were reserved for issuance upon the exercise of outstanding awards granted under the 2010 Plan. The 2010 Plan was terminated upon approval of the 2019 Plan; therefore, no further grants may be made under the 2010 Plan.

### *2013 Employee Stock Purchase Plan*

Our ESPP permits eligible employees to purchase shares of our common stock at a discount and consists of consecutive, overlapping 24-month offering periods, each consisting of four six-month purchase periods. On the first day of each offering period, each employee who is enrolled in the ESPP will automatically receive an option to purchase up to a whole number of shares of our common stock. The purchase price of each of the shares purchased, in a given purchase period, will be equal to 85% of the closing price of a share of our common stock, on the first day of the offering period or the last day of the purchase period, whichever is lower. During the year ended December 31, 2022, 111,155 shares of common stock were purchased for total proceeds of approximately \$0.1 million. During the year ended December 31, 2021, 57,561 shares of common stock were purchased for total proceeds of approximately \$0.1 million.

### *Compensation Expense*

Total stock-based compensation expense related to all equity awards was comprised of the following:

	Year Ended December 31,	
	2022	2021
	(in thousands)	
Research and development	\$ 1,291	\$ 830
General and administrative	2,330	1,865
Total stock-based compensation expense	<u>\$ 3,621</u>	<u>\$ 2,695</u>

As of December 31, 2022, we had approximately \$8.1 million of total unrecognized compensation cost related to unvested common stock options, restricted stock units and awards under our ESPP, which are expected to be recognized over a weighted-average period of two years.

## [Table of Contents](#)

### Stock Options

We estimate the fair value of stock options at the date of grant using the Black-Scholes valuation model with the following weighted-average assumptions:

	December 31,	
	2022	2021
Risk-free interest rate	2.1%	0.9%
Expected annual dividend yield	—	—
Expected stock price volatility	105.0%	106.3%
Expected term of options	5.9 years	5.9 years

The valuation assumptions were determined as follows:

- *Risk-free interest rate:* The yield on zero-coupon U.S. Treasury securities for a period that was commensurate with the expected term of the awards.
- *Expected annual dividend yield:* The estimate for annual dividends was zero because we have not historically paid a dividend and do not intend to do so in the foreseeable future.
- *Expected stock price volatility:* We determined the expected volatility by using our available implied and historical price information.
- *Expected term of options:* The expected term of the awards represents the period of time that the awards were expected to be outstanding. We use the simplified method to estimate expected term as we do not have sufficient historical exercise data to provide a reasonable basis on which to estimate the expected term. Under this method, the expected life equals the average of the vesting term and the original contractual term of the option.

A summary of our stock option activity for the year ended December 31, 2022 is as follows:

	Stock Options	Weighted-Average Exercise Price per Share	Weighted-Average Remaining Contractual Life (years)	Aggregate Intrinsic Value (in millions)
Outstanding at January 1, 2022	12,689,439	\$ 3.53		
Granted	2,886,324	1.36		
Exercised	(17,708)	0.83		
Forfeited	(238,129)	1.46		
Expired	(656,229)	8.30		
Outstanding at December 31, 2022	<u>14,663,697</u>	\$ 2.93	6.3	\$ —
Exercisable at December 31, 2022	<u>10,903,188</u>	\$ 3.33	5.6	\$ —

The weighted-average fair value per share of options granted during the years ended December 31, 2022 and 2021 was \$1.10 and \$2.69, respectively.

The aggregate intrinsic value of options outstanding at December 31, 2022 was calculated based on the positive difference, if any, between the closing fair market value of our common stock on December 31, 2022 and the exercise price of the underlying options.

The aggregate intrinsic value of options exercised during the year ended December 31, 2022 was nominal. The aggregate intrinsic value of options exercised during the year ended December 31, 2021 was \$0.8 million.



## [Table of Contents](#)

No related income tax benefits were recorded during the years ended December 31, 2022 or 2021.

We settle employee stock option exercises with newly issued shares of our common stock.

### *Restricted Stock Units*

A summary of our RSU activity for the year ended December 31, 2022 is as follows:

	Restricted Stock Units	Weighted-Average Grant Date Fair Value per Unit
Outstanding, non-vested at January 1, 2022	50,000	\$ 2.93
Granted	2,950,483	1.08
Vested	(50,000)	2.93
Forfeited	(10,667)	1.08
Outstanding, non-vested at December 31, 2022	<u>2,939,816</u>	\$ 1.08

The total fair value of RSUs vested during the year ended December 31, 2022 was nominal. No RSUs vested during the year ended December 31, 2021.

#### 4. Cash, Cash Equivalents and Available-for-Sale Securities

As of December 31, 2022 and 2021, we had cash and cash equivalents of \$38.3 million and \$80.7 million, respectively. We have not incurred any unrealized gains or losses on our cash and cash equivalents balances as of December 31, 2022 and 2021.

During the years ended December 31, 2022 and 2021, we held debt securities classified as available-for-sale securities. We had no material realized gains or losses on our available-for-sale securities for the years ended December 31, 2022 and 2021.

#### 5. Fair Value

We measure certain financial instruments at fair value on a recurring basis. The Company's assets which are required to be measured on a recurring basis consist of cash and cash equivalents totaling \$38.3 million and \$80.7 million as of December 31, 2022 and 2021, respectively. The Company's liabilities which are required to be measured on a recurring basis consist of a warrant liability in the amount of \$0.2 million as of December 31, 2022 and 2021.

Cash and cash equivalents, which are measured using Level 1 inputs, consist of highly liquid deposit accounts and money market funds that are intended to consistently transact at a target net asset value of \$1.00. Accordingly, the carrying amounts reflected in the condensed consolidated balance sheets for cash and cash equivalents approximate their fair value.

Warrant liability relates to potential future warrants that may be issued. The fair value of the warrant liability on the date of the commitment and on each re-measurement date for those warrants classified as liabilities was estimated using the Monte Carlo simulation model, which involves a series of simulated future stock price paths over the remaining life of the commitment. The fair value is estimated by taking the average of the fair values under each of many Monte Carlo simulations. The fair value estimate is affected by our stock price, as well as estimated future financing needs, including timing and sources of the financing and subjective variables including expected stock price volatility over the remaining life of the commitment and risk-free interest rate. Due to the nature of these inputs, the valuation of the warrants is considered a Level 3 measurement.

## [Table of Contents](#)

The fair value of the warrant liability as of December 31, 2022 has been included in accrued expenses and other current liabilities on our consolidated balance sheet. The fair value of the warrant liability as of December 31, 2021 has been included in other liabilities on our consolidated balance sheet. See Note 9 for further discussions of the accounting for the warrants.

There have been no changes to our valuation methods during the year ended December 31, 2022. We had no available-for-sale securities that were classified as Level 3 at any point during the year ended December 31, 2022.

The carrying amounts reflected in the consolidated balance sheets for prepaid expenses and other current assets, other assets, accounts payable and accrued expenses and other current liabilities approximate their fair value due to their short-term maturities.

### 6. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following:

	December 31,	
	2022	2021
	(in thousands)	
Prepaid expenses	\$1,429	\$1,143
Other current assets	560	399
Total prepaid expenses and other current assets	<u>\$1,989</u>	<u>\$1,542</u>

### 7. Property and Equipment

Property and equipment consist of the following:

	December 31,	
	2022	2021
	(in thousands)	
Computer equipment and software	\$ 1,921	\$ 1,904
Furniture and fixtures	446	446
Leasehold improvements	1,743	1,743
	4,110	4,093
Less accumulated depreciation	(3,310)	(2,852)
	<u>\$ 800</u>	<u>\$ 1,241</u>

## [Table of Contents](#)

### 8. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	December 31,	
	2022	2021
	(in thousands)	
Accrued clinical	\$4,290	\$ 4,998
Accrued professional services	785	88
Accrued consulting	742	475
Accrued compensation and benefits	605	2,835
Accrued development	335	755
Liability related to sale of future royalties, net, current portion	1,218	897
Operating lease liability, current portion	593	519
Other	655	413
Total accrued expenses	<u>\$9,223</u>	<u>\$10,980</u>

### 9. Liabilities Related to Sale of Future Royalties

#### *HCR Agreement*

In 2016, we and Verastem Inc., or Verastem, entered into an amended and restated license agreement, or the Verastem Agreement, under which we granted to Verastem an exclusive worldwide license in oncology indications for the research, development, commercialization, and manufacture of duvelisib, or Copiktra<sup>®</sup>, an oral, dual inhibitor of PI3K delta and gamma, and products containing duvelisib, which we refer to as Licensed Products. In September 2020, Verastem completed a disposition of its rights, title, and interest in and to duvelisib to Secura Bio, Inc., or Secura Bio, whereby Secura Bio assumed all liabilities and obligations under the Verastem Agreement. We now refer to the Verastem Agreement as the Secura Bio Agreement.

Secura Bio is obligated to pay us royalties on worldwide net sales of Licensed Products ranging from the mid-single digits to the high-single digits, a portion of which we are obligated to share with Takeda Pharmaceuticals Company Limited, or Takeda, as described in Note 11.

In March 2019, we entered into a royalty purchase agreement, or the HCR Agreement, with HealthCare Royalty Partners III, L.P., or HCR, providing for the acquisition by HCR of our interest in certain royalty payments based on worldwide annual net sales of Licensed Products under the Secura Bio Agreement for gross proceeds of \$30.0 million, which is non-refundable. After sharing with Takeda in accordance with the Takeda Amendment, as defined in Note 11, we retained \$22.5 million in gross proceeds, or approximately \$20.9 million in net proceeds. Under the HCR Agreement, HCR obtained the right to receive the royalty payments up to agreed upon thresholds of royalties, the amount of which depends on when the aggregate royalties received by HCR reach specified thresholds. If the specified threshold has been met through royalty payments from Secura Bio or if we elect to make a payment to meet the threshold amount, the HCR Agreement will automatically terminate and all rights to the royalty stream under the HCR Agreement will revert back to us. If the specified threshold has not been achieved by June 30, 2025, the HCR Agreement will continue through the term of the Secura Bio Agreement.

We recognized the receipt of the \$30.0 million payment from HCR as a liability, net of debt discount and issuance costs of approximately \$2.4 million. As the basis for our determination, we considered, in accordance with the relevant accounting guidance, the potential for the royalty stream to revert back to us if specified royalty thresholds have been met and our right to terminate the HCR Agreement by making a payment to achieve the threshold. We are not obligated to repay any of the proceeds received under the HCR Agreement. In order to

## [Table of Contents](#)

determine the amortization of the liability, we are required to estimate the total amount of future net royalty payments to be made to HCR over the term of the HCR Agreement. The total threshold of net royalties to be paid, less the net proceeds received, will be recorded as interest expense over the life of the liability. We impute interest on the unamortized portion of the liability using the effective interest method. Interest and debt discount amortization expense is reflected as non-cash interest expense in the Consolidated Statements of Operations and Comprehensive Loss. Over the course of the HCR Agreement, the actual interest rate will be affected by the amount and timing of royalty revenue recognized and changes in forecasted royalty revenue. On a quarterly basis, we reassess the effective interest rate and adjust the rate prospectively as needed.

The following table shows the activity within the liability account for the years ended December 31, 2022 and 2021:

	December 31,	
	2022	2021
	(in thousands)	
Liability related to sale of future royalties - beginning balance	\$28,038	\$28,869
Non-cash royalty revenue	(1,373)	(984)
Non-cash interest expense recognized	153	153
Liability related to sale of future royalties, net - ending balance	\$26,818	\$28,038
Less: current portion	(1,218)	(897)
Liability related to sale of future royalties, net, less current portion	<u>\$25,600</u>	<u>\$27,141</u>

As royalties are due to HCR by Secura Bio, the balance of the recognized liability will be effectively repaid over the life of the HCR Agreement. There are a number of factors that could materially affect the amount and timing of royalty payments from Secura Bio, none of which are within our control.

### *BVF Agreement*

On January 8, 2020, or the BVF Closing Date, we entered into a funding agreement, or the BVF Funding Agreement, with BVF Partners, L.P., or BVF, and Royalty Security, LLC, a wholly-owned subsidiary of BVF, or the Buyer. BVF was subsequently replaced as a party to the BVF Funding Agreement with Royalty Security Holdings, LLC. The BVF Funding Agreement provides for the acquisition by the Buyer of our interest in all royalty payments based on worldwide annual net sales of a clinical-stage product candidate IPI-926, or patidegib, part of the hedgehog inhibitor program we licensed to PellePharm Inc., or PellePharm, in 2013, or the BVF Licensed Product, excluding relevant Trailing Mundipharma Royalties, as defined in Note 11, which is related to patidegib. We refer to all BVF Licensed Product royalties owed to us less Trailing Mundipharma Royalties as the Royalty or Royalties. In January 2023, PellePharm announced that Sol-Gel Technologies, Ltd., or Sol-Gel, acquired all rights and obligations under the license agreement. We now refer to the license agreement with PellePharm as the Sol-Gel Agreement. Such Royalties are owed to us pursuant to the Sol-Gel Agreement, as further described in Note 11.

Pursuant to the BVF Funding Agreement, we received a non-refundable payment of \$20.0 million, or the Upfront Purchase Price, less certain transaction expenses. We transferred to the Buyer (i) the Royalty, (ii) the Sol-Gel Agreement (subject to our rights to milestone payments and rights to equity in Sol-Gel under the Sol-Gel Agreement), and (iii) certain patent rights established in the BVF Funding Agreement, with (i), (ii), and (iii) together referred to as Transferred Assets. We preserved our rights under the Sol-Gel Agreement to receive potential regulatory, commercial, and success-based milestone payments. We have the option to terminate the BVF Funding Agreement by purchasing 100% of the outstanding equity interests of the Buyer under specified

## [Table of Contents](#)

terms for a specified amount under the BVF Funding Agreement through January 8, 2023. In addition, the BVF Funding Agreement may be terminated by mutual written agreement between us and the Buyer.

We recognized the proceeds received under the BVF Funding Agreement as a liability that will be amortized using the effective interest method over the life of the arrangement. We recorded the receipt of the \$20.0 million Upfront Purchase Price as a liability, net of debt issuance costs of approximately \$0.4 million and warrant liability of \$0.3 million. We are not obligated to repay any of the proceeds received under the BVF Funding Agreement. In order to determine the amortization of the liability, we are required to estimate the total amount of potential future net royalty payments to be made by Sol-Gel to the Buyer over the term of the BVF Funding Agreement. The total estimated net royalties to be paid, less the net proceeds received, will be recorded as interest expense over the life of the liability. Interest and debt discount amortization expense is reflected as non-cash interest expense for the years ended December 31, 2022 and 2021 in our consolidated statements of operations and comprehensive loss. Over the course of the BVF Funding Agreement, the actual interest rate will be affected by the amount and timing of royalty revenue recognized, if any, and changes in forecasted royalty revenue. There are a number of factors that could materially affect the amount and timing of royalty payments from Sol-Gel, none of which are within our control. On a quarterly basis, we will reassess the effective interest rate and adjust the rate prospectively as needed.

The following table shows the activity within the liability account for the years ended December 31, 2022 and 2021:

	December 31,	
	2022	2021
	(in thousands)	
Liability related to sale of future royalties - beginning balance	\$ 21,586	\$ 21,559
Non-cash interest expense recognized	27	27
Liability related to sale of future royalties, net - ending balance	<u>\$ 21,613</u>	<u>\$ 21,586</u>

For so long as we have not exercised an option to repurchase the Buyer's equity interest under the BVF Funding Agreement, (a) if, during the 36-month period following the BVF Closing Date, we issue a specified number of shares of our common stock, which we refer to as the Warrant Threshold, and (b) any shares in excess of the Warrant Threshold are issued for consideration to us of less than \$3.75 per share (as adjusted for any stock splits, reverse stock splits or other similar recapitalization events), or the Threshold Price, then we are obligated to issue to BVF warrants to purchase a number of shares of our common stock. Such warrants would equal 50% of the number of qualifying shares at an exercise price equal to 1.5 times the price per share of such qualifying shares issued. The requirement to issue warrants to BVF does not apply to certain issuances of our common stock. As of December 31, 2022, the Warrant Threshold has been met and any future qualifying shares of our common stock issued below the Price Threshold will result in warrants to purchase our common stock to be issued to BVF. No warrants have been issued to BVF as of December 31, 2022. Our obligation to issue warrants to BVF under these terms expired on January 8, 2023 without any warrants being issued to BVF.

We determined that the commitment to issue warrants represents a freestanding financial instrument and accounted for it as a liability as of the BVF Closing Date. The fair value of the warrant liability was estimated using the Monte Carlo simulation model. The fair value of the warrant liability as of December 31, 2022 has been included in accrued expenses and other current liabilities on our consolidated balance sheet. The fair value of the warrant liability as of December 31, 2021 has been included in other liabilities on our consolidated balance sheet. Changes in fair value of the warrant liability are included in investment and other income (expense) in our consolidated statements of operations and comprehensive loss. See Note 5 for further discussions of the fair value of the warrants.

## [Table of Contents](#)

### 10. Commitments and Contingencies

On April 5, 2019, we entered into a lease agreement, or the Lease, with Sun Life Assurance Company of Canada, or the Landlord, effective April 3, 2019, or the Commencement Date, for the lease of approximately 10,097 square feet of office space at 1100 Massachusetts Avenue, Cambridge, Massachusetts, or the Leased Premises. The term of the Lease commenced on the Commencement Date and expires on August 1, 2024, or the Expiration Date, approximately five years after the Rent Commencement Date as defined below.

Beginning August 1, 2019, or the Rent Commencement Date, the total base rent of the Lease was \$47,961 per month and increases by approximately 3% on each anniversary of the Rent Commencement Date until the Expiration Date. In addition to the base rent, we are also responsible for our share of the operating expenses, insurance, real estate taxes and certain capital costs, and we are responsible for utility expenses in the Leased Premises, all in accordance with the terms of the Lease. Pursuant to the terms of the Lease, we provided a security deposit in the form of a letter of credit in the initial amount of \$300,000, which was reduced to \$150,000 during the year ended December 31, 2021 in accordance with the terms of the Lease. The remaining portion of the security deposit plus the associated bank fee of \$7,500 is included in our consolidated balance sheet as restricted cash as of December 31, 2022 and 2021. The Landlord provided a lease incentive allowance of \$0.6 million to fund certain improvements to be made by us to the Leased Premises.

Subject to certain conditions specified in the Lease, we have the right to extend the term of the Lease for two years, if we provide notice to the Landlord not earlier than twelve months, nor later than nine months, prior to expiration of the Lease. The base rent for the extension term shall be equal to the greater of the base rent in effect for the last year of the initial lease term or a fair market base rent determined according to the terms of the Lease.

The Lease contains customary provisions allowing the Landlord to, among other things, accelerate payments under the Lease or terminate the Lease in its entirety if we fail to remedy a default of any of our obligations under the Lease within specified time periods or upon our bankruptcy or insolvency.

We have recorded a right-of-use asset and lease liability related to our data center lease and the Lease. The lease of our data center expired during the year ended December 31, 2021. The following is a summary of our current lease included in the respective balance sheet classifications:

	December 31,	
	2022	2021
	(in thousands)	
<b>Assets</b>		
Operating lease right-of-use assets	<u>\$697</u>	<u>\$1,064</u>
<b>Liabilities</b>		
Accrued expenses and other current liabilities	\$593	\$ 519
Operating lease liability	<u>324</u>	<u>917</u>
Total lease liabilities	<u>\$917</u>	<u>\$1,436</u>

As of December 31, 2022, the weighted average term remaining on our lease is 1.6 years, and the weighted average discount rate is 10%. As of December 31, 2021, the weighted average term remaining on our lease was 2.6 years, and the weighted average discount rate was 10%.

Operating lease costs, including variable costs, of \$0.7 million were incurred during both the years ended December 31, 2022 and 2021. Cash paid for amounts included in the measurement of lease liabilities were \$0.6 million and \$0.7 million during the years ended December 31, 2022 and 2021, respectively.

## [Table of Contents](#)

As of December 31, 2022, future minimum lease payments of our operating lease liabilities are as follows:

	Operating Leases (in thousands)
2023	\$ 658
2024	334
Total future minimum lease payments	992
Less: imputed interest	(75)
Total lease liability	\$ 917

### 11. Strategic Agreements

We have worldwide development and commercialization rights to eganelisib, subject to certain obligations to our licensor, Takeda Pharmaceutical Company Limited, or Takeda, as described in more detail below. Additionally, we are obligated to pay Mundipharma International Corporation Limited, or Mundipharma, and Purdue Pharmaceutical Products L.P., or Purdue, a 4% royalty in the aggregate on worldwide net sales of products that were previously subject to our strategic alliance with Mundipharma and Purdue that was terminated in 2012. Such products include eganelisib; duvelisib, the PI3K delta and gamma inhibitor that we licensed to Verastem in 2016, the rights to which Verastem sold to Secura Bio in 2020; and IPI-926, or patidegib, part of the hedgehog inhibitor program we licensed to PellePharm in 2013, and which license is now held by Sol-Gel. We refer to such royalties as Trailing Mundipharma Royalties. After Mundipharma and Purdue have recovered approximately \$260.0 million in royalty payments from all products that were previously subject to the strategic alliance, which represents the funding paid to us for research and development services performed by us under this strategic alliance, the Trailing Mundipharma Royalties will be reduced to a 1% royalty on net sales in the United States of such products. As of December 31, 2022, Mundipharma and Purdue have recovered \$3.5 million.

#### *PellePharm / Sol-Gel Technologies*

In June 2013, we entered into a license agreement with PellePharm, under which we granted PellePharm exclusive global development and commercialization rights to our hedgehog inhibitor program, including patidegib. In January 2023, PellePharm announced that Sol-Gel acquired all rights and obligations under the license agreement. We refer to our license agreement with PellePharm as the Sol-Gel Agreement and products covered by the Sol-Gel Agreement as Hedgehog Products. We assessed this arrangement in accordance with ASC 606 and concluded that at the date of contract inception there was only one performance obligation, consisting of the license, which was satisfied at contract inception.

Under the Sol-Gel Agreement, Sol-Gel is obligated to pay us up to \$9.0 million in remaining regulatory and commercial-based milestone payments through the first commercial sale of a Hedgehog Product. Sol-Gel is also obligated to pay us up to \$37.5 million in success-based milestone payments upon the achievement of certain annual net sales thresholds, as well as a share of certain revenue received by Sol-Gel in the event that Sol-Gel sublicenses its rights under the Sol-Gel Agreement and tiered royalties on annual net sales of Hedgehog Products subject to specified conditions. The remaining milestones have not been recognized as they represent variable consideration that is constrained. In making this assessment, we considered numerous factors, including the fact that achievement of the milestones is outside of our control and contingent upon the future success of clinical trials, Sol-Gel's actions, and the receipt of regulatory approval. As the single performance obligation was previously satisfied, all regulatory and commercial-based milestones will be recognized as revenue in full in the period in which the constraint is removed. Any consideration related to sales-based milestone payments, including royalties, will be recognized when the related sales occur as these amounts have been determined to relate predominantly to the license granted to Sol-Gel and therefore are recognized at the later of when the performance obligation is satisfied, or the related sales occur.

## Table of Contents

Sol-Gel is also obligated to pay us tiered royalties on annual net sales of Hedgehog Products, which are subject to reduction after a certain aggregate funding threshold has been achieved. On January 8, 2020, we entered into the BVF Funding Agreement, as further described in Note 9, pursuant to which we sold our interest in all royalty payments based on worldwide annual net sales of the BVF Licensed Product, excluding Trailing Mundipharma Royalties related to patidegib.

### *Takeda*

In July 2010, we entered into a development and license agreement with Intellikine, Inc., or Intellikine, under which we obtained rights to discover, develop and commercialize pharmaceutical products targeting the gamma and/or delta isoforms of PI3K, including eganelisib and duvelisib. In January 2012, Intellikine was acquired by Takeda. In December 2012, we amended and restated our development and license agreement with Takeda and further amended the agreement in July 2014, September 2016, July 2017, and March 2019. We refer to the amended and restated development and license agreement, as amended, as the Takeda Agreement.

### *Duvelisib*

Pursuant to the Takeda Agreement, prior to March 4, 2019, we were obligated to share equally with Takeda all revenue arising from certain qualifying transactions for duvelisib, including the Secura Bio Agreement, subject to certain exceptions including revenue we receive as reimbursement for duvelisib research and development expenses. On March 4, 2019, we entered into the fourth amendment to the Takeda Agreement, or the Takeda Amendment. Pursuant to the Takeda Amendment, Takeda agreed (i) to the sale of certain royalty payments based on worldwide annual net sales of Licensed Products under the Secura Bio Agreement to HCR, (ii) to forego its rights to an equal share of the royalties due from Secura Bio during the term of the HCR Agreement, and (iii) not to seek any payment from HCR with respect to the royalties owed to Takeda. As consideration for the Takeda Amendment, we paid Takeda \$6.7 million representing 25% of the \$30.0 million in gross proceeds we received from the closing of the HCR Agreement, net of 25% of the expenses incurred by us in connection with the HCR Agreement. In addition, we agreed to pay Takeda 25% of the royalties that would have been payable to us by Secura Bio but for the consummation of the HCR Agreement, which we refer to as the Interim Obligation. During the years ended December 31, 2022 and 2021, we recognized \$0.3 million and \$0.2 million, respectively, of Interim Obligation amounts owed to Takeda as royalty expense.

We have the right to extinguish the Interim Obligation by payment to Takeda of an amount equal to (i) the \$6.7 million payment multiplied by the multiple set forth in the table below corresponding to the time period in which such extinguishing payment is made, minus (ii) any payments made to Takeda pursuant to the Interim Obligation:

Time Period	Multiple
From the Takeda Amendment Effective Date until June 30, 2022	145%
From July 1, 2022 through June 30, 2023	155%
From July 1, 2023 through June 30, 2024	165%
From July 1, 2024 through June 30, 2025	175%

The Interim Obligation shall expire upon the termination of the HCR Agreement and the reversion of related royalties to us, at which time our obligations to share the royalties payable under the Secura Bio Agreement equally with Takeda shall be reinstated.

### *Eganelisib*

Pursuant to the Takeda Agreement, we are obligated to pay Takeda \$3.0 million in a remaining success-based development milestone payment and up to \$165.0 million in remaining regulatory and commercial-based milestone payments for one product candidate other than duvelisib, which could be eganelisib.



## [Table of Contents](#)

### 12. Income Taxes

We did not have any income tax expense for the years ended December 31, 2022 or 2021.

Our income tax expense for the years ended December 31, 2022 and 2021 differed from the expected U.S. federal statutory income tax expense as set forth below:

	Years Ended December 31,	
	2022	2021
	(in thousands)	
Expected federal tax benefit	\$ (9,317)	\$ (9,505)
Permanent differences	215	191
State taxes, net of the deferred federal benefit	(1,986)	(3,024)
Tax credit carryforwards	(1,533)	(1,416)
Adjustments to deferred tax assets and deferred tax liabilities	560	226
Other	15	(93)
Change in valuation allowance	12,046	13,621
Income tax expense (benefit)	<u>\$ —</u>	<u>\$ —</u>

The significant components of our deferred tax assets and liabilities are as follows:

	Years Ended December 31,	
	2022	2021
	(in thousands)	
Deferred tax assets (liabilities):		
Net operating loss carryforwards	\$ 170,880	\$ 164,969
Tax credit carryforwards	45,270	44,302
Intangible assets	13,212	15,151
Capitalized research and development costs	8,104	—
Accrued expenses	655	1,255
Stock-based compensation	5,183	5,109
Sale of future royalties	13,212	13,557
Other	(105)	22
Valuation allowance	(256,411)	(244,365)
Net deferred tax assets (liabilities)	<u>\$ —</u>	<u>\$ —</u>

We have recorded a valuation allowance against our deferred tax assets in each of the years ended December 31, 2022, and 2021 because we believe that it is more likely than not that these assets will not be realized. The valuation allowance increased by approximately \$12.0 million during the year ended December 31, 2022 primarily due to new federal tax regulations effective for the year ended December 31, 2022 requiring that research and development costs be capitalized and amortized over future periods compared to previous tax regulations which allowed for such expenses to be fully deductible in the year incurred. The increase in the valuation allowance is also largely attributable to the increase in our unbenefited net operating loss for the current period. The valuation allowance increased by approximately \$13.6 million during the year ended December 31, 2021 primarily as a result of the increase in our unbenefited net operating loss for the period.

Subject to the limitations described below, at December 31, 2022, we have cumulative net operating loss carryforwards of approximately \$653.2 million and \$533.3 million available to reduce federal and state taxable income, respectively. For federal purposes, the net operating loss carryforwards have begun to expire and will continue to expire through 2037 for losses incurred before January 1, 2018. Federal losses generated after

## Table of Contents

December 31, 2017 do not expire. As of December 31, 2022, we have approximately \$128.5 million of federal losses that do not expire. The state net operating loss carryforwards begin to expire in 2031 and continue to expire through 2041. In addition, we have cumulative federal and state tax credit carryforwards of \$37.7 million and \$9.6 million, respectively, available to reduce federal and state income taxes which expire through 2041 and 2036, respectively. Our net operating loss carryforwards and tax credit carryforwards are limited as a result of certain ownership changes, as defined under Sections 382 and 383 of the Internal Revenue Code. This limits the annual amount of these tax attributes that can be utilized to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on our value immediately prior to an ownership change. Subsequent ownership changes may affect the limitation in future years. The net operating losses and tax credit carryforwards that have and will expire unused in the future as a result of Section 382 and 383 limitations have been excluded from the amounts disclosed above. The latest Section 382 study was performed through December 31, 2021. Ownership changes after that date could further reduce the Company's ability to utilize the net operating loss and other attribute carryforwards.

At December 31, 2022 and 2021, we had no unrecognized tax benefits. As of December 31, 2022 and 2021, we had no accrued interest or penalties related to uncertain tax positions and no amounts have been recognized in our consolidated statements of operations and comprehensive loss. We will recognize interest and penalties related to uncertain tax positions in income tax expense. For all years through December 31, 2022, we generated research credits but have not conducted a study to document the qualified activities. This study may result in an adjustment to our research and development credit carryforwards; however, until a study is completed and any adjustment is known, no amounts are being presented as an uncertain tax position. A full valuation allowance has been provided against our research and development credits and, if an adjustment is required, this adjustment would be offset by an adjustment to the deferred tax asset established for the research and development credit carryforwards and the valuation allowance.

We file U.S. federal and Massachusetts state income tax returns. The statute of limitations for assessment by the Internal Revenue Service, or IRS, and state tax authorities is closed for tax years prior to 2019, although carryforward attributes that were generated prior to tax year 2019 may still be adjusted upon examination by the IRS or state tax authorities if they either have been or will be used in a future period.

### 13. Stockholders' (Deficit) Equity

#### *Common Stock Sales Facility*

On June 28, 2019, we entered into a Capital on Demand Sales Agreement with JonesTrading Institutional Services LLC, or JonesTrading, and on July 29, 2019 we amended and restated the sales agreement to add B. Riley Securities (f/k/a B. Riley FBR, Inc.), or B. Riley Securities, as a party to the agreement. On July 27, 2021, we entered into an amendment to the agreement to increase the maximum aggregate offering price of the shares of common stock that we may issue and sell from time to time under the agreement by \$75.0 million to an aggregate of \$95.0 million. We refer to the amended and restated sales agreement, as amended, as the ATM Sales Agreement. During the year ended December 31, 2022, a portion of the aggregate offering price totaling \$11.8 million expired without sale. As of December 31, 2022, we had an aggregate of \$75.0 million available for future sales. Pursuant to the ATM Sales Agreement we may offer and sell shares of our common stock from time to time through JonesTrading or B. Riley Securities, each acting as our sales agent. We have agreed to pay commissions to the sales agents for their services in acting as agents in the sale of our common stock in the amount of up to 3.0% of the gross proceeds from sales of our common stock pursuant to the ATM Sales Agreement. Sales of shares of our common stock under the ATM Sales Agreement may be made by any method that is deemed to be an "at-the-market-offering" as defined in Rule 415(a) (4) promulgated under the Securities Act of 1933, as amended. With our prior written approval, JonesTrading or B. Riley Securities may also sell the shares by any other method permitted by law, including in negotiated transactions. We and JonesTrading or B. Riley Securities may suspend or terminate the offering of shares upon notice to the other parties and subject to other conditions. During the year ended December 31, 2022, we did not sell any shares under the ATM Sales

## [Table of Contents](#)

Agreement. During the year ended December 31, 2021, we issued and sold 89,520 shares of common stock at a weighted average price per share of \$3.83 at-the-market pursuant to the ATM Sales Agreement for \$0.3 million in net proceeds.

### *Public Offering*

On February 11, 2021, we entered into a purchase agreement with Piper Sandler & Co., as representative of the underwriters named therein, pursuant to which we issued and sold to the underwriters in an underwritten public offering an aggregate of 24,150,000 shares of our common stock, including 3,150,000 shares of common stock sold in connection with the exercise in full of a 15% over-allotment option by the underwriters. The public offering price was \$3.80 per share. The gross proceeds to us from this offering were approximately \$91.8 million. After underwriting discounts and commissions and offering expenses, we received net proceeds from the offering of approximately \$85.8 million.

### *Warrants*

On February 24, 2014, we entered into a facility agreement with affiliates of Deerfield Management Company, L.P., or Deerfield. In connection with the execution of the original facility agreement, we issued to Deerfield warrants to purchase an aggregate of 1,000,000 shares of common stock at an exercise price of \$13.83 per share. The warrants have dividend rights to the same extent as if the warrants were exercised into shares of common stock. The warrants expire on the seventh anniversary of their issuance and contain certain limitations that prevent the holder from acquiring shares upon exercise of a warrant that would result in the number of shares beneficially owned by the holder exceeding 9.985% of the total number of shares of common stock then issued and outstanding. During the year ended December 31, 2021, the warrants expired without being exercised.

## 14. Defined Contribution Benefit Plan

We sponsor a 401(k) retirement plan in which substantially all of our full-time employees are eligible to participate. Participants may contribute a percentage of their annual compensation to this plan, subject to statutory limitations. During the years ended December 31, 2022 and 2021, we matched participants' contributions up to 6% of the participant's pre-tax salary. Our matching contributions for the years ended December 31, 2022 and 2021 was \$0.3 million and \$0.2 million, respectively.

## 15. Subsequent Events

On February 22, 2023, we, MEI Pharma, Inc., a Delaware corporation, or MEI, and Merger Sub, Inc., a Delaware corporation and a wholly owned subsidiary of MEI, or the Merger Sub, entered into an Agreement and Plan of Merger, or the Merger Agreement, pursuant to which, among other matters, and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into Infinity, with Infinity continuing as a wholly owned subsidiary of MEI and the surviving corporation of the merger, which transaction is referred to herein as the Merger. If the Merger is completed, the combined company will combine the expertise and resources of MEI and Infinity to advance a pipeline of three clinical-stage oncology drug candidates.

We expect to devote significant time and resources to the completion of the Merger. However, there can be no assurances that such activities will result in the completion of the Merger. Further, the completion of the Merger may ultimately not deliver the anticipated benefits or enhance shareholder value. If the Merger is not completed, we will consider alternative courses of action. We consider one of the following courses of action to be the most likely alternatives if the Merger is not completed:

- *Pursue another strategic transaction.* We may resume the process of evaluating a potential strategic transaction, including the sale of the company or its assets. Based on our prior assessment, we do not expect that we would have the necessary time or financial resources to pursue another strategic transaction like the proposed Merger.

---

## [Table of Contents](#)

- *Wind down the company.* If the Merger does not close and we are unable to enter into another strategic transaction, our board of directors may conclude that it is in the best interest of stockholders to cease normal operations and wind down the company through bankruptcy or dissolution proceedings. In such case, there would be no assurances as to the amount or timing of available cash remaining, if any, to distribute to stockholders after paying our obligations and setting aside funds for reserves.

In conjunction with their approval of the Merger Agreement, our board of directors approved a strategic restructuring to preserve our resources. As a result, we have reduced our overall headcount by four positions, representing approximately 13% of our workforce at the time we entered into the Merger Agreement. We expect to incur approximately \$1.6 million and \$0.1 million in total restructuring charges in general and administrative expenses and research and development expenses, respectively in the first quarter of 2023. These charges primarily consist of severance payments, employee benefits and related taxes, and stock-based compensation. Of the aggregate restructuring costs, we expect approximately \$0.9 million to be settled through future cash expenditures. We expect the workforce reduction will be substantially completed by March 31, 2023.

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) is the type of information that the registrant treats as private or confidential. Double asterisks denote omissions.

AGREEMENT AND PLAN OF MERGER

among

INFINITY PHARMACEUTICALS, INC.

MEI PHARMA, INC.

and

MEADOW MERGER SUB, INC.

Dated as of February 22, 2023

**TABLE OF CONTENTS**  
(continued)

	<b>Page</b>
ARTICLE I THE MERGER; CLOSING; SURVIVING COMPANY	A-1
1.1.    The Merger	A-1
1.2.    Closing	A-2
1.3.    Effective Time	A-2
1.4.    The Certificate of Incorporation	A-2
1.5.    The Bylaws	A-2
1.6.    Directors and Officers of Meadow	A-2
1.7.    Directors and Officers of the Surviving Company	A-2
ARTICLE II EFFECT OF THE MERGER ON SECURITIES; EXCHANGE	A-2
2.1.    Effect on Capital Stock	A-2
2.2.    Exchange of Certificates	A-3
2.3.    Treatment of Equity Awards and Warrants	A-6
2.4.    Withholding Rights	A-6
2.5.    Calculation of Meadow Net Cash	A-6
2.6.    Calculation of Iris Net Cash	A-8
ARTICLE III REPRESENTATIONS AND WARRANTIES OF IRIS	A-9
3.1.    Organizational Documents	A-9
3.2.    Due Organization; Subsidiaries	A-9
3.3.    Capitalization	A-10
3.4.    Authority; Binding Nature of Agreement	A-11
3.5.    Non-Contravention; Consents	A-11
3.6.    SEC Documents; Financial Statements	A-12
3.7.    Absence of Changes	A-14
3.8.    Absence of Undisclosed Liabilities	A-14
3.9.    Title to Assets	A-14
3.10.   Legal Proceedings; Orders	A-14
3.11.   Contracts	A-15
3.12.   Employee and Labor Matters; Benefits Plans	A-16
3.13.   Environmental Matters	A-20
3.14.   Taxes	A-20
3.15.   Intellectual Property	A-21
3.16.   Regulatory Matters	A-24
3.17.   Insurance; Real Estate	A-26
3.18.   Registration Statement and Joint Proxy Statement/Prospectus	A-27
3.19.   Transactions with Affiliates	A-27

**TABLE OF CONTENTS**  
(continued)

	<b>Page</b>
3.20. Brokers and Finders	A-27
3.21. Opinion of Financial Advisor	A-27
3.22. Anti-Bribery	A-27
3.23. Ownership of Meadow Common Stock	A-28
ARTICLE IV REPRESENTATIONS AND WARRANTIES OF MEADOW AND MERGER SUB	A-28
4.1. Organizational Documents	A-28
4.2. Due Organization; Subsidiaries	A-28
4.3. Capitalization	A-29
4.4. Authority; Binding Nature of Agreement	A-30
4.5. Non-Contravention; Consents	A-30
4.6. SEC Filings; Financial Statements	A-32
4.7. Absence of Changes	A-33
4.8. Absence of Undisclosed Liabilities	A-33
4.9. Title to Assets	A-33
4.10. Legal Proceedings; Orders	A-34
4.11. Contracts	A-34
4.12. Employee and Labor Matters; Benefits Plans	A-36
4.13. Environmental Matters	A-39
4.14. Taxes	A-40
4.15. Intellectual Property	A-41
4.16. Regulatory Matters	A-44
4.17. Insurance; Real Estate	A-46
4.18. Registration Statement and Joint Proxy Statement/Prospectus	A-47
4.19. Transactions with Affiliates	A-47
4.20. Brokers and Finders	A-47
4.21. Opinion of Financial Advisor	A-47
4.22. Anti-Bribery	A-47
4.23. Ownership and Operations of Merger Sub	A-47
4.24. Ownership of Iris Common Stock	A-48
ARTICLE V COVENANTS	A-48
5.1. Interim Operations	A-48
5.2. Iris Acquisition Proposals; Iris Change in Recommendation	A-52
5.3. Meadow Acquisition Proposals; Meadow Change in Recommendation	A-56
5.4. Information Supplied	A-60

**TABLE OF CONTENTS**  
(continued)

	<b>Page</b>
5.5. Stockholder Meetings	A-61
5.6. Regulatory Approvals and Related Matters	A-63
5.7. Access; Consultation	A-63
5.8. Stock Exchange Listing, De-listing and De-registration	A-64
5.9. [**]	A-64
5.10. [**]	A-64
5.11. Publicity	A-64
5.12. Expenses	A-64
5.13. Indemnification; Directors' and Officers' Insurance	A-64
5.14. Takeover Statute	A-66
5.15. Control of Iris's or Meadow's Operations	A-66
5.16. Directors and Officers; Post-Closing Company Headquarters and Name	A-66
5.17. Section 16(b)	A-66
5.18. Approval by Sole Stockholder of Merger Sub	A-67
5.19. Stockholder Litigation	A-67
5.20. Tax Treatment	A-67
5.21. Employee Matters	A-68
5.22. Obligations of Merger Sub and Surviving Company	A-69
ARTICLE VI CONDITIONS	A-69
6.1. Conditions to Each Party's Obligation to Effect the Merger	A-69
6.2. Conditions to Obligations of Meadow and Merger Sub	A-69
6.3. Conditions to Obligation of Iris	A-70
6.4. Frustration of Conditions	A-70
ARTICLE VII TERMINATION	A-71
7.1. Termination by Mutual Consent	A-71
7.2. Termination by Either Meadow or Iris	A-71
7.3. Termination by Iris	A-71
7.4. Termination by Meadow	A-72
7.5. Iris Termination Fee and Expense Reimbursement	A-72
7.6. Meadow Termination Fee and Expense Reimbursement	A-72
7.7. Effect of Termination and Abandonment	A-73
7.8. Remedies	A-73
ARTICLE VIII MISCELLANEOUS AND GENERAL	A-74
8.1. Survival	A-74



**TABLE OF CONTENTS**  
(continued)

	<b>Page</b>
8.2. Amendment	A-74
8.3. Assignability	A-74
8.4. Waiver	A-74
8.5. Entire Agreement; Counterparts; Exchanges by Electronic Transmission	A-74
8.6. Governing Law and Venue; Waiver of Jury Trial	A-74
8.7. Notices	A-75
8.8. No Third Party Beneficiaries	A-76
8.9. Severability	A-76
8.10. No Other Representations and Warranties	A-76
8.11. Construction	A-77
8.12. Certain Definitions: For the purposes of this Agreement:	A-78
8.13. Specific Performance	A-86

Exhibits

Exhibit A	Form of Certificate of Merger
Exhibit B	Form of Certificate of Incorporation
Exhibit C	Form of Bylaws
Exhibit D	Directors and Officers of Meadow

Schedules

Schedule I	[**]
Schedule II	Net Cash

## DEFINED TERMS INDEX

<u>Defined Term</u>	<u>Section</u>
Accounting Firm	Section 2.5(e)
Agreement	Preamble
Anticipated Closing Date	Section 2.5(a)
Bankruptcy and Equity Exception	Section 3.4(a)
Briefing Book	Section 5.9
Bylaws	Section 1.5
Cash Determination Time	Section 2.5(a)
Certificate	Section 2.1(a)(ii)
Certificate of Incorporation	Section 1.4
Certificate of Merger	Section 1.3
[**]	Section 5.9
[**]	Section 5.9
Closing	Section 1.2
Closing Date	Section 1.2
COVID-19 Measures and Responses	Section 5.1(a)
Current Employee	Section 5.21(a)
DGCL	Recitals
DOL	Section 3.12(b)
Effective Time	Section 1.3
[**]	Section 5.9
ESPP Option	Section 2.3(c)
Exchange Agent	Section 2.2(a)
Exchange Fund	Section 2.2(a)
Excluded Share	Section 2.1(a)(i)
Excluded Shares	Section 2.1(a)(i)
FDA Ethics Policy	Section 3.16(h)
[**]	Section 5.9
Indemnified Persons	Section 5.13(a)
IRB	Section 3.16(l)
Iris	Preamble
Iris Acquisition Proposal	Section 5.2(d)
Iris Alternative Acquisition Agreement	Section 5.2(e)
Iris Balance Sheet	Section 3.7
Iris Board	Recitals
Iris Board Recommendation	Recitals
Iris Budget	Section 5.1(a)(v)
Iris Certifications	Section 3.6(a)
Iris Change in Recommendation	Section 5.2(e)
Iris Common Stock	Section 3.3(a)
Iris Delivery Date	Section 2.6(a)
Iris Disclosure Schedule	Article III
Iris Dispute Notice	Section 2.6(b)
Iris Equity Awards	Section 2.3(d)
Iris Final Net Cash	Section 2.6(c)
Iris In-bound License	Section 3.15(d)
Iris In-Licensed IP	Section 3.15(e)
Iris Intervening Event	Section 5.2(d)
Iris Leased Real Property	Section 3.17(b)
Iris Material Contract	Section 3.11(a)

## Table of Contents

<u>Defined Term</u>	<u>Section</u>
Iris Net Cash Calculation	Section 2.6(a)
Iris Net Cash Schedule	Section 2.6(a)
Iris Out-bound License	Section 3.15(d)
Iris Permits	Section 3.16(c)
Iris Preferred Stock	Section 3.3(a)
Iris Products	Section 3.16(e)
Iris Real Estate Leases	Section 3.17(b)
Iris Registered IP	Section 3.15(a)
Iris Reports	Section 3.16(g)
Iris Response Date	Section 2.6(b)
Iris Sensitive Data	Section 3.15(h)
Iris SEC Documents	Section 3.6(a)
Iris Stockholder Approval	Section 3.4(b)
Iris Stock Incentive Plans	Section 3.3(d)
Iris Stockholders Meeting	Section 5.5(a)
Iris Superior Proposal	Section 5.2(d)
Iris 2010 Stock Incentive Plan	Section 3.3(d)
Iris 2019 Equity Incentive Plan	Section 3.3(d)
IRS	Section 3.12(b)
Joint Proxy Statement/Prospectus	Section 5.4
Meadow	Preamble
Meadow Alternative Acquisition Agreement	Section 5.3(e)
Meadow Balance Sheet	Section 4.7
Meadow Board	Recitals
Meadow Board Recommendation	Recitals
Meadow Budget	Section 5.1(a)(v)
Meadow Certifications	Section 4.6(a)
Meadow Change in Recommendation	Section 5.3(e)
Meadow Common Stock	Section 4.3(a)
Meadow Delivery Date	Section 2.5(a)
Meadow Disclosure Schedule	Article IV
Meadow Dispute Notice	Section 2.5(b)
Meadow Final Net Cash	Section 2.5(c)
Meadow In-bound License	Section 4.15(d)
Meadow Inducement Plan	Section 4.3(d)
Meadow In-Licensed IP	Section 4.15(e)
Meadow Leased Real Property	Section 4.17(b)
Meadow Net Cash Calculation	Section 2.5(a)
Meadow Net Cash Schedule	Section 2.5(a)
Meadow Out-bound License	Section 4.15(d)
Meadow Permits	Section 4.16(c)
Meadow Product	Section 4.16(e)
Meadow Real Estate Lease	Section 4.17(b)
Meadow Registered IP	Section 4.15(a)
Meadow Reports	Section 4.16(g)
Meadow Response Date	Section 2.5(b)
Meadow SEC Documents	Section 4.6(a)
Meadow Sensitive Data	Section 4.15(h)
Meadow Share Issuance	Section 4.4(a)
Meadow Stockholder Approval	Section 4.4(b)
Meadow Stock Plans	Section 4.3(d)

## Table of Contents

<u>Defined Term</u>	<u>Section</u>
Meadow Stockholders Meeting	Section 5.5(b)(i)
Meadow 2008 Equity Compensation Plan	Section 4.3(d)
Merger	Recitals
Merger Consideration	Section 2.1(a)(i)
Merger Sub	Preamble
Parties	Preamble
Party	Preamble
Payor	Section 7.8(a)
Pre-Closing Period	Section 5.1(a)
Recall	Section 3.16(f)
Recipient	Section 7.8(a)
Registration Statement	Section 5.4
Reports	Section 3.16(g)
Representatives	Section 5.2(a)
S-8 Registration Statement	Section 2.3(e)
Shares	Recitals
Surviving Company	Section 1.1
Tax Opinion	Section 5.20(d)
Termination Date	Section 7.2(a)
Termination Fee	Section 7.8(a)
Uncertificated Shares	Section 2.1(a)(ii)
Warn Act	Section 3.12(s)
Willful Breach	Section 7.7
Iris 401(k) Plan	Section 5.21(c)

## AGREEMENT AND PLAN OF MERGER

**THIS AGREEMENT AND PLAN OF MERGER** (hereinafter referred to as this “**Agreement**”), dated as of February 22, 2023, among Infinity Pharmaceuticals, Inc., a Delaware corporation (“**Iris**”), MEI Pharma, Inc., a Delaware corporation (“**Meadow**”), and Meadow Merger Sub, Inc., a Delaware corporation and a wholly owned Subsidiary of Meadow (“**Merger Sub**”). Meadow, Merger Sub and Iris are each sometimes referred to herein as a “**Party**” and collectively as the “**Parties**”.

### RECITALS

**A.** The Parties wish to effect a business combination through the merger of Merger Sub with and into Iris, with Iris being the surviving corporation (the “**Merger**”).

**B.** In connection with the Merger, each outstanding share of Iris Capital Stock (“**Shares**”) issued and outstanding immediately prior to the Effective Time shall be cancelled and each holder of Shares shall have the right to receive the Merger Consideration upon the terms and subject to the conditions set forth in this Agreement and in accordance with the General Corporation Law of the State of Delaware (the “**DGCL**”) (other than Shares to be cancelled in accordance with [Section 2.1\(a\)\(iii\)](#)).

**C.** The board of directors of Iris (the “**Iris Board**”) has (i) determined that the Contemplated Transactions, including the Merger, are advisable and in the best interests of Iris and its stockholders, (ii) approved and declared advisable this Agreement and the Contemplated Transactions and (iii) resolved to recommend the adoption of this Agreement by Iris’s stockholders (the “**Iris Board Recommendation**”).

**D.** The board of directors of Meadow (the “**Meadow Board**”) has (i) determined that the Contemplated Transactions, including the Merger and the Meadow Share Issuance, are advisable and in the best interests of Meadow and its stockholders, (ii) approved and declared advisable this Agreement and the Contemplated Transactions and (iii) resolved to recommend the approval of the Meadow Share Issuance by Meadow’s stockholders (the “**Meadow Board Recommendation**”).

**E.** The board of directors of Merger Sub, by resolutions duly adopted, has (i) determined that the Contemplated Transactions, including the Merger, are advisable and in the best interests of Merger Sub and its sole stockholder, (ii) approved and declared advisable this Agreement and the Contemplated Transactions and (iii) resolved to recommend the adoption of this Agreement by Meadow as its sole stockholder.

**F.** For U.S. federal income Tax purposes, it is intended that (i) the Merger will qualify as a “reorganization” within the meaning of Section 368(a) of the Internal Revenue Code of 1986, as amended (the “**Code**”) (such treatment, the “**Intended Tax Treatment**”) and (ii) this Agreement be, and it is hereby adopted as a “plan of reorganization” within the meaning of Treasury Regulations Section 1.368-2(g).

**NOW, THEREFORE**, in consideration of the premises, and of the representations, warranties, covenants and agreements contained herein, the Parties hereby agree as follows:

### ARTICLE I THE MERGER; CLOSING; SURVIVING COMPANY

1.1. The Merger. Upon the terms and subject to the conditions set forth in this Agreement, at the Effective Time, Merger Sub shall be merged with and into Iris and the separate corporate existence of Merger Sub shall thereupon cease. Iris shall be the surviving company in the Merger (sometimes hereinafter referred to as the “**Surviving Company**”), and the separate corporate existence of Iris with all its rights, privileges, immunities, powers and franchises shall continue unaffected by the Merger, except as set forth in [Article II](#). The Merger shall have the effects specified in this Agreement and the DGCL.

## Table of Contents

1.2. Closing. The closing of the Merger (the “**Closing**”) shall take place (a) via electronic exchange of the required Closing documentation set forth in Section 1.3 and Article VI, as soon as reasonably practicable, and in no event later than three Business Days following the day on which the last to be satisfied or waived of each of the conditions set forth in Article VI (other than those conditions that by their nature are to be satisfied at the Closing, but subject to the satisfaction or waiver of those conditions) shall have been satisfied or waived in accordance with this Agreement or (b) at such other place and time and/or on such other date as Iris and Meadow may otherwise agree in writing (the date on which the Closing occurs, the “**Closing Date**”).

1.3. Effective Time. Upon the Closing, Iris and Meadow will cause the certificate of merger with respect to the Merger in the form attached hereto as Exhibit A (the “**Certificate of Merger**”) to be executed, acknowledged and filed with the Secretary of State of the State of Delaware as provided in the DGCL. The Merger shall become effective at the time when the Certificate of Merger has been duly filed with the Secretary of State of the State of Delaware or at such later time as may be agreed upon by the Parties in writing and set forth in the Certificate of Merger in accordance with the DGCL (the “**Effective Time**”).

1.4. The Certificate of Incorporation. At the Effective Time, the certificate of incorporation of Iris shall be amended and restated in its entirety to read as set forth in Exhibit B hereto and as so amended and restated shall be the certificate of incorporation of the Surviving Company (the “**Certificate of Incorporation**”), until thereafter amended as provided therein or by applicable Law, subject to Section 5.13(b).

1.5. The Bylaws. At the Effective Time, the bylaws of Iris shall be amended and restated in their entirety to read as set forth in Exhibit C hereto and as so amended and restated shall be the bylaws of the Surviving Company (the “**Bylaws**”), until thereafter amended as provided therein, in the Certificate of Incorporation or by applicable Law, subject to Section 5.13(b).

1.6. Directors and Officers of Meadow. The Parties shall take all actions necessary so that the directors and officers of Meadow immediately following the Effective Time, each to hold office in accordance with Meadow’s Organizational Documents, shall be as set forth in Section 5.16 after giving effect to the provisions of Section 5.16(a), or such other Persons as shall be mutually agreed upon by Meadow and Iris in writing prior to the Effective Time until their successors have been duly elected or appointed and qualified or until their earlier death, resignation or removal in accordance with the Certificate of Incorporation, the Bylaws and applicable Law, subject to Section 5.13(b).

1.7. Directors and Officers of the Surviving Company. At the Effective Time, until their successors are duly elected or appointed and qualified in accordance with the Certificate of Incorporation, the Bylaws and applicable Law, (i) the directors of Merger Sub as of immediately prior to the Effective Time shall be the directors of the Surviving Company and (ii) the officers of Merger Sub as of immediately prior to the Effective Time shall be the officers of the Surviving Company.

## **ARTICLE II EFFECT OF THE MERGER ON SECURITIES; EXCHANGE**

### 2.1. Effect on Capital Stock.

(a) At the Effective Time, as a result of the Merger and without any action on the part of the holder of any capital stock of Iris, Meadow or Merger Sub:

(i) Merger Consideration. Each Share issued and outstanding immediately prior to the Effective Time (other than Shares held in treasury, if any (each such Share, an “**Excluded Share**” and, collectively, “**Excluded Shares**”)) shall be automatically converted into the right to receive a number of shares of Meadow Common Stock equal to the Exchange Ratio (the aggregate shares of Meadow Common Stock issued by applying the Exchange Ratio in accordance with this Section 2.1 and cash in lieu of any fractional shares of Meadow Common Stock payable pursuant to Section 2.2(e), the “**Merger Consideration**”).

## Table of Contents

(ii) At the Effective Time, all of the Shares (other than Excluded Shares) shall cease to be outstanding, shall be cancelled and shall cease to exist, and (A) each certificate (a “**Certificate**”) formerly representing any of the Shares (other than Excluded Shares) and (B) each book-entry account formerly representing any uncertificated Shares (“**Uncertificated Shares**”) (other than Excluded Shares) shall thereafter represent only the right to receive the Merger Consideration, any distributions or dividends payable pursuant to Section 2.2(c), and cash in lieu of any fractional shares of Meadow Common Stock payable pursuant to Section 2.2(e), without interest, in each case to be issued or paid in consideration therefor upon surrender of such Certificate in accordance with Section 2.2, in the case of certificated Shares, and upon receipt by the Exchange Agent of an “agent’s message” in customary form in accordance with Section 2.2(h) in the case of Uncertificated Shares.

(iii) Cancellation of Excluded Shares. Each Excluded Share shall, by virtue of the Merger and without any action on the part of Iris, Meadow, Merger Sub or the holder thereof, cease to be outstanding, shall be cancelled without payment of any consideration therefor and shall cease to exist.

(b) Merger Sub. Each share of common stock, par value \$0.001 per share, of Merger Sub issued and outstanding immediately prior to the Effective Time shall be converted into and become one validly issued, fully paid and nonassessable share of common stock, \$0.001 par value per share, of the Surviving Company, and such converted shares shall constitute the only outstanding shares of capital stock of the Surviving Company immediately following the Effective Time.

(c) Adjustments to Exchange Ratio. If, between the time of calculating the Exchange Ratio and the Effective Time, the outstanding shares of Iris Capital Stock or Meadow Common Stock shall have been changed into, or exchanged for, a different number of shares or a different class or series of shares, by reason of any stock dividend, subdivision, reclassification, recapitalization, split, reverse split, combination or exchange of shares or other like change, the Exchange Ratio shall, to the extent necessary, be equitably adjusted to reflect such change to the extent necessary to provide the holders of Iris Capital Stock with the same economic effect as contemplated by this Agreement prior to such stock dividend, subdivision, reclassification, recapitalization, split, reverse split, combination or exchange of shares or other like change; provided, however, that nothing herein will be construed to permit Iris or Meadow to take any action with respect to Iris Capital Stock or Meadow Common Stock, respectively, that is prohibited or not expressly permitted by the terms of this Agreement.

### 2.2. Exchange of Certificates.

(a) Exchange Agent and Exchange Fund. Prior to the Effective Time, Meadow shall designate Computershare Trust Company, N.A., its transfer agent, as the exchange agent in connection with the Merger (the “**Exchange Agent**”). The Exchange Agent shall also act as the agent for Iris’s stockholders for the purpose of receiving their surrendered Certificates and Uncertificated Shares and shall obtain no rights or interests in the Shares represented thereby. At the Closing, Meadow shall issue and cause to be deposited with the Exchange Agent: evidence of book-entry shares representing non-certificated shares of Meadow Common Stock issuable pursuant to Section 2.1(a) and Section 2.3. The shares of Meadow Common Stock and cash amounts so deposited with the Exchange Agent, together with any dividends or distributions received by the Exchange Agent with respect to such shares of Meadow Common Stock, are referred to collectively as the “**Exchange Fund**.”

(b) Exchange Procedures. Promptly after the Effective Time (and in any event within five Business Days thereafter), the Exchange Agent shall mail to each holder of record of Shares represented by a Certificate (other than holders of Excluded Shares) or Uncertificated Shares that were issued and outstanding immediately prior to the Effective Time (i) a letter of transmittal in customary form specifying that delivery shall be effected, and risk of loss and title to the Certificates shall pass, only upon delivery of the Certificates (or affidavits of loss in lieu of the Certificates as provided in Section 2.2(g)) or Uncertificated Shares to the Exchange Agent, such letter of transmittal to be in such form and have such other provisions as Meadow and Iris may reasonably agree, and (ii) instructions for surrendering the Certificates (or affidavits of loss in lieu of the Certificates as provided in

## Table of Contents

Section 2.2(g)) or Uncertificated Shares (including instructions for sending an “agent’s message” in customary form (or such other evidence, if any, as the Exchange Agent may reasonably request)) to the Exchange Agent. Upon surrender of a Certificate (or affidavit of loss in lieu of the Certificate as provided in Section 2.2(g)) to the Exchange Agent in accordance with the terms of such letter of transmittal or with respect to Uncertificated Shares receipt of an “agent’s message” in customary form (or such other evidence, if any, as the Exchange Agent may reasonably request) by the Exchange Agent, the holder of such surrendered Certificate or Uncertificated Share shall be entitled to receive in exchange therefor non-certificated shares of Meadow Common Stock in book-entry form and cash in lieu of any fractional share of Meadow Common Stock pursuant to Section 2.2(e) and any dividends or other distributions pursuant to Section 2.2(c), less in each case any required Tax withholdings as provided in Section 2.4. The Certificate or Uncertificated Share so surrendered shall forthwith be cancelled. Until due surrender of the Certificates or Uncertificated Shares, each Certificate and Uncertificated Share that immediately prior to the Effective Time represented shares of Company Common Stock shall be deemed, from and after the Effective Time, to represent only the right to receive shares of Meadow Common Stock (and any distributions or dividends payable pursuant to Section 2.2(c)) and cash in lieu of any fractional share of Meadow Common Stock pursuant to Section 2.2(e). In the event of a transfer of ownership of Shares that is not registered in the transfer records of Iris, the applicable portion of Merger Consideration to be exchanged upon due surrender of the Certificate or Uncertificated Share pursuant to Section 2.1(a) may be issued and paid to such transferee if the Certificate formerly representing such Shares is presented to the Exchange Agent, accompanied by all documents required to evidence and effect such transfer and to evidence that any applicable stock transfer Taxes have been paid or are not applicable.

(c) Distributions with Respect to Unexchanged Shares. All shares of Meadow Common Stock to be issued pursuant to the Merger shall be deemed issued and outstanding as of the Effective Time and whenever a dividend or other distribution is declared by Meadow in respect of the Meadow Common Stock, the record date for which is after the Effective Time, that declaration shall include dividends or other distributions in respect of all shares of Meadow Common Stock issuable in the Merger. No dividends or other distributions in respect of the Meadow Common Stock issued pursuant to the Merger shall be paid to any holder of any un-surrendered Certificate or Uncertificated Share that was issued and outstanding immediately prior to the Effective Time until such Certificate (or affidavit of loss in lieu thereof as provided in Section 2.2(g)) or Uncertificated Share is surrendered for exchange in accordance with this Article II. Subject to the effect of applicable Laws, following surrender of any such Certificate (or affidavit of loss in lieu thereof as provided in Section 2.2(g)) or Uncertificated Share, there shall be issued and/or paid to the holder of the whole shares of Meadow Common Stock issued in exchange therefor, without interest thereon, (a) at the time of such surrender, the dividends or other distributions with a record date after the Effective Time theretofore payable with respect to such whole shares of Meadow Common Stock and not paid and (b) at the appropriate payment date, the dividends or other distributions payable with respect to such whole shares of Meadow Common Stock with a record date after the Effective Time, but with a payment date subsequent to surrender.

(d) Transfers. From and after the Effective Time, there shall be no transfers on the stock transfer books of Iris of the Shares that were outstanding immediately prior to the Effective Time.

(e) Fractional Shares. No certificate or scrip representing fractional shares of Meadow Common Stock shall be issued upon the surrender for exchange of Certificates or Uncertificated Shares that were issued and outstanding immediately prior to the Effective Time, and such fractional share interests shall not entitle the owner thereof to vote or to any other rights of a stockholder of Meadow. The Exchange Agent, acting as agent for the holders of Shares otherwise entitled to receive fractional shares of Meadow Common Stock, will aggregate all fractional shares of Meadow Common Stock that would otherwise have been required to be distributed and cause them to be sold in the open market for the accounts of such holders. Notwithstanding any other provision of this Agreement, each holder of Shares who would otherwise have been entitled to receive a fraction of a share of Meadow Common Stock shall receive, in lieu thereof, cash, rounded to the nearest whole cent and without interest, in an amount equal to the proceeds from such sale by the Exchange Agent, if any, less any reasonable brokerage commissions or other fees, transfer Taxes or other out-of-pocket transaction costs, as



## Table of Contents

well as any expenses of the Exchange Agent incurred from the sale of such fractional shares of Meadow Common Stock in accordance with such holder's fractional interest in the aggregate number of shares of Meadow Common Stock sold. The Parties acknowledge that payment of the cash consideration in lieu of issuing fractional shares of Meadow Common Stock was not separately bargained-for consideration but merely represents a mechanical rounding off for purposes of avoiding the expense and inconvenience to Meadow that would otherwise be caused by the issuance of fractional shares of Meadow Common Stock.

(f) Termination of Exchange Fund. Any portion of the Exchange Fund (including the proceeds of any investments of the Exchange Fund) that remains unclaimed by the holders of Shares that were issued and outstanding immediately prior to the Effective Time for 180 days after the Effective Time shall be delivered, at Meadow's option, to Meadow. Any former holder of Shares (other than Excluded Shares) who has not theretofore complied with Section 2.2(b), shall thereafter look only to Meadow for delivery of any shares of Meadow Common Stock, payment of cash in lieu of fractional shares and any dividends and other distributions in respect of the Meadow Common Stock to be issued or paid pursuant to the provisions of this Article II (after giving effect to any required Tax withholdings as provided in Section 2.4) upon due surrender of its Certificates (or affidavits of loss in lieu of the Certificates as provided in Section 2.2(g)) or Uncertificated Shares that were issued and outstanding immediately prior to the Effective Time, without any interest thereon. Notwithstanding the foregoing, none of the Surviving Company, Meadow, Exchange Agent or any other Person shall be liable to any former holder of Shares for any amount properly delivered to a public official pursuant to applicable abandoned property, escheat or similar Laws. To the fullest extent permitted by Law, immediately prior to the date any Merger Consideration would otherwise escheat to or become the property of any Governmental Entity, such Merger Consideration shall become the property of Meadow, free and clear of all claims or interest of any Person previously entitled thereto.

(g) Lost, Stolen or Destroyed Certificates. In the event any Certificate representing Shares (other than Excluded Shares) that were issued and outstanding immediately prior to the Effective Time shall have been lost, stolen or destroyed, upon the making of an affidavit of that fact by the Person claiming such Certificate to be lost, stolen or destroyed, and, if required by the Exchange Agent's customary practices, the entry by such Person into an indemnification agreement in customary form providing an indemnity against any claim that may be made against it with respect to such Certificate, the Exchange Agent will issue in exchange for such lost, stolen or destroyed Certificate, the cash in lieu of fractional shares, shares of Meadow Common Stock and any dividends and other distributions in respect of the Meadow Common Stock that would have been issuable or payable pursuant to the provisions of this Article II (after giving effect to any required Tax withholdings as provided in Section 2.4) had such lost, stolen or destroyed Certificate been surrendered.

(h) Uncertificated Shares. Any holder of Uncertificated Shares that were issued and outstanding immediately prior to the Effective Time shall not be required to deliver a Certificate or an executed letter of transmittal to the Exchange Agent to receive the Merger Consideration, any dividends or other distributions payable pursuant to Section 2.2(c) and cash in lieu of any fractional shares of Meadow Common Stock payable pursuant to Section 2.2(e) that such holder is entitled to receive pursuant to this Article II in respect of such Uncertificated Shares. In lieu thereof, each registered holder of one or more Uncertificated Shares whose Shares were converted into the right to receive the Merger Consideration, any distributions or dividends payable pursuant to Section 2.2(c) and cash in lieu of any fractional shares of Meadow Common Stock payable pursuant to Section 2.2(e), shall, upon receipt by the Exchange Agent of an "agent's message" in customary form (or such other evidence, if any, as the Exchange Agent may reasonably request), be entitled to receive, and Meadow and the Surviving Company shall cause the Exchange Agent to pay and deliver as soon as reasonably practicable after the Effective Time, the Merger Consideration, any dividends or other distributions payable pursuant to Section 2.2(c) and cash in lieu of any fractional shares of Meadow Common Stock payable pursuant to Section 2.2(e), for each such Uncertificated Share, and such Uncertificated Shares of such holder shall forthwith be cancelled. No interest will be paid or accrued on any amount payable to a holder of Uncertificated Shares.

2.3. Treatment of Equity Awards and Warrants.

(a) At the Effective Time, each (i) Iris Stock Incentive Plan and (ii) outstanding Iris Options, whether vested or unvested, will be assumed by Meadow. Each such Iris Option so assumed by Meadow under this Agreement shall continue to have, and be subject to, the same terms and conditions applicable to such Iris Options immediately prior to the Effective Time (after giving effect to the full acceleration of vesting of such options applicable to the Iris Options in connection with the Closing), except that (A) such option will be exercisable for that number of shares of Meadow Common Stock equal to the number of shares of Iris Common Stock subject to such option immediately prior to the Effective Time multiplied by the Exchange Ratio and rounded down to the next nearest share of Meadow Common Stock, and (B) the exercise price per share shall be the exercise price per share in effect for that option immediately prior to the Effective Time divided by the Exchange Ratio and rounded up to the next nearest cent. At or prior to the Effective Time, Meadow shall take all corporate action necessary to reserve for issuance a sufficient number of shares of Meadow Common Stock for delivery of options assigned to and assumed by it in accordance with this [Section 2.3\(b\)](#).

(b) Any RSUs (vested or unvested) shall be distributed before the Effective Time in accordance with their terms and any Shares resulting therefrom shall be treated in accordance with the terms of this Agreement. No Iris RSUs shall be outstanding from and after the Effective Time.

(c) (i) Iris and the Iris Board shall take such actions as may be necessary, including providing advance written notice to each holder of options thereunder ("**ESPP Options**"), prior to the Effective Time such that: (i) the Purchase Periods and Offering Periods (each, as defined in the Iris ESPP) then in effect under the Iris ESPP shall be terminated by the Iris Board in accordance with the terms of the Iris ESPP and (ii) all outstanding ESPP Options shall be exercised to the extent of accumulated payroll deductions as of a date specified by the Iris Board in such notice, which date shall not be less than ten (10) days preceding the Effective Time. No ESPP Options shall be outstanding from and after the Effective Time.

(d) Further Action. Prior to the Effective Time, Iris and the Iris Board shall adopt any resolutions which are reasonably necessary to effectuate the treatment of the Iris Options and Iris RSUs (collectively, the "**Iris Equity Awards**"), and the Iris ESPP and the ESPP Options thereunder, set forth in clauses (a) through (c) of this [Section 2.3](#) prior to the Effective Time. At or prior to the Effective Time, Iris shall terminate the Iris ESPP.

(e) As soon as practicable following the Closing Date, Meadow will file an appropriate registration statement on Form S-8 or other appropriate form with respect to the offering of the shares of Meadow Common Stock issuable upon vesting of the assumed Iris Options (the "**S-8 Registration Statement**") and will use reasonable best efforts to maintain the effectiveness of the S-8 Registration Statement thereafter for so long as any of such Iris Options remain outstanding.

2.4. Withholding Rights. Each of Meadow, the Merger Sub, Iris, Surviving Company and the Exchange Agent shall be entitled to deduct and withhold from the consideration otherwise payable to Persons pursuant to this Agreement any amounts it is required to deduct and withhold with respect to the making of such payment under the Code or any other applicable state, local or foreign Tax Law. To the extent that amounts are so withheld and timely remitted by Meadow, the Merger Sub, Iris, the Surviving Company or the Exchange Agent, as the case may be, to the applicable Governmental Entity, such amounts shall be treated for all purposes of this Agreement as having been paid to such Person in respect of which such deduction and withholding was made.

2.5. Calculation of Meadow Net Cash.

(a) Not more than seven Business Days nor less than four Business Days prior to the anticipated date for Closing (as mutually agreed in good faith by Meadow and Iris) (the "**Anticipated Closing Date**"), Meadow will deliver to Iris a schedule (the "**Meadow Net Cash Schedule**") setting forth, in reasonable detail, Meadow's good faith estimated calculation of its Net Cash (the "**Meadow Net Cash Calculation**") and the date of delivery of such schedule, the "**Meadow Delivery Date**") as of 8:00 p.m. Eastern Time on the last Business Day prior to the Anticipated Closing Date (the "**Cash Determination Time**"), prepared in accordance with GAAP and

## Table of Contents

certified by Meadow's chief financial officer (or if there is no chief financial officer at such time, the principal financial and accounting officer of Meadow). Meadow shall make available to Iris, its accountants and/or counsel, the work papers and back-up materials used or useful in preparing the Meadow Net Cash Schedule, as reasonably requested by Iris (subject, in each case, to the execution of customary non-reliance, confidentiality or similar agreements).

(b) Within three Business Days following the Meadow Delivery Date (the last day of such period, the "**Meadow Response Date**"), Iris will have the right to dispute all or any part or parts of the Meadow Net Cash Calculation by delivering a written notice to that effect (a "**Meadow Dispute Notice**") to Meadow. Any Meadow Dispute Notice shall identify in reasonable detail (to the extent then known) the nature and amounts of any proposed revisions to the Meadow Net Cash Calculation.

(c) If (i) Iris notifies Meadow in writing on or prior to the Meadow Response Date that it has no objections to the Meadow Net Cash Calculation or (ii) Iris has failed to deliver a Meadow Dispute Notice as provided in Section 2.5(b) prior to 8:00 p.m. Eastern Time on the Meadow Response Date, then the Meadow Net Cash Calculation as set forth in the Meadow Net Cash Schedule shall be deemed to have been finally determined for purposes of this Agreement and to represent Meadow's Net Cash at the Cash Determination Time (the "**Meadow Final Net Cash**") for purposes of this Agreement.

(d) If Iris delivers a Meadow Dispute Notice prior to 8:00 p.m. Eastern Time on the Meadow Response Date, then Representatives of Meadow and Iris shall promptly, and in no event later than one calendar day after the Meadow Response Date, meet and attempt in good faith to resolve the disputed item(s) and negotiate an agreed-upon determination of Meadow's Net Cash, which agreed-upon amount of Net Cash shall be deemed to have been finally determined for purposes of this Agreement and to represent the Meadow Final Net Cash for purposes of this Agreement.

(e) If Representatives of Meadow and Iris are unable to negotiate an agreed-upon determination of Meadow Final Net Cash pursuant to Section 2.5(d) within two calendar days after delivery of the Meadow Dispute Notice (or such other period as Meadow and Iris may mutually agree upon in writing), then any remaining disagreements as to the calculation of Meadow's Net Cash shall be referred to KPMG or another independent auditor of recognized national standing mutually agreed upon by Meadow and Iris (the "**Accounting Firm**"). Meadow shall promptly deliver to the Accounting Firm all work papers and back-up materials used in preparing the Meadow Net Cash Schedule, and Iris shall promptly deliver to the Accounting Firm all work papers and back-up materials used in preparing the Meadow Dispute Notice except, in each case, to the extent doing so could result in the loss of attorney client privilege or similar immunity or protection. Meadow and Iris shall use commercially reasonable efforts to cause the Accounting Firm to make its determination within five calendar days of accepting its selection. Iris and Meadow shall be afforded the opportunity to present to the Accounting Firm any material related to the unresolved disputes and to discuss the issues with the Accounting Firm; provided, however, that no such presentation or discussion shall occur without the presence of a Representative of each of Iris and Meadow. The determination of the Accounting Firm shall be limited to the disagreements submitted to the Accounting Firm. The determination of the amount of Meadow's Net Cash made by the Accounting Firm shall be made in writing delivered to each of Iris and Meadow, shall be final and binding on Iris and Meadow and shall be deemed to have been finally determined for purposes of this Agreement and to represent the Meadow Final Net Cash for purposes of this Agreement, absent fraud or manifest error. The Parties shall delay the Closing until the resolution of the matters described in this Section 2.5(e). The fees and expenses of the Accounting Firm shall be allocated (and shall, to the extent allocable to Meadow, serve as a deduction from Meadow Final Net Cash) between Meadow and Iris in the same proportion that the disputed amount of Meadow's Net Cash that was unsuccessfully disputed by such Party (as finally determined by the Accounting Firm) bears to the total disputed amount of the Net Cash amount and such portion of the costs and expenses of the Accounting Firm borne by Meadow and any other fees, costs or expenses incurred by Meadow following the Meadow Delivery Date in connection with the procedures set forth in this Section 2.5(e) shall be deducted from the final determination of the amount of Net Cash. If this Section 2.5(e) applies as to the determination of the

## Table of Contents

Meadow Final Net Cash, upon resolution of the matter in accordance with this Section 2.5(e), the Parties shall not be required to determine the Net Cash again even though the Closing Date may occur later than the Anticipated Closing Date, except that either Party may require a re-determination of Meadow Final Net Cash if the Closing Date is more than ten calendar days after the Anticipated Closing Date.

### 2.6. Calculation of Iris Net Cash.

(a) Not more than seven Business Days nor less than four Business Days prior to Anticipated Closing Date, Iris will deliver to Meadow a schedule (the “**Iris Net Cash Schedule**”) setting forth, in reasonable detail, Iris’s good faith estimated calculation of its Net Cash (the “**Iris Net Cash Calculation**”) and the date of delivery of such schedule, the “**Iris Delivery Date**”) as of the Cash Determination Time, prepared in accordance with GAAP and certified by Iris’s chief financial officer (or if there is no chief financial officer at such time, the principal financial and accounting officer of Iris). Iris shall make available to Meadow, its accountants and/or counsel, the work papers and back-up materials used or useful in preparing the Iris Net Cash Schedule, as reasonably requested by Meadow (subject, in each case, to the execution of customary non-reliance, confidentiality or similar agreements).

(b) Within three Business Days following the Iris Delivery Date (the last day of such period, the “**Iris Response Date**”), Meadow will have the right to dispute all or any part or parts of the Iris Net Cash Calculation by delivering a written notice to that effect (a “**Iris Dispute Notice**”) to Iris. Any Iris Dispute Notice shall identify in reasonable detail (to the extent then known) the nature and amounts of any proposed revisions to the Iris Net Cash Calculation.

(c) If (i) Meadow notifies Iris in writing on or prior to the Iris Response Date that it has no objections to the Iris Net Cash Calculation or (ii) Meadow has failed to deliver an Iris Dispute Notice as provided in Section 2.6(b) prior to 8:00 p.m. Eastern Time on the Iris Response Date, then the Iris Net Cash Calculation as set forth in the Iris Net Cash Schedule shall be deemed to have been finally determined for purposes of this Agreement and to represent Iris’s Net Cash at the Cash Determination Time (the “**Iris Final Net Cash**”) for purposes of this Agreement.

(d) If Meadow delivers an Iris Dispute Notice prior to 8:00 p.m. Eastern Time on the Iris Response Date, then Representatives of Iris and Meadow shall promptly, and in no event later than one calendar day after the Iris Response Date, meet and attempt in good faith to resolve the disputed item(s) and negotiate an agreed-upon determination of Iris’s Net Cash, which agreed-upon amount of Net Cash shall be deemed to have been finally determined for purposes of this Agreement and to represent the Iris Final Net Cash for purposes of this Agreement.

(e) If Representatives of Iris and Meadow are unable to negotiate an agreed-upon determination of Iris Final Net Cash pursuant to Section 2.6(d) within two calendar days after delivery of the Iris Dispute Notice (or such other period as Iris and Meadow may mutually agree upon in writing), then any remaining disagreements as to the calculation of Iris’s Net Cash shall be referred to the Accounting Firm. Iris shall promptly deliver to the Accounting Firm all work papers and back-up materials used in preparing the Iris Net Cash Schedule, and Meadow shall promptly deliver to the Accounting Firm all work papers and back-up materials used in preparing the Iris Dispute Notice except, in each case, to the extent doing so could result in the loss of attorney client privilege or similar immunity or protection. Iris and Meadow shall use commercially reasonable efforts to cause the Accounting Firm to make its determination within five calendar days of accepting its selection. Meadow and Iris shall be afforded the opportunity to present to the Accounting Firm any material related to the unresolved disputes and to discuss the issues with the Accounting Firm; provided, however, that no such presentation or discussion shall occur without the presence of a Representative of each of Meadow and Iris. The determination of the Accounting Firm shall be limited to the disagreements submitted to the Accounting Firm. The determination of the amount of Net Cash made by the Accounting Firm shall be made in writing delivered to each of Meadow and Iris, shall be final and binding on Meadow and Iris and shall be deemed to have been finally determined for

purposes of this Agreement and to represent the Iris Final Net Cash for purposes of this Agreement, absent fraud or manifest error. The Parties shall delay the Closing until the resolution of the matters described in this [Section 2.6\(e\)](#). The fees and expenses of the Accounting Firm shall be allocated (and shall, to the extent allocable to Iris, serve as a deduction from Iris Final Net Cash) between Iris and Meadow in the same proportion that the disputed amount of the Net Cash that was unsuccessfully disputed by such Party (as finally determined by the Accounting Firm) bears to the total disputed amount of the Net Cash amount and such portion of the costs and expenses of the Accounting Firm borne by Iris and any other fees, costs or expenses incurred by Iris following the Iris Delivery Date in connection with the procedures set forth in this [Section 2.6\(e\)](#) shall be deducted from the final determination of the amount of Net Cash. If this [Section 2.6\(e\)](#) applies as to the determination of the Iris Final Net Cash, upon resolution of the matter in accordance with this [Section 2.6\(e\)](#), the Parties shall not be required to determine the Net Cash again even though the Closing Date may occur later than the Anticipated Closing Date, except that either Party may require a re-determination of Iris Final Net Cash if the Closing Date is more than ten calendar days after the Anticipated Closing Date.

### ARTICLE III REPRESENTATIONS AND WARRANTIES OF IRIS

Iris represents and warrants to Meadow as set forth in the statements contained in this [Article III](#) except as set forth in the Iris SEC Documents filed with, or furnished to, the SEC prior to the date hereof and publicly available on the SEC's Electronic Data Gathering Analysis and Retrieval system (but (i) without giving effect to any amendment thereof filed with, or furnished to, the SEC on or after the date hereof and (ii) excluding any disclosures contained under the heading "Risk Factors" and any disclosure of risks included in any "forward-looking statements" disclaimer or in any other section to the extent they are forward-looking statements or cautionary, predictive or forward-looking in nature) or in the disclosure letter delivered by Iris to Meadow at or before the execution and delivery of this Agreement (the "**Iris Disclosure Schedule**"). The Iris Disclosure Schedule shall be arranged in numbered and lettered sections corresponding to the numbered and lettered sections contained in this [Article III](#), and the disclosure in any section of the Iris Disclosure Schedule shall be deemed to qualify other sections in this [Article III](#) to the extent that it is reasonably apparent on the face of such disclosure that such disclosure also qualifies or applies to such other sections.

3.1. [Organizational Documents](#). Iris has made available to Meadow accurate and complete copies of the Organizational Documents of Iris and each of its Subsidiaries in effect as of the date of this Agreement. Neither Iris nor any of its Subsidiaries is in material breach or violation of its respective Organizational Documents.

3.2. [Due Organization; Subsidiaries](#).

(a) Iris is a corporation duly incorporated, validly existing and in good standing under the Laws of the State of Delaware, and has all necessary corporate power and authority: (i) to conduct its business in the manner in which its business is currently being conducted; (ii) to own or lease and use its property and assets in the manner in which its property and assets are currently owned or leased and used; and (iii) to perform its obligations under all Contracts by which it is bound, except where the failure to have such power or authority would not have an Iris Material Adverse Effect.

(b) Iris is duly licensed and qualified to do business and is in good standing (to the extent applicable in such jurisdiction), under the Laws of all jurisdictions where the nature of its business requires such licensing or qualification other than in jurisdictions where the failure to be so qualified would not have an Iris Material Adverse Effect.

(c) Each of Iris's Subsidiaries is identified in [Section 3.2\(c\)](#) of the Iris Disclosure Schedule; and neither Iris nor any of the entities identified in [Section 3.2\(c\)](#) of the Iris Disclosure Schedule owns any capital stock of, or any equity, ownership or profit sharing interest of any nature in, or controls directly or indirectly, any other

## Table of Contents

entity other than the entities identified in Section 3.2(c) of the Iris Disclosure Schedule. Each of Iris's Subsidiaries is a corporation or other legal entity duly organized, validly existing and, if applicable, in good standing under the Laws of the jurisdiction of its organization and has all necessary corporate or other power and authority to conduct its business in the manner in which its business is currently being conducted and to own or lease and use its property and assets in the manner in which its property and assets are currently owned or leased and used, except where the failure to have such power or authority would not have an Iris Material Adverse Effect.

(d) Neither Iris nor any of its Subsidiaries is or has otherwise been, directly or indirectly, a party to, member of or participant in any partnership, joint venture or similar business entity. Neither Iris nor any of its Subsidiaries has agreed or is obligated to make or is bound by any Contract under which it may become obligated to make, any future investment in or capital contribution to any other entity. Neither Iris nor any of its Subsidiaries has, at any time, been a general partner of, or has otherwise been liable for any of the debts or other obligations of, any general partnership, limited partnership or other entity.

### 3.3. Capitalization.

(a) The authorized capital stock of Iris as of the date of this Agreement consists of 200,000,000 shares of common stock, par value \$0.001 per share ("**Iris Common Stock**"), of which 89,411,471 shares have been issued and are outstanding as of the close of business on the Reference Date, and 1,000,000 shares of preferred stock, par value \$0.001 per share ("**Iris Preferred Stock**"), of which no shares are issued and outstanding as of the date of this Agreement. Iris does not hold any shares of its capital stock in its treasury.

(b) As of the date hereof, there are no Iris Warrants outstanding.

(c) All of the outstanding shares of Iris Common Stock have been duly authorized and validly issued and are fully paid and nonassessable. None of the outstanding shares of Iris Common Stock is entitled or subject to any preemptive right, right of participation, right of maintenance or any similar right and none of the outstanding shares of Iris Common Stock is subject to any right of first refusal in favor of Iris. Except as contemplated herein, there is no Iris Contract relating to the voting or registration of, or restricting any Person from purchasing, selling, pledging or otherwise disposing of (or granting any option or similar right with respect to), any shares of Iris Common Stock. Iris is not a party to any Contract pursuant to which it may become obligated to repurchase, redeem or otherwise acquire any outstanding shares of Iris Common Stock or other securities.

(d) Except for the Iris 2010 Stock Incentive Plan (the "**Iris 2010 Stock Incentive Plan**") and the Iris 2019 Equity Incentive Plan (the "**Iris 2019 Equity Incentive Plan**," together with the Iris 2010 Stock Incentive Plan, the "**Iris Stock Incentive Plans**") and the award agreements thereunder, the Iris Inducement Grants and the Iris ESPP, Iris does not have any stock option plan or any other plan, program, agreement or arrangement providing for any equity-based compensation for any Person. As of the close of business on the Reference Date, Iris has authorized 37,090,804 shares of Iris Common Stock for issuance under the Iris Stock Incentive Plans, of which 3,964,372 shares have been issued and are currently outstanding. As of the close of business on the Reference Date, 16,790,384 shares of Iris Common Stock have been reserved for issuance pursuant to equity awards previously granted and currently outstanding under the Iris Stock Incentive Plans and 3,185,172 shares remain available for future issuance pursuant to the Iris Stock Incentive Plans and the Iris ESPP.

(e) Except for the Iris Inducement Grants, the Iris Options, the Iris RSUs and the ESPP Options, there is no: (i) outstanding subscription, option, call, warrant or right (whether or not currently exercisable) to acquire any shares of the capital stock or other securities of Iris or any of its Subsidiaries; or (ii) outstanding security, instrument or obligation that is or may become convertible into or exchangeable for any shares of the capital stock or other securities of Iris or any of its Subsidiaries. There are no outstanding or authorized stock appreciation, phantom stock, profit participation or other similar rights with respect to Iris or any of its Subsidiaries.

## Table of Contents

(f) All outstanding shares of Iris Common Stock, Iris Options, Iris RSUs, Iris Inducement Grants, ESPP Options and other securities of Iris have been issued and granted in material compliance with (i) all applicable securities Laws and other applicable Laws, and (ii) all requirements set forth in applicable Contracts. No Iris Options have an exercise price that has been or may be less than the fair market value of the underlying stock as of the date such Iris Option was granted or has any feature for the deferral of compensation that could render the grant subject to Section 409A of the Code.

### 3.4. Authority; Binding Nature of Agreement.

(a) Iris has all requisite corporate power and authority to execute and deliver this Agreement, to perform its obligations hereunder and, subject to receipt of the Iris Stockholder Approval, to consummate the Contemplated Transactions. The Iris Board (at a meeting duly called and held or by written consent in lieu of a meeting) has: (i) determined that the Contemplated Transactions, including the Merger, are advisable and in the best interests of Iris and its stockholders, (ii) approved and declared advisable this Agreement and the Contemplated Transactions, and (iii) subject to Section 5.2, resolved to make the Iris Board Recommendation. As of the date of this Agreement, such resolutions have not been amended or withdrawn. This Agreement has been duly executed and delivered by Iris and, assuming the due authorization, execution and delivery by Meadow, constitutes the valid and binding obligation of Iris, enforceable against Iris in accordance with its terms except, in each case, as enforcement may be limited by bankruptcy, insolvency, reorganization or similar Laws affecting creditors' rights generally and by general principles of equity (the "**Bankruptcy and Equity Exception**").

(b) Except for the adoption of this Agreement by the affirmative vote of the holders of a majority of the outstanding Shares entitled to vote thereon (such approval, the "**Iris Stockholder Approval**"), no other corporate proceedings on the part of the Iris stockholders are necessary to authorize, adopt or approve, as applicable, this Agreement or the Contemplated Transactions.

### 3.5. Non-Contravention; Consents.

(a) Subject to (I) obtaining the Iris Stockholder Approval, (II) the filing of the Certificate of Merger required by the DGCL, (III) (A) the filing with the SEC of the Joint Proxy Statement/Prospectus in definitive form, (B) the filing with the SEC, and declaration of effectiveness under the Securities Act of the Registration Statement, and (C) the filing with the SEC of such reports and other filings under, and such other compliance with, the Exchange Act and the Securities Act, and the rules and regulations thereunder, as may be required in connection with this Agreement and the Contemplated Transactions, (IV) such Consents, registrations, declarations, notices or filings as are required to be made or obtained under the securities or "blue sky" laws of various states in connection with the issuance of the shares of Meadow Common Stock to be issued as the Merger Consideration and (V) such filings with and approvals of Nasdaq as are required to permit the consummation of the Merger and the listing of the shares of Meadow Common Stock to be issued as the Merger Consideration, neither (x) the execution, delivery or performance of this Agreement by Iris, nor (y) the consummation by Iris of the Contemplated Transactions, will (with or without notice or lapse of time):

(i) result in a violation or breach of any of the provisions of the Organizational Documents of Iris or any of its Subsidiaries;

(ii) result in a violation or breach of, or give any Governmental Entity the right to exercise any remedy or obtain any relief under, any Law or any order, writ, injunction, judgment or decree to which Iris or any of its Subsidiaries, or any of the assets owned by Iris or any of its Subsidiaries, is subject;

(iii) result in a violation or breach of any of the terms or requirements of, or give any Governmental Entity the right to revoke, withdraw, suspend, cancel, terminate or modify, any Governmental Authorization that is held by Iris or its Subsidiaries;



## Table of Contents

(iv) result in a violation or breach of, or result in a default under, any provision of any Iris Material Contract, or give any Person the right to: (i) declare a default or exercise any remedy under any Iris Material Contract; (ii) any material payment, rebate, chargeback, penalty or change in delivery schedule under any Iris Material Contract; (iii) accelerate the maturity or performance of any Iris Material Contract; or (iv) cancel, terminate or modify any term of any Iris Material Contract; or

(v) result in the imposition or creation of any Lien upon or with respect to any asset owned by Iris or any of its Subsidiaries (except for Permitted Liens);

except in the case of clauses (ii), (iii), (iv) and (v) of this Section 3.5(a) for any such violations, remedies, relief, revocations, withdrawals, suspensions, cancellations, termination, modifications, breaches, defaults, payments, rebates, chargebacks, penalties, changes, accelerations or Liens that would not have an Iris Material Adverse Effect.

(b) Except for (i) the filing of the Certificate of Merger with the Secretary of State of the State of Delaware pursuant to the DGCL, (ii) (A) the filing with the SEC of the Joint Proxy Statement/Prospectus in definitive form, (B) the filing with the SEC, and declaration of effectiveness under the Securities Act of the Registration Statement, and (C) the filing with the SEC of such reports and other filings under, and such other compliance with, the Exchange Act and the Securities Act, and the rules and regulations thereunder, as may be required in connection with this Agreement, and the Contemplated Transactions, (iii) such filings with and approvals of Nasdaq as are required to permit the consummation of the Merger and the listing of the shares of Meadow Common Stock to be issued as the Merger Consideration and (iv) such consents, waivers, approvals, orders, authorizations, registrations, declarations and filings as may be required under applicable federal and state securities Laws, neither Iris nor any of its Subsidiaries is or will be required to make any filing with or give any notice to, or to obtain any Consent from, any Governmental Entity in connection with (x) the execution, delivery or performance by Iris of this Agreement, or (y) the consummation by Iris of the Contemplated Transactions, which if individually or in the aggregate were not given or obtained, would reasonably be expected to prevent or materially delay the ability of Iris to consummate the Contemplated Transactions or that would have an Iris Material Adverse Effect. Assuming the accuracy of the representation set forth in Section 4.24, the Iris Board has taken all actions necessary to ensure that the restrictions applicable to business combinations contained in Section 203 of the DGCL are, and will be, inapplicable to the execution, delivery and performance of this Agreement and to the consummation of the Contemplated Transactions. To Iris's Knowledge, no other takeover statute or similar Law applies or purports to apply to the Merger, this Agreement, or any of the Contemplated Transactions.

### 3.6. SEC Documents; Financial Statements.

(a) Other than such documents that can be obtained on the SEC's website at [www.sec.gov](http://www.sec.gov), Iris has made available to Meadow accurate and complete copies of all registration statements, proxy statements, Iris Certifications (as defined below) and other statements, reports, schedules, forms and other documents filed by Iris with the SEC between January 1, 2020 and the date hereof (the "**Iris SEC Documents**"). Since the date of the Iris Balance Sheet, all material statements, reports, schedules, forms and other documents required to have been filed by Iris or its officers with the SEC have been so filed on a timely basis. As of the time it was filed with the SEC (or, if amended or superseded by a filing prior to the date of this Agreement, then on the date of such filing), each of the Iris SEC Documents complied in all material respects with the applicable requirements of the Securities Act or the Exchange Act (as the case may be) and, as of the time they were filed, none of the Iris SEC Documents contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading (or, in the case of an Iris SEC Document that is a registration statement, as amended or supplemented, if applicable, filed pursuant to the Securities Act, as of the date such registration statement or amendment became effective, contained any untrue statement of a material fact or omitted to state any material fact required to be stated therein or necessary to make the statements made therein not misleading); provided,



## Table of Contents

however, that no representation is made as to the accuracy of any financial projections or forward-looking statements or the completeness of any information furnished by Iris to the SEC solely for the purposes of complying with Regulation FD promulgated under the Exchange Act. The certifications and statements required by (i) Rule 13a-14 under the Exchange Act and (ii) 18 U.S.C. §1350 (Section 906 of the Sarbanes-Oxley Act) relating to the Iris SEC Documents (collectively, the “**Iris Certifications**”) are accurate and complete in all material respects and comply as to form and content in all material respects with all applicable Laws. As used in this Section 3.6, the term “file” and variations thereof shall be broadly construed to include any manner in which a document or information is furnished, supplied or otherwise made available to the SEC.

(b) The financial statements (including any related notes) contained or incorporated by reference in the Iris SEC Documents: (i) complied as to form in all material respects with the published rules and regulations of the SEC applicable thereto; (ii) were prepared in accordance with GAAP (except as may be indicated in the notes to such financial statements or, in the case of unaudited financial statements, except as permitted by the SEC on Form 10-Q under the Exchange Act, and except that the unaudited financial statements may not contain footnotes and are subject to normal and recurring year-end adjustments) applied on a consistent basis unless otherwise noted therein throughout the periods indicated; and (iii) fairly present, in all material respects, the financial position of Iris and its consolidated Subsidiaries as of the respective dates thereof and the results of operations and cash flows of Iris and its consolidated Subsidiaries for the periods covered thereby. Other than as expressly disclosed in the Iris SEC Documents filed between January 1, 2020 and the date hereof there has been no material change in Iris’s accounting methods or principles that would be required to be disclosed in Iris’s financial statements in accordance with GAAP.

(c) As of the date of this Agreement, Iris is in compliance in all material respects with the applicable current listing and governance rules and regulations of Nasdaq.

(d) Iris maintains a system of internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) that is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP and to provide reasonable assurance (i) that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, (ii) that receipts and expenditures are made only in accordance with authorizations of management and the Iris Board and (iii) regarding prevention or timely detection of the unauthorized acquisition, use or disposition of Iris’s assets that could have a material effect on Iris’s financial statements. Iris has evaluated the effectiveness of Iris’s system of internal control over financial reporting as of December 31, 2021, and, to the extent required by applicable Law, presented in any applicable Iris SEC Document that is a report on Form 10-K or Form 10-Q (or any amendment thereto) its conclusions about the effectiveness of the internal control over financial reporting as of the end of the period covered by such report or amendment based on such evaluation. Iris has disclosed, based on its most recent evaluation of internal control over financial reporting, to Iris’s auditors and audit committee (and made available to Meadow a summary of the significant aspects of such disclosure) (A) all significant deficiencies, if any, in the design or operation of internal control over financial reporting that are reasonably likely to adversely affect Iris’s ability to record, process, summarize and report financial information and (B) any known fraud that involves management or other employees who have a significant role in Iris’s internal control over financial reporting. Iris has not identified, based on its most recent evaluation of internal control over financial reporting, any material weaknesses in the design or operation of Iris’s internal control over financial reporting.

(e) Iris maintains “disclosure controls and procedures” (as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act) that are reasonably designed to ensure that information required to be disclosed by Iris in the periodic reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the required time periods, and that all such information is accumulated and communicated to Iris’s management as appropriate to allow timely decisions regarding required disclosure and to make the Iris Certifications.

## Table of Contents

3.7. Absence of Changes. Except (a) for reasonable and good faith actions or omissions taken to comply with applicable Law or guidance by Governmental Entity in connection with the COVID-19 pandemic or (b) as contemplated or permitted by or in connection with the execution and delivery of this Agreement, between the date of Iris latest consolidated unaudited balance sheet (the “**Iris Balance Sheet**”) and the date of this Agreement, Iris has conducted its business in the Ordinary Course of Business in all material respects (except for the execution and performance of this Agreement and the discussions, negotiations and transactions related thereto, including the Contemplated Transactions) and there has not been any (i) Iris Material Adverse Effect (disregarding for purposes of this Section 3.7 clause (2) of the definition thereof) or (ii) action, event or occurrence that would have required the consent of Meadow pursuant to Section 5.1(a) (other than paragraphs (ii), (vi) and (xi) of Section 5.1(a) and paragraph (xiv) as it relates to paragraphs (ii), (vi) and (xi) of Section 5.1(a)) had such action, event or occurrence taken place after the execution and delivery of this Agreement.

3.8. Absence of Undisclosed Liabilities. As of the date of this Agreement and other than as contemplated by this Agreement, neither Iris nor any of its Subsidiaries has any liability, debt or obligation, individually or in the aggregate, of a type required to be recorded or reflected on Iris’s balance sheet or disclosed in the footnotes thereto under GAAP except for liabilities, debts or obligations: (a) disclosed, reflected or reserved against in Iris Balance Sheet or disclosed in the notes thereto included in the Iris SEC Documents; (b) that have been incurred by Iris or any of its Subsidiaries since the date of the Iris Balance Sheet in the Ordinary Course of Business; (c) for performance of obligations of Iris or any of its Subsidiaries under the Iris Material Contracts which have not resulted from a breach of such Iris Material Contracts, breach of warranty, tort, infringement or violation of Law; (d) incurred in connection with the Contemplated Transactions; (e) that would not have an Iris Material Adverse Effect; or (f) described in Section 3.8 of the Iris Disclosure Schedule.

3.9. Title to Assets. Iris and each of its Subsidiaries owns, and has good and valid title to, or, in the case of leased properties and assets, valid leasehold interests in, all material tangible properties or material tangible assets and material equipment used or held for use in its business or operations or purported to be owned by it, including: (a) all material tangible assets reflected on the Iris Balance Sheet; and (b) all other material tangible assets reflected in the books and records of Iris or any of its Subsidiaries as being owned by Iris or such Subsidiary. All of such assets are owned or, in the case of leased assets, leased by Iris or its applicable Subsidiary free and clear of any Liens, other than Permitted Liens.

### 3.10. Legal Proceedings; Orders.

(a) As of the date of this Agreement, to Iris’s Knowledge, there is no pending Legal Proceeding and no Person has threatened in writing to commence any Legal Proceeding: (i) that involves (A) Iris, (B) any of its Subsidiaries, (C) any Iris Associate (in his or her capacity as such) or (D) any of the material assets owned or used by Iris or its Subsidiaries; or (ii) that challenges, or that may have the effect of preventing, delaying, making illegal or otherwise interfering with, the Contemplated Transactions.

(b) Between January 1, 2020 and the date hereof, no Legal Proceeding has been pending against Iris or any of its Subsidiaries that resulted in any liability that is material to Iris and its Subsidiaries, taken as a whole.

(c) There is no material order, writ, injunction, judgment or decree to which Iris or any of its Subsidiaries, or any of the material assets owned or used by Iris or any of its Subsidiaries, is subject. To Iris’s Knowledge, as of the date hereof no officer or employee of Iris or any of its Subsidiaries is subject to any unsatisfied order, writ, injunction, judgment or decree that prohibits such officer or employee from engaging in or continuing any conduct, activity or practice relating to the business of Iris or any of its Subsidiaries or to any material assets owned or used by Iris or any of its Subsidiaries.

3.11. Contracts.

(a) Section 3.11(a) of the Iris Disclosure Schedule lists the following Iris Contracts in effect as of the date of this Agreement (other than any Iris Benefit Plan) under which Iris or any of its Subsidiaries has any remaining material rights or obligations (each, a “**Iris Material Contract**”):

(i) a material contract as defined in Item 601(b)(10) of Regulation S-K as promulgated under the Securities Act;

(ii) each Contract that is material to the business or operations of Iris and its Subsidiaries, taken as a whole, containing (A) any covenant limiting the freedom of Iris or any of its Subsidiaries to engage in any line of business or compete with any Person, (B) any “most-favored nations” pricing provisions or marketing or distribution rights related to any products or territory, (C) any exclusivity provision or (D) any agreement to purchase minimum quantity of goods or services;

(iii) each Contract relating to capital expenditures and requiring payments after the date of this Agreement in excess of \$100,000 pursuant to its express terms and not cancelable without penalty;

(iv) each Contract relating to the disposition or acquisition of material assets or any ownership interest in any entity;

(v) each Contract providing for the creation of any mortgages, indentures, loans, notes or credit agreements, security agreements or other agreements or instruments providing for the creation of material Indebtedness of Iris or any of its Subsidiaries or creating any material Liens with respect to any material assets of Iris or any of its Subsidiaries;

(vi) each Contract requiring payment by or to Iris or any of its Subsidiaries after the date of this Agreement in excess of \$500,000 pursuant to its express terms relating to: (A) any distribution agreement (identifying any that contain exclusivity provisions); (B) any agreement involving provision of services or products with respect to any pre-clinical or clinical development activities of Iris or any of its Subsidiaries; (C) any dealer, distributor, joint marketing, alliance, joint venture, cooperation, development or other agreement currently in force under which Iris or any of its Subsidiaries has continuing obligations to develop or market any product, technology or service, or any agreement pursuant to which Iris or any of its Subsidiaries has continuing obligations to develop any Intellectual Property Rights that will not be owned, in whole or in part, by Iris or any of its Subsidiaries; or (D) any Contract to license any third party to manufacture or produce any product, service or technology of Iris or any of its Subsidiaries or any Contract to sell, distribute or commercialize any products or service of Iris or any of its Subsidiaries, in each case, except for Contracts entered into in the Ordinary Course of Business;

(vii) each Iris Real Estate Lease;

(viii) each Contract with any Governmental Entity, other than clinical trial agreements, sponsored research agreements or material transfer agreements entered into in the Ordinary Course of Business;

(ix) each Iris Out-bound License and Iris In-bound License;

(x) each Contract that is material to the business or operations of Iris and its Subsidiaries, taken as a whole, containing any royalty, dividend or similar arrangement based on the revenues or profits of Iris or any of its Subsidiaries;

(xi) each Contract that is not terminable at will with no more than 60 days’ prior notice (with no penalty or payment) by Iris or its Subsidiaries, as applicable, and which involves payment or receipt by Iris or its Subsidiaries after the date of this Agreement under any such Contract of more than \$100,000 in the aggregate, or obligations after the date of this Agreement in excess of \$100,000 in the aggregate;

## Table of Contents

(xii) each collective bargaining agreement or other similar Contract with any labor organization, union, group or association covering employees of Iris; or

(xiii) each Contract (A) for the employment or engagement of any employee, consultant or independent contractor providing such Person with annual compensation or fees in excess of \$250,000, (B) providing for the payment of any cash or other compensation or benefits upon the consummation of the Merger, (C) restricting Iris's ability to terminate the employment or services of any employee, consultant or independent contractor thereof at any time for any lawful reason or for no reason without penalty, or (D) providing for severance or similar termination payments, retention or change in control payments, or for the acceleration of vesting or grant of any incentive equity or similar compensation.

(b) Iris has made available to Meadow accurate and complete copies of all Iris Material Contracts, including all material amendments thereto, in each case in effect on the date hereof but excluding any purchase orders and/or work orders issued under an Iris Material Contract in the Ordinary Course of Business. There are no Iris Material Contracts that are not in written form. As of the date of this Agreement, none of Iris, any of its Subsidiaries or, to Iris's Knowledge, any other party to an Iris Material Contract, has breached, violated or defaulted under, or received notice that it breached, violated or defaulted under, any of the terms or conditions of, or Laws applicable to, any Iris Material Contract in such manner as would permit any other party to cancel or terminate any such Iris Material Contract, or would permit any other party to seek damages or pursue other legal remedies which would reasonably be expected to be material to Iris and its Subsidiaries, taken as a whole. As to Iris and its Subsidiaries, as of the date of this Agreement, each Iris Material Contract is valid, binding, enforceable and in full force and effect, subject to the Bankruptcy and Equity Exception. Between the date of the Iris Balance Sheet and the date hereof, no counterparty to an Iris Material Contract has notified Iris in writing (or, to the Knowledge of Iris, otherwise) that it intends to terminate or not renew an Iris Material Contract.

### 3.12. Employee and Labor Matters; Benefits Plans.

(a) Section 3.12(a) of the Iris Disclosure Schedule is a list of all Iris Benefit Plans in effect on the date of this Agreement, including each such Iris Benefit Plan that provides for retirement, change in control, stay or retention deferred compensation, incentive compensation, severance or retiree medical or life insurance benefits.

(b) As applicable with respect to each material Iris Benefit Plan, Iris has made available to Meadow, true and complete copies of (i) each Iris Benefit Plan, including all amendments thereto, and in the case of an unwritten material Iris Benefit Plan, a written description thereof, (ii) all current trust documents, investment management contracts, custodial agreements, administrative services agreements and insurance and annuity contracts relating thereto, (iii) the current summary plan description and each summary of material modifications thereto, (iv) the most recently filed annual reports with any Governmental Entity (*e.g.*, Form 5500 and all schedules thereto), (v) the most recent determination, opinion or advisory letter from the Internal Revenue Service ("**IRS**") with respect to each Iris Benefit Plan intended to qualify under Section 401(a) of the Code, (vi) the most recent summary annual reports, nondiscrimination testing reports, actuarial reports, financial statements and trustee reports, (vii) all non-routine correspondence received from or provided to the United States Department of Labor ("**DOL**"), the Pension Benefit Guaranty Corporation, the IRS or any other Governmental Entity between January 1, 2020 and the date hereof and (viii) all notices and filings concerning IRS or DOL or other Governmental Entity audits or investigations, including with respect to "prohibited transactions" within the meaning of Section 406 of ERISA or Section 4975 of the Code, between January 1, 2020 and the date of this Agreement.

(c) Each Iris Benefit Plan has been established, maintained, funded, operated and administered in compliance in all material respects with its terms and any related documents or agreements and the applicable provisions of ERISA, the Code and all other applicable Laws.

(d) The Iris Benefit Plans which are "employee pension benefit plans" within the meaning of Section 3(2) of ERISA and which are intended to meet the qualification requirements of Section 401(a) of the

## Table of Contents

Code have received determination or opinion letters from the IRS on which they may currently rely to the effect that such plans are qualified under Section 401(a) of the Code and the related trusts are exempt from federal income Taxes under Section 501(a) of the Code, respectively, or are covered by advisory or opinion letters with respect to a volume submitter or prototype plan, and, to Iris's Knowledge, nothing has occurred that would reasonably be expected to materially adversely affect the qualification of such Iris Benefit Plan or the tax exempt status of the related trust.

(e) None of Iris, any of its Subsidiaries or any Iris ERISA Affiliate has maintained, contributed to, been required to contribute to, or had any actual or contingent liability with respect to, (i) any "employee pension benefit plan" (within the meaning of Section 3(2) of ERISA) that is subject to Title IV or Section 302 of ERISA or Section 412 of the Code, (ii) any "multiemployer plan" (within the meaning of Section 3(37) of ERISA), (iii) any "multiple employer plan" (within the meaning of Section 413 of the Code), (iv) any "multiple employer welfare arrangement" (within the meaning of Section 3(40) of ERISA), or (v) any "voluntary employees beneficiary association" within the meaning of Section 501(c)(9) of the Code. The obligations of all Iris Benefit Plans that provide health, welfare or similar insurance are fully insured by bona fide third-party insurers. No Iris Benefit Plan is maintained through a human resources or benefit outsourcing entity, professional employer organization or other similar provider.

(f) As of the date of this Agreement, there are no pending audits or investigations by any Governmental Entity involving any Iris Benefit Plan, and no pending or, to Iris's Knowledge, threatened claims (except for individual claims for benefits payable in the normal operation of the Iris Benefit Plans), suits or proceedings involving any Iris Benefit Plan, any fiduciary thereof or service provider thereto. To Iris's Knowledge, there have been no "prohibited transactions" (as that term shall have the meaning specified in Section 406 of ERISA or Section 4975 of the Code) involving any Iris Benefit Plan, any fiduciary thereof or service provider thereto. Since January 1, 2020, all material contributions and premium payments required to have been timely made under any of the Iris Benefit Plans or by applicable Law (without regard to any waivers granted under Section 412 of the Code), have been timely made and neither Iris nor any of its Subsidiaries has any liability for any such unpaid contributions with respect to any Iris Benefit Plan, all benefits accrued under any unfunded Iris Benefit Plan have been paid, accrued or otherwise adequately reserved in accordance with GAAP, and all reports, returns and similar documents required to be filed with any Governmental Entity or distributed to any plan participant have been timely filed or distributed.

(g) None of Iris or any of its Subsidiaries, or, to Iris's Knowledge, any fiduciary, trustee or administrator of any Iris Benefit Plan, has engaged in, or in connection with the Contemplated Transactions will engage in, any transaction with respect to any Iris Benefit Plan which would subject any such Iris Benefit Plan, Iris or any of its Subsidiaries to a Tax, penalty or liability for a "prohibited transaction" under Section 406 of ERISA or Section 4975 of the Code.

(h) No Iris Benefit Plan provides death, medical, dental, vision, life insurance or other welfare benefits beyond termination of service or retirement, other than coverage mandated by Law or at the participant or beneficiary's sole expense or, as described in Section 3.12(h) of the Iris Disclosure Schedule, as provided with respect to continuation health coverage as part of severance, and none of Iris or any of its Subsidiaries has any obligation to provide (whether under an Iris Benefit Plan or otherwise) nor has made a written or oral representation promising the same.

(i) Neither the execution of this Agreement, nor the consummation of the Contemplated Transactions will either alone or in connection with any other event(s), except with respect to acceleration of vesting on equity compensation and the Iris 401(k) Plan as described in this Agreement, (i) result in any payment (whether of severance pay or otherwise) becoming due to or forgiveness of indebtedness for any current or former employee, director, officer, independent contractor or other service provider of Iris or any of its Subsidiaries, (ii) increase any amount of compensation or benefits otherwise payable to any current or former employee, director, officer, independent contractor or other service provider of Iris or any of its Subsidiaries, (iii) result in the acceleration of

## Table of Contents

the time of payment, funding or vesting of any benefits under any Iris Benefit Plan, (iv) require any contribution or payment to fund any obligation under any Iris Benefit Plan or (v) limit the right to merge, amend or terminate any Iris Benefit Plan (or result in adverse consequences for so doing).

(j) Neither the execution of this Agreement, nor the consummation of the Contemplated Transactions (either alone or when combined with the occurrence of any other event, including a termination of employment) will result in the receipt or retention by any person who is a “disqualified individual” (within the meaning of Section 280G of the Code) with respect to Iris and its Subsidiaries of any payment or benefit that is characterized as a “parachute payment” (within the meaning of Section 280G of the Code), determined without regard to the application of Section 280G(b)(5) of the Code.

(k) Each Iris Benefit Plan providing for deferred compensation that constitutes a “nonqualified deferred compensation plan” (as defined in Section 409A(d)(1) of the Code and the regulations promulgated thereunder) is, and has been, established, administered and maintained in material compliance in both form and operation with the requirements of Section 409A of the Code and the regulations promulgated thereunder. Iris does not have any liability for nonreporting or underreporting of income subject to Section 409A of the Code.

(l) No Person has any “gross up” agreements with Iris or any of its Subsidiaries or other assurance of reimbursement by Iris or any of its Subsidiaries for any Taxes imposed under Section 409A or Section 4999 of the Code.

(m) There are, and since January 1, 2020, there have been, no actual, threatened or pending negotiations, strikes, labor disputes, work stoppages, requests for representation, pickets, work slow-downs due to labor disagreements or any Proceedings or arbitrations that involve the labor or employment relations of Iris or any of its Subsidiaries. Neither Iris nor any of its Subsidiaries is a party to or bound by, or has a duty to bargain under, any collective bargaining agreement or other Contract with a labor union or labor organization representing any of its employees, and there is no labor union or labor organization representing or, to Iris’s Knowledge, purporting to represent or seeking to represent any employees of Iris or its Subsidiaries, including through the filing of a petition for representation election.

(n) Iris and each of its Subsidiaries is, and since January 1, 2020 has been, in material compliance with all applicable Laws respecting labor, employment, employment practices, and terms and conditions of employment, including worker classification, discrimination, wrongful termination, harassment and retaliation, equal employment opportunities, fair employment practices, meal and rest periods, immigration and I-9, reasonable accommodation, disability rights or benefits, child labor, working conditions, meal and break periods, privacy, employee safety and health, wages (including overtime wages), unemployment and workers’ compensation, leaves of absence, hours of work and orders, regulations, ordinances and guidelines by any Governmental Entity regarding COVID-19 (including any “stay at home” orders or other similar orders, regulations or guidelines). Except as would not be reasonably likely to result in a liability that is material to Iris and its Subsidiaries, taken as a whole, with respect to employees of Iris or any of its Subsidiaries, each of Iris and its Subsidiaries, since January 1, 2020: (i) has withheld and reported all amounts required by Law or by agreement to be withheld and reported with respect to wages, salaries and other payments, benefits, or compensation to employees, (ii) is not liable for any arrears of wages (including overtime wages), premiums, commissions, paid time off, on-call payments, bonus, benefits, severance pay or any Taxes or any penalty for failure to comply with any of the foregoing, and (iii) is not liable for any payment to any trust or other fund governed by or maintained by or on behalf of any Governmental Entity, with respect to unemployment compensation benefits, disability, social security or other benefits or obligations for employees (other than routine payments to be made in the Ordinary Course of Business). As of the date of this Agreement, there are no actions, suits, claims, charges, demands, lawsuits, investigations, audits or administrative matters pending or, to Iris’s Knowledge, threatened or reasonably anticipated against Iris or any of its Subsidiaries or Iris Associates (in his or her capacity as such) relating to any current or former employee, applicant for employment, consultant, employment agreement or Iris Benefit Plan (other than routine claims for benefits). All U.S. based employees of

## Table of Contents

Iris and its Subsidiaries are employed “at-will” and their employment can be terminated without advance notice or payment of severance in excess of sixty (60) days.

(o) Except as would not be reasonably likely to result in a liability that is material to Iris and its Subsidiaries, taken as a whole, with respect to each individual who currently renders services to Iris or any of its Subsidiaries, Iris and each of its Subsidiaries has accurately classified each such individual as an employee, independent contractor, or otherwise under all applicable Laws and, for each individual classified as an employee, Iris has accurately classified him or her as overtime eligible or overtime ineligible under all applicable Laws. Neither Iris nor any of its Subsidiaries has any material liability with respect to any misclassification of: (a) any Person as an independent contractor rather than as an employee, (b) any employee leased from another employer, or (c) any employee currently or formerly classified as exempt from overtime wages. No employees are employed on a work visa or work permit.

(p) There is not and has not been since January 1, 2020, nor, to Iris’s Knowledge, is there or has there been since January 1, 2020 any threat of, any strike, slowdown, work stoppage, lockout, union election petition, demand for recognition, or any similar activity or dispute, or, to Iris’s Knowledge, any union organizing activity, against Iris or any of its Subsidiaries. No event has occurred, and, to Iris’s Knowledge, no condition or circumstance exists, that would reasonably be expected directly or indirectly to give rise to or provide a basis for the commencement of any such strike, slowdown, work stoppage, lockout, union election petition, demand for recognition, or any similar activity or dispute.

(q) Neither Iris nor any of its Subsidiaries has failed to comply in all material respects with ERISA Sections 601 to 608 and Code Section 4980B and Iris has, for any relevant period, offered the requisite number of “full-time employees” group health coverage that is “affordable” and of “minimum value” (as such terms are defined by the employer shared responsibility provisions of the Patient Protection and Affordable Care Act).

(r) No Iris Benefit Plan is or has been maintained outside the jurisdiction of the United States, or covers or covered any employee permanently residing or working outside the United States.

(s) Since January 1, 2020, neither Iris nor its Subsidiaries has caused (i) a plant closing as defined in the Worker Adjustment and Retraining Notification Act (the “**WARN Act**”) affecting any single site of employment of Iris or its Subsidiaries or one or more operating units within any site of employment of Iris or its Subsidiaries or (ii) a mass layoff as defined in the WARN Act, nor has Iris or its Subsidiaries been affected by any transaction or engaged in layoffs or employment terminations sufficient in number to trigger application of any similar foreign, state or local Law. No employee of Iris or its Subsidiaries has suffered an employment loss, as defined in the WARN Act, within the 90-day period ending on the Closing Date. Since January 1, 2020, neither Iris nor its Subsidiaries has implemented any material workplace changes such as layoffs, furloughs, permanent office closures, or reductions in compensation, benefits or hours.

(t) No Legal Proceedings are as of the date hereof open and pending (or between January 1, 2020 and the date hereof have been settled or otherwise closed) against Iris or any of its Subsidiaries with respect to the employment of, or failure to employ, any individual, including any brought with or by the Equal Employment Opportunity Commission, the Office of Federal Contract Compliance Programs, or other Governmental Entity regulating the employment or compensation of individuals (or, with respect to discrimination, unlawful harassment, retaliation, or similar wrongdoing, pursuant to internal complaint procedures), and no employee of Iris or any of its Subsidiaries has made, between January 1, 2020 and the date hereof, a written complaint of discrimination, unlawful harassment, retaliation, or other similar wrongdoing or, to Iris’s Knowledge, between January 1, 2022 and the date hereof, an oral complaint. Between January 1, 2020 and the date hereof, neither Iris nor any of its Subsidiaries has received any requests for, or conducted, an internal investigation of any officer, manager, or supervisor of Iris or any of its Subsidiaries with respect to any claims with respect to discrimination, unlawful harassment, retaliation, or other similar wrongdoing. Neither Iris nor any of its Subsidiaries is a party to any settlement agreement with a current or former officer, manager, employee, or contractor of any of them



## Table of Contents

resolving allegations of sexual or other unlawful harassment, discrimination, or retaliation by any current or former officer, manager, employee, or contractor of Iris or any of its Subsidiaries. Iris and its Subsidiaries have promptly, thoroughly and impartially investigated all employment discrimination, sexual or other unlawful harassment, and retaliation allegations of, or against, any employee in accordance with applicable Law. With respect to each such allegation with potential merit, the applicable employer has taken prompt corrective action reasonably calculated to prevent further discrimination and harassment or retaliation, and neither Iris nor any of its Subsidiaries reasonably expects to incur any material Liability with respect to any such allegation.

3.13. Environmental Matters. Iris and each of its Subsidiaries are in compliance, and, to Iris's Knowledge, since January 1, 2020 have complied with all applicable Environmental Laws, which compliance includes the possession by Iris and its Subsidiaries of all permits and other Governmental Authorizations required under applicable Environmental Laws and compliance with the terms and conditions thereof, except for any failure to be in such compliance that, either individually or in the aggregate, would not reasonably be expected to be material to Iris and its Subsidiaries, taken as a whole. Neither Iris nor any of its Subsidiaries has received between January 1, 2020 and the date hereof, any written notice or other communication (in writing or otherwise), whether from a Governmental Entity or other Person, that alleges that Iris or any of its Subsidiaries is not in compliance with or has liability pursuant to any Environmental Law, except where such failure to comply would not reasonably be expected to be material to Iris and its Subsidiaries, taken as a whole. To Iris's Knowledge, no current or (during the time a prior property was leased or controlled by Iris or any of its Subsidiaries) prior property leased or controlled by Iris or any of its Subsidiaries has had a release of or exposure to Hazardous Materials in material violation of or as would reasonably be expected to result in any material liability of Iris or any of its Subsidiaries pursuant to Environmental Law.

### 3.14. Taxes.

(a) Iris and each of its Subsidiaries have timely filed all income Tax Returns and other material Tax Returns that they were required to file under applicable Law. All such Tax Returns are correct and complete in all material respects and have been prepared in substantial compliance with all applicable Law. No written claim has ever been made prior to the date hereof by any Governmental Entity in any jurisdiction where Iris or any of its Subsidiaries does not file a particular Tax Return or pay a particular Tax that Iris or such Subsidiary is subject to taxation by that jurisdiction.

(b) All income Taxes and other material Taxes due and owing by Iris or any of its Subsidiaries on or before the date hereof (whether or not shown on any Tax Return) have been fully paid. The unpaid Taxes of Iris and its Subsidiaries did not, as of the date of the Iris Balance Sheet, materially exceed the reserve for Tax liability (excluding any reserve for deferred Taxes established to reflect timing differences between book and Tax items) set forth on the face of the Iris Balance Sheet.

(c) All Taxes that Iris or any of its Subsidiaries are or were required by Law to withhold or collect have been duly and timely withheld or collected in all material respects on behalf of its respective employees, independent contractors, stockholders, lenders, customers or other third parties and have been timely paid to the proper Governmental Entity or other Person or properly set aside in accounts for this purpose.

(d) There are no Liens for material Taxes (other than Taxes not yet due and payable) upon any of the assets of Iris or any of its Subsidiaries.

(e) No outstanding deficiencies for income Taxes or any other material Taxes with respect to Iris or any of its Subsidiaries have been claimed, proposed or assessed by any Governmental Entity in writing. There are no pending or ongoing, nor, to Iris's Knowledge, threatened audits, assessments or other actions for or relating to any liability in respect of a material amount of Taxes of Iris or any of its Subsidiaries. Neither Iris nor any of its Subsidiaries (nor any of their predecessors) has waived any statute of limitations in respect of any income Taxes or other material Taxes or agreed to any extension of time with respect to any income Tax or other material Tax assessment or deficiency, which waiver or extension is still in effect.



## Table of Contents

(f) Neither Iris nor any of its Subsidiaries has been a United States real property holding corporation within the meaning of Section 897(c)(2) of the Code during the applicable period specified in Section 897(c)(1)(A)(ii) of the Code.

(g) Neither Iris nor any of its Subsidiaries is a party to any material Tax allocation agreement, Tax sharing agreement, Tax indemnity agreement, or similar agreement or arrangement, other than customary commercial contracts entered into in the Ordinary Course of Business the principal subject matter of which is not the allocation of Taxes.

(h) Neither Iris nor any of its Subsidiaries will be required to include any material item of income in, or exclude any material item of deduction from, taxable income for any Tax period (or portion thereof) ending after the Closing Date as a result of any: (i) change in method of accounting for Tax purposes made on or prior to the Closing Date; (ii) use of an improper method of accounting for a Tax period (or portion thereof) ending on or prior to the Closing Date; (iii) “closing agreement” as described in Section 7121 of the Code (or any similar provision of state, local or foreign Law) executed on or prior to the Closing Date; (iv) installment sale or open transaction disposition made on or prior to the Closing Date; (v) prepaid amount received or deferred revenue accrued on or prior to the Closing Date; or (vi) application of Section 367(d) of the Code to any transfer of intangible property on or prior to the Closing Date. Iris has not made any election under Section 965(h) of the Code.

(i) Neither Iris nor any of its Subsidiaries has ever been (i) a member of a consolidated, combined or unitary Tax group (other than such a group the common parent of which is Iris) or (ii) a party to any joint venture, partnership, or other arrangement that is treated as a partnership for U.S. federal income Tax purposes. Neither Iris nor any of its Subsidiaries has any liability for any material Taxes of any Person (other than Iris and any of its Subsidiaries) under Treasury Regulations Section 1.1502-6 (or any similar provision of state, local, or foreign Law), as a transferee or successor, or otherwise.

(j) Neither Iris nor any of its Subsidiaries (i) is a “passive foreign investment company” within the meaning of Section 1297 of the Code; or (ii) has ever had a permanent establishment (within the meaning of an applicable Tax treaty) or otherwise had an office or fixed place of business in a country other than the country in which it is organized.

(k) Neither Iris nor any of its Subsidiaries has participated in or been a party to a transaction that, as of the date of this Agreement, constitutes a “listed transaction” that is required to be reported to the IRS pursuant to Section 6011 of the Code and applicable Treasury Regulations thereunder.

(l) Neither Iris nor any of its Subsidiaries has taken any action or knows of any fact that would reasonably be expected to prevent the Merger from qualifying for the Intended Tax Treatment.

(m) Neither Iris nor any of its Subsidiaries has availed itself of any Tax relief pursuant to any pandemic response laws (including the CARES Act) that could reasonably be expected to materially impact the Tax payment and/or Tax reporting obligations of Iris and its Affiliates (including Meadow and its Subsidiaries) after the Closing Date.

(n) For purposes of this Section 3.14, each reference to Iris or any of its Subsidiaries shall be deemed to include any Person that was liquidated into, merged with, or is otherwise a predecessor to, Iris of any of its Subsidiaries.

### 3.15. Intellectual Property.

(a) Section 3.15(a) of the Iris Disclosure Schedule identifies (i) the name of the applicant/registrant, (ii) the jurisdiction of application/registration, (iii) the grant application or registration number and (iv) any other co-owners, for each item of Registered IP within the Iris IP (the “**Iris Registered IP**”). Each of the patents and

## Table of Contents

patent applications included in the Iris Registered IP within the Iris IP properly identifies by name each and every inventor of the inventions claimed therein as determined in accordance with applicable Laws of the United States and, to Iris's Knowledge, each of the patents and patent applications included in the Iris Registered IP within the Iris Licensed IP properly identifies by name each and every inventor of the inventions claimed therein as determined in accordance with applicable Laws of the United States. As of the date of this Agreement, no interference, opposition, reissue, reexamination or other proceeding of any nature (other than ex parte initial or continuing examination proceedings in front of a government agency) is pending or threatened in writing, in which the scope, validity, enforceability or ownership of any Iris Owned IP within the Iris Registered IP is being or has been contested or challenged and, to Iris's Knowledge, no interference, opposition, reissue, reexamination or other proceeding of any nature (other than ex parte initial or continuing examination proceedings in front of a government agency) is pending or threatened in writing, in which the scope, validity, enforceability or ownership of any Iris Licensed IP within the Iris Registered IP is being or has been contested or challenged. To Iris's Knowledge, all Iris Registered IP is in effect, valid, subsisting and enforceable.

(b) Iris or its Subsidiaries solely and exclusively owns or has rights to all right, title and interest in and to all material Iris Owned IP, free and clear of all Liens other than Permitted Liens, except as would not have an Iris Material Adverse Effect. Each Iris Associate involved in the creation or development of any material Iris Owned IP, pursuant to such Iris Associate's activities on behalf of Iris or its Subsidiaries, has signed a valid, enforceable written agreement containing a present assignment of all such Iris Associate's rights in such material Iris Owned IP to Iris or its Subsidiaries (without further payment being owed to any such Iris Associate and without any restrictions or obligations on Iris's or its Subsidiaries' ownership or use thereof) and confidentiality provisions protecting the Iris Owned IP, which, to Iris's Knowledge, has not been materially breached by such Iris Associate.

(c) No funding, facilities or personnel of any Governmental Entity or any university, college, research institute or other educational or academic institution has been used, in whole or in part, to create any Iris Owned IP, except for any such funding or use of facilities or personnel that does not result in such Governmental Entity or institution obtaining ownership or other rights (including any "march in" rights or a right to direct the location of manufacturing of products) to such Iris Owned IP or the right to receive royalties or other consideration for the practice of such Iris Owned IP.

(d) Section 3.15(d) of the Iris Disclosure Schedule sets forth each license agreement pursuant to which Iris or any of its Subsidiaries (i) is granted a license under any material Intellectual Property Right owned by any third party that is used by Iris or any of its Subsidiaries in its business as currently conducted (each an "**Iris In-bound License**") or (ii) grants to any third party a license under any material Iris IP or any material Intellectual Property Right licensed to Iris or any of its Subsidiaries under an Iris In-bound License (each an "**Iris Out-bound License**") (provided, that, the Iris In-bound Licenses shall not include clinical trial agreements, services agreements, non-disclosure agreements, commercially available software-as-a-service offerings, off-the-shelf software licenses or generally available patent license agreements entered into in the Ordinary Course of Business on a non-exclusive basis; and the Iris Out-bound Licenses shall not include clinical trial agreements, services agreements, non-disclosure agreements, or non-exclusive outbound licenses entered into in the Ordinary Course of Business on a non-exclusive basis and that do not grant any commercial rights to any products or services of Iris or any of its Subsidiaries).

(e) To Iris's Knowledge, the Iris Products and the operation of the business of Iris and its Subsidiaries as currently conducted do not infringe any valid and enforceable patent of an Intellectual Property Right of any other Person, that is not licensed to Iris or any of its Subsidiaries under an Iris In-bound License, or misappropriate or otherwise violate any other Intellectual Property Right owned by any other Person, and no other Person is infringing, misappropriating or otherwise violating any Iris IP or any material Intellectual Property Rights exclusively licensed to Iris or any of its Subsidiaries ("**Iris In-Licensed IP**"). As of the date of this Agreement, no Legal Proceeding is pending (or is threatened in writing) (A) against Iris or any of its Subsidiaries alleging that the operation of the businesses of Iris or its Subsidiaries infringes or constitutes the

## Table of Contents

misappropriation or other violation of any Intellectual Property Rights of another Person or (B) by Iris or any of its Subsidiaries alleging that another Person has infringed, misappropriated or otherwise violated any of the Iris IP or any Iris In-Licensed IP. Between January 1, 2020 and the date hereof, neither Iris nor any of its Subsidiaries has received any written notice or other written communication alleging that the operation of the businesses of Iris or any of its Subsidiaries infringes or constitutes the misappropriation or other violation of any Intellectual Property Right of another Person.

(f) None of the Iris IP or, to Iris's Knowledge, any Iris In-Licensed IP is subject to any pending or outstanding injunction, directive, order, judgment or other disposition of dispute that adversely and materially restricts the use, transfer, registration or licensing by Iris or any of its Subsidiaries of any such Iris IP or Iris In-Licensed IP.

(g) None of Iris or its Subsidiaries is now or has ever been a member or promoter of, or a contributor to, any industry standards body or any similar organization that would reasonably be expected to require or obligate Iris or any of its Subsidiaries to grant or offer to any other Person any license or right to any Iris IP.

(h) The operation of Iris's and its Subsidiaries' business are in substantial compliance with all applicable Laws pertaining to data privacy and data security of any personally identifiable information and sensitive business information (collectively, "**Iris Sensitive Data**"), except to the extent that such noncompliance has not and would not have an Iris Material Adverse Effect. Since January 1, 2020, there have been (i) no material losses or thefts of data or security breaches relating to Iris Sensitive Data used in the business of Iris or its Subsidiaries, (ii) no violations of any security policy of Iris or its Subsidiaries regarding any such Iris Sensitive Data, (iii) no unauthorized access or unauthorized use of any Iris Sensitive Data used in the business of Iris or its Subsidiaries and (iv) no unintended or improper disclosure of any personally identifiable information in the possession, custody or control of Iris or its Subsidiaries or a contractor or agent acting on behalf of Iris or its Subsidiaries, in each case of (i) through (iv), except as would not have an Iris Material Adverse Effect.

(i) Each of Iris and its Subsidiaries has complied, and continues to comply, with the Data Protection Legislation, including with the principles relating to processing Personal Data under Article 5 of the GDPR, with requirements to process Personal Data lawfully under Articles 6 and 9 of the GDPR, to provide processing information regarding the processing of Personal Data under Articles 13 and 14 of the GDPR, to engage data processors under Article 28 of the GDPR, to maintain a record of processing activities under Article 30 of the GDPR, to protect Personal Data under Article 32 of the GDPR, to notify supervisory authorities or data subjects under Articles 33 and 34 of the GDPR, to conduct data protection impact assessments under Articles 35 and 36 of the GDPR, to transfer Personal Data under Chapter V of the GDPR, except, in each case, as would not have an Iris Material Adverse Effect.

(j) Each of Iris and its Subsidiaries has implemented, and regularly assessed its implementation of, appropriate technical and organisational measures necessary to ensure that Personal Data is protected against loss, destruction and damage, unauthorised access, use, modification, disclosure or other misuse, except as would not have an Iris Material Adverse Effect.

(k) (i) None of Iris or its Subsidiaries transfers Personal Data outside of the European Economic Area and/or United Kingdom unless Iris or such Subsidiary, as applicable, has ensured that the recipient has adequate safeguards to protect such Personal Data including, but not solely depending on, the execution of standard contractual clauses in the form approved by the European Commission from time to time or equivalent data transfer agreements or arrangements (including binding corporate rules) in compliance with applicable provisions of Data Protection Legislation; (ii) where any transfers of Personal Data formerly relied-upon the EU-US or Swiss-US Privacy Shield framework, Iris or such Subsidiary, as applicable, has ensured that the Personal Data transfers are lawful through an alternative mechanism or derogation in accordance with the GDPR; (iii) where reasonably required, Iris or such Subsidiary, as applicable, has conducted a risk assessment regarding the transfer of Personal Data pursuant to standard contractual clauses or binding corporate rules and has concluded that such

## Table of Contents

transfers are adequately protected; and (iv) none of Iris or its Subsidiaries has suspended or terminated a transfer of Personal Data or notified a supervisory authority of any concerns regarding a transfer of Personal Data pursuant to standard contractual clauses or binding corporate rules and nor are there circumstances which reasonably justify such a notification, except, in each case of clauses (i), (ii), (iii) and (iv), as would not have an Iris Material Adverse Effect.

(l) Between January 1, 2020 and the date hereof, none of Iris or its Subsidiaries has become aware of a Personal Data Breach affecting the processing of Personal Data (whether by Iris or any of its Subsidiaries or any data processor engaged directly or indirectly to process Personal Data).

(m) Between January 1, 2020 and the date hereof, none of Iris or its Subsidiaries has received a written notice or allegation, or is aware, of any actual or alleged or threatened unlawful access, loss, destruction, restriction, anonymization and/or deletion of Personal Data or other incident prejudicing or revealing a material weakness in, the security of the Personal Data or any other breach of the Data Protection Legislation relating to Personal Data while in its possession or under its control.

(n) Between January 1, 2020 and the date hereof, none of Iris or its Subsidiaries has received a written claim, complaint, allegation or other notice of a concern (whether directly or indirectly) from or on behalf of a Data Subject regarding its Personal Data processing activities.

(o) Between January 1, 2020 and the date hereof, none of Iris or its Subsidiaries has received a written notice from any supervisory authority of any investigation, enquiry, request for information and/or for co-operation regarding its Personal Data processing activities.

### 3.16. Regulatory Matters.

(a) Iris and each of its Subsidiaries are, and since January 1, 2020 have been, in compliance in all respects with all applicable Laws, including the FDCA and any other similar Laws administered or promulgated by the FDA or other comparable Governmental Entity, except for any noncompliance which would not have an Iris Material Adverse Effect. Without limiting the foregoing, the Iris Products have been manufactured, packaged, labeled, tested, stored, shipped, handled, warehoused, and distributed in accordance with all applicable Laws and Iris Permits (as defined below), commensurate with the Iris Products' stage of development, and are not and have not been adulterated, misbranded, or prohibited from introduction into interstate commerce under applicable Law. To Iris's Knowledge, as of the date hereof no investigation, inspection, claim, suit, proceeding, audit or other action by any Governmental Entity is pending or threatened against Iris or any of its Subsidiaries.

(b) There is no agreement, judgment, injunction, order or decree binding upon Iris or any of its Subsidiaries which (i) has or would reasonably be expected to have the effect of prohibiting or materially impairing any material business practice of Iris or any of its Subsidiaries, any acquisition of material property by Iris or any of its Subsidiaries or the conduct of any material portion of the business by Iris or any of its Subsidiaries as currently conducted, (ii) is reasonably likely to have a material adverse effect on Iris's ability to comply with or perform any covenant or obligation under this Agreement, or (iii) is reasonably likely to have the effect of preventing, materially delaying, making illegal or otherwise materially interfering with the Contemplated Transactions.

(c) Iris and its Subsidiaries have at all times since January 1, 2020 held and have operated in compliance with all Governmental Authorizations that are necessary for the conduct of the business of Iris and its Subsidiaries as currently being conducted (the "**Iris Permits**"), except where such failures to hold or remain so in compliance would not have an Iris Material Adverse Effect. All such Iris Permits are valid and are in full force and effect, and, assuming the notices, filings or other Consents listed on Section 3.16(c) of the Iris Disclosure Schedule have been made or obtained, will continue to be so upon consummation of the Contemplated Transactions, except as would not have an Iris Material Adverse Effect.

## [Table of Contents](#)

(d) Section 3.15(d) of the Iris Disclosure Schedule identifies each Iris Permit. Iris and its Subsidiaries hold all right, title and interest in and to all Iris Permits free and clear of any Lien. All fees and charges with respect to such Iris Permits, as of the date hereof, have been paid in full and all filing, reporting and maintenance obligations have been completely and timely satisfied, except as would not have an Iris Material Adverse Effect. Iris and each of its Subsidiaries are in material compliance with the terms of the Iris Permits. To Iris's Knowledge, as of the date hereof no Legal Proceeding is pending or threatened, which seeks to revoke, limit, suspend, or materially modify any Iris Permit.

(e) To Iris's Knowledge, as of the date hereof there are no proceedings pending or threatened with respect to an alleged material violation by Iris or any of its Subsidiaries of the FDCA or any other similar Law administered or promulgated by any comparable Governmental Entity. As of the date hereof, neither Iris, any of its Subsidiaries nor to Iris's Knowledge, any Person providing services to Iris or any of its Subsidiaries with respect to Iris's product candidate eganelisib and currently contemplated uses (the "**Iris Products**") has received any written notice, including any warning letter, untitled letter, cyber letter, FDA Form-483, Establishment Inspection Report, written notice of other adverse finding, notice of integrity review, notice of investigation, request for corrective or remedial action, or notice of deficiency or violation, or similar written communication from the FDA or any other Governmental Entity alleging that Iris or its Subsidiaries, their respective operations, or the Iris Products are in material violation of any applicable Law or Iris Permit.

(f) No Iris Product has been or has been requested by a Governmental Authority or other Person to be recalled, withdrawn, removed, suspended, seized, the subject of a corrective action, or discontinued (whether voluntarily or otherwise) (collectively "**Recall**"). Neither Iris, nor, to Iris's Knowledge, any Governmental Authority or other Person, has sought, is seeking, or, to Iris's Knowledge, has or is currently threatening or contemplating any Recall of an Iris Product.

(g) As required under applicable Law or pursuant to a Governmental Authorization, Iris and its Subsidiaries have maintained, filed, or furnished to the applicable Governmental Entities or Person all filings, documents, claims, reports, notices, and other submissions (the "**Reports**"), required to be maintained, filed, or furnished on a timely basis, and, at the time of maintenance, filing, or furnishing all such Reports were complete and accurate when submitted, or were subsequently updated, changed, corrected, or modified, except where the failures to so maintain, file, furnish, update, change, correct or modify would not have an Iris Material Adverse Effect.

(h) Neither Iris, its Subsidiaries, nor to Iris's Knowledge, any Person providing services to Iris or its Subsidiaries has made an untrue statement of a material fact or fraudulent statement to the FDA or a Governmental Entity, failed to disclose a material fact required to be disclosed to the FDA or a Governmental Entity, or made a statement, or failed to make a statement that, would reasonably be expected to provide a basis for the FDA to invoke its policy respecting "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities" Final Policy set forth in 56 Fed. Reg. 46191 (September 10, 1991) and any amendments thereto (the "**FDA Ethics Policy**"). Neither Iris, its Subsidiaries, nor to Iris's Knowledge, any Person providing services to Iris or its Subsidiaries has ever been investigated by the FDA or other Governmental Entity for data or healthcare program fraud. Neither Iris, its Subsidiaries, nor to Iris's Knowledge, any Person providing services to Iris or its Subsidiaries is the subject of any pending or, to Iris's Knowledge, threatened investigation pursuant to the FDA Ethics Policy, or resulting from any other untrue or false statement or omission.

(i) Neither Iris, its Subsidiaries, nor any Person providing services to Iris or its Subsidiaries, nor their respective officers, directors, partners, employees, or agents have been:

(i) debarred or suspended pursuant to 21 U.S.C. § 335a;

(ii) excluded under 42 U.S.C. § 1320a-7 or any similar law, rule or regulation of any Governmental Entity;

## Table of Contents

(iii) excluded, debarred, suspended or deemed ineligible to participate in federal procurement and non-procurement programs, including those produced by the U.S. General Services Administration;

(iv) charged, named in a complaint, convicted, or otherwise found liable in any Legal Proceeding that falls within the ambit of 21 U.S.C. § 331, 21 U.S.C. § 333, 21 U.S.C. § 334, 21 U.S.C. § 335a, 21 U.S.C. § 335b, 42 U.S.C. § 1320a – 7, 31 U.S.C. §§ 3729 – 3733, 42 U.S.C. § 1320a-7a, or any other applicable Law;

(v) disqualified or deemed ineligible pursuant to 21 C.F.R. Parts 312, 511, or 812, or otherwise restricted, in whole or in part, or subject to an assurance; or

(vi) had a pending Legal Proceeding, or otherwise received any written notice from any Governmental Entity or any Person threatening, investigating, or pursuing (i)-(v) above.

(j) Iris has not been restrained by a Governmental Authority nor other Person in its ability to conduct or have conducted the manufacturing, operation, storage, import, export, distribution, warehousing, packaging, labeling, handling, shipping, and/or nonclinical, clinical, or other testing of the Iris Products.

(k) All clinical, pre-clinical and other studies and tests conducted by or on behalf of, or sponsored by, Iris or any of its Subsidiaries, or in which Iris or any of its Subsidiaries or the Iris Products has participated were and, if still pending, are being conducted in compliance in all material respects with all applicable Laws and regulations enforced by the FDA or any comparable Governmental Entity, including, to the extent applicable, 21 C.F.R. Parts 50, 54, 56, 58, 312 and 812. The study reports, protocols, and statistical analysis plans for all such studies and tests accurately, completely, and fairly reflect the results from such studies and tests. Iris has not received written notice of any complaints, information, or adverse drug experience reports related to an Iris Product that would have an Iris Material Adverse Effect.

(l) As of the date hereof, neither Iris, its Subsidiaries, nor to Iris's Knowledge, any Person providing services to Iris or its Subsidiaries has received any written notice, correspondence, or other written communications from the FDA, any other Governmental Entity, any Institutional Review Board ("IRB"), or other Person or board, such as, but not limited to, a data safety monitoring board, responsible for the oversight of the conduct of any study conducted by or on behalf of, or sponsored by, Iris or any of its Subsidiaries, or in which Iris or the Iris Products is participating, requiring or threatening the termination, hold, material adverse modification or suspension of any clinical study that is being or is proposed to be conducted. All clinical studies conducted or sponsored by or on behalf of Iris or its Subsidiaries were and, if still pending, are being conducted in all material respects in accordance with all applicable Laws, the protocols, procedures and controls designed and approved for such studies, and in accordance with any requirement of an IRB or other Person or board responsible for review or oversight of such studies.

### 3.17. Insurance; Real Estate.

(a) Iris has made available to Meadow accurate and complete copies of all material insurance policies and all material self-insurance programs and arrangements relating to the business, assets, liabilities and operations of Iris and each of its Subsidiaries in effect on the date hereof. Each of such insurance policies is in full force and effect and Iris and each of its Subsidiaries are in compliance in all material respects with the terms thereof. Other than customary end of policy notifications from insurance carriers, between January 1, 2020 and the date hereof, neither Iris nor any of its Subsidiaries has received any written notice or other written communication regarding any actual or possible: (i) cancellation or invalidation of any insurance policy; or (ii) refusal or denial of any coverage, reservation of rights or rejection of any material claim under any insurance policy. Iris and each of its Subsidiaries have provided timely written notice to the appropriate insurance carrier(s) of each Legal Proceeding that is currently pending against Iris or any of its Subsidiaries for which Iris or such Subsidiary has insurance coverage, and no such carrier has issued a denial of coverage or a reservation of rights with respect to any such Legal Proceeding or informed Iris or any of its Subsidiaries of its intent to do so.

## Table of Contents

(b) Neither Iris nor any of its Subsidiaries owns, or has ever owned, any real property. Section 3.17(b) of the Iris Disclosure Schedule sets forth a true and complete list of all real properties with respect to which Iris or any of its Subsidiaries directly or indirectly holds a valid leasehold interest as well as any other real estate that is in the possession of or leased by Iris or any of its Subsidiaries (the “**Iris Leased Real Property**”), and a true and complete list of all leases under which any such real property is leased or possessed (the “**Iris Real Estate Leases**”), each of which is in full force and effect, with no existing material default by Iris thereunder. Iris’s or its applicable Subsidiary’s use and operation of each such Iris Leased Real Property conforms to all applicable Laws in all material respects, and Iris or its applicable Subsidiary has exclusive possession of each such Iris Leased Real Property and has not granted any occupancy rights to tenants or licensees with respect to such Iris Leased Real Property. Neither Iris nor any of its Subsidiaries has assigned, transferred or pledged any interest in any of the Iris Real Estate Leases. In addition, each of Iris and its applicable Subsidiary has a valid leasehold interest in (or a valid right to use and occupy) the Iris Leased Real Property, free and clear of all Liens other than Permitted Liens. To Iris’s Knowledge, neither the whole nor any part of the Iris Leased Real Property is subject to any pending suit for condemnation or other taking by any Governmental Entity, and no such condemnation or other taking is threatened or contemplated. The Iris Leased Real Property comprises all of the real property used in, and is necessary for, the operation of the business of Iris and its Subsidiaries as currently conducted. All structures and buildings on the Iris Leased Real Property are adequately maintained and are in good operating condition and repair for the requirements of the business of Iris and its Subsidiaries as currently conducted.

3.18. Registration Statement and Joint Proxy Statement/Prospectus. None of the information supplied or to be supplied by Iris in writing for inclusion or incorporation by reference in (a) the Registration Statement will, at the time the Registration Statement or any amendment or supplement thereto is declared effective under the Securities Act, contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein not misleading in any material respect or (b) the Joint Proxy Statement/Prospectus will, at the date it is first mailed to each of Iris’s stockholders and Meadow’s stockholders or at the time of the Iris Stockholders Meeting, contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they are made, not misleading in any material respect. The Joint Proxy Statement/Prospectus will comply as to form in all material respects with the requirements of the Exchange Act and the rules and regulations thereunder, except that no representation is made by Iris with respect to statements made or incorporated by reference therein based on information supplied Meadow for inclusion or incorporation by reference therein.

3.19. Transactions with Affiliates. Since April 25, 2022, no event has occurred as of the date hereof that would be required to be reported by Iris pursuant to Item 404 of Regulation S-K as promulgated under the Securities Act.

3.20. Brokers and Finders. Except for Aquilo Partners, no broker, finder or investment banker is entitled to any brokerage fee, finder’s fee, opinion fee, success fee, transaction fee or other fee or commission in connection with the Contemplated Transactions based upon arrangements made by or on behalf of Iris or any of its Subsidiaries.

3.21. Opinion of Financial Advisor. As of the date of this Agreement, the Iris Board has received the opinion, that will subsequently be provided in writing, of the Aquilo Partners that, as of the date of such opinion and based upon and subject to the various qualifications, assumptions, limitations and other matters set forth therein, the Exchange Ratio is fair, from a financial point of view, to holders of Shares. Iris shall, promptly following the execution of this Agreement by all Parties, furnish a copy of each such written opinion to Meadow solely for informational purposes (it being agreed that none of Meadow or Merger Sub, nor any of their respective Affiliates or Representatives, shall have the right to rely on such opinion).

3.22. Anti-Bribery. None of Iris, any of its Subsidiaries or any of their respective directors, officers, employees or, to Iris’s Knowledge, agents or any other Person acting on their behalf has directly or indirectly



## Table of Contents

made any bribes, rebates, payoffs, influence payments, kickbacks, illegal payments, illegal political contributions, or other payments, in the form of cash, gifts, or otherwise, or taken any other action or made or failed to make any other statement, in violation of Anti-Bribery Laws except, in each case, as would not be material to Iris's business or operations. Neither Iris nor any of its Subsidiaries nor any of their respective officers, employees or agents is or has been, in any capacity relating to Iris or such Subsidiary, the subject of any debarment or exclusionary claims, actions, proceedings, or, to Iris's Knowledge, investigation by any Governmental Entity with respect to potential violations of Anti-Bribery Laws except, in each case, as would not be material to Iris's business or operations. None of Iris, any of its Subsidiaries or any of their respective officers, employees or, to Iris's Knowledge, agents is or has been subject to mandatory or permissive debarment for any basis specified at 21 U.S.C. 335a, and none of Iris, any of its Subsidiaries or any of their respective principals (as defined at 48 C.F.R. 52.209-5(a)(2)) would be required to certify affirmatively to any element of the certification at 48 C.F.R. 52.209-5.

3.23. Ownership of Meadow Common Stock. Since January 1, 2020, neither Iris nor any of its Subsidiaries has "owned" (as such term is defined in Section 203(c) of the DGCL), directly or indirectly, any shares of Meadow Common Stock or other securities convertible into, exchangeable into or exercisable for shares of Meadow Common Stock. There are no voting trusts or other agreements or understandings to which Iris or any its Subsidiaries is a party with respect to the voting of the capital stock or other equity interest of Meadow or any of its Subsidiaries.

### **ARTICLE IV REPRESENTATIONS AND WARRANTIES OF MEADOW AND MERGER SUB**

Meadow represents and warrants to Iris as set forth in the statements contained in this Article IV except as set forth in the Meadow SEC Documents filed with, or furnished to, the SEC prior to the date hereof and publicly available on the SEC's Electronic Data Gathering Analysis and Retrieval system (but (i) without giving effect to any amendment thereof filed with, or furnished to, the SEC on or after the date hereof and (ii) excluding any disclosures contained under the heading "Risk Factors" and any disclosure of risks included in any "forward-looking statements" disclaimer or in any other section to the extent they are forward-looking statements or cautionary, predictive or forward-looking in nature) or in the disclosure letter delivered by Meadow to Iris at or before the execution and delivery by Meadow of this Agreement (the "**Meadow Disclosure Schedule**"). The Meadow Disclosure Schedule shall be arranged in numbered and lettered sections corresponding to the numbered and lettered sections contained in this Article IV, and the disclosure in any section of the Meadow Disclosure Schedule shall be deemed to qualify other sections in this Article IV to the extent that it is reasonably apparent on the face of such disclosure that such disclosure also qualifies or applies to such other sections.

4.1. Organizational Documents. Meadow has made available to Iris accurate and complete copies of the Organizational Documents of Meadow, Merger Sub and each of Meadow's other Subsidiaries in effect as of the date of this Agreement. Neither Meadow, nor Merger Sub nor any of Meadow's other Subsidiaries is in material breach or violation of its respective Organizational Documents.

#### 4.2. Due Organization; Subsidiaries.

(a) Each of Meadow and Merger Sub is a corporation duly incorporated, validly existing and in good standing under the Laws of the State of Delaware, and has all necessary corporate power and authority: (i) to conduct its business in the manner in which its business is currently being conducted; (ii) to own or lease and use its property and assets in the manner in which its property and assets are currently owned or leased and used; and (iii) to perform its obligations under all Contracts by which it is bound, except where the failure to have such power or authority would not have a Meadow Material Adverse Effect.

(b) Meadow is duly licensed and qualified to do business and is in good standing (to the extent applicable in such jurisdiction), under the Laws of all jurisdictions where the nature of its business requires such



## Table of Contents

licensing or qualification other than in jurisdictions where the failure to be so qualified would not have a Meadow Material Adverse Effect.

(c) Each of Meadow's Subsidiaries is identified in Section 4.2(c) of the Meadow Disclosure Schedule; and neither Meadow nor any of the entities identified in Section 4.2(c) of the Meadow Disclosure Schedule owns any capital stock of, or any equity, ownership or profit sharing interest of any nature in, or controls directly or indirectly, any other entity other than the entities identified in Section 4.2(c) of the Meadow Disclosure Schedule. Each of Meadow's Subsidiaries is a corporation or other legal entity duly organized, validly existing and, if applicable, in good standing under the Laws of the jurisdiction of its organization and has all necessary corporate or other power and authority to conduct its business in the manner in which its business is currently being conducted and to own or lease and use its property and assets in the manner in which its property and assets are currently owned or leased and used, except where the failure to have such power or authority would not have a Meadow Material Adverse Effect.

(d) Neither Meadow nor any of its Subsidiaries is or has otherwise been, directly or indirectly, a party to, member of or participant in any partnership, joint venture or similar business entity. Neither Meadow nor any of its Subsidiaries has agreed or is obligated to make or is bound by any Contract under which it may become obligated to make, any future investment in or capital contribution to any other entity. Neither Meadow nor any of its Subsidiaries has, at any time, been a general partner of, or has otherwise been liable for any of the debts or other obligations of, any general partnership, limited partnership or other entity.

### 4.3. Capitalization.

(a) The authorized capital stock of Meadow as of the date of this Agreement consists of (i) 226,000,000 shares of common stock, par value \$0.00000002 per share (the "**Meadow Common Stock**"), of which 133,260,865 shares have been issued and are outstanding as of the close of business on the Reference Date and (ii) 100,000 shares of preferred stock of Meadow, par value \$0.01 per share, of which no shares are issued and outstanding as of the date of this Agreement. Meadow has authorized a sufficient number of shares of Meadow Common Stock to issue the Merger Consideration. Meadow does not hold any shares of its capital stock in its treasury.

(b) Section 4.3(b) of the Meadow Disclosure Schedule lists, as of the Reference Date, (A) each holder of issued and outstanding Meadow Warrants, (B) the number and type of shares subject to each Meadow Warrant, (C) the exercise price of each Meadow Warrant and (D) the termination date of each Meadow Warrant.

(c) All of the outstanding shares of Meadow Common Stock have been duly authorized and validly issued and are fully paid and nonassessable. None of the outstanding shares of Meadow Common Stock is entitled or subject to any preemptive right, right of participation, right of maintenance or any similar right and none of the outstanding shares of Meadow Common Stock is subject to any right of first refusal in favor of Meadow. The shares of Meadow Common Stock issuable as Merger Consideration will be, when issued, duly authorized and validly issued and fully paid and nonassessable, and not subject to, or issued in violation of, any preemptive right, right of participation, right of maintenance, right of first refusal or any similar right. Except as contemplated herein, there is no Meadow Contract relating to the voting or registration of, or restricting any Person from purchasing, selling, pledging or otherwise disposing of (or granting any option or similar right with respect to), any shares of Meadow Common Stock. Meadow is not a party to any Contract pursuant to which it may become obligated to repurchase, redeem or otherwise acquire any outstanding shares of Meadow Common Stock or other securities.

(d) Except for Meadow's Amended and Restated 2008 Stock Omnibus Equity Compensation Plan (the "**Meadow 2008 Equity Compensation Plan**") and Meadow's 2021 Inducement Grant Equity Compensation Plan (the "**Meadow Inducement Plan**," and together with the Meadow 2008 Equity Compensation Plan, the "**Meadow Stock Plans**") and the award agreements thereunder, Meadow does not have any stock option plan or

## Table of Contents

any other plan, program, agreement or arrangement providing for any equity-based compensation for any Person. As of the close of business on the Reference Date, Meadow has authorized 39,514,794 shares of Meadow Common Stock for issuance under the Meadow Stock Plans, of which 2,283,122 shares have been issued and are currently outstanding, and of which 0 shares are subject to Meadow's right of repurchase. As of the close of business on the Reference Date, 23,134,854 shares of Meadow Common Stock have been reserved for issuance upon exercise of Meadow Options previously granted and currently outstanding under the Meadow 2008 Equity Compensation Plan, and 1,995,478 shares Meadow Common Stock have been reserved for issuance upon exercise of Meadow Options previously granted and currently outstanding under the Meadow Inducement Plan. Meadow has authorized and reserved a sufficient number of shares of Meadow Common Stock to assume the Iris Equity Awards at the Closing.

(e) Except for the Meadow Warrants, and the Meadow Options, there is no: (i) outstanding subscription, option, call, warrant or right (whether or not currently exercisable) to acquire any shares of the capital stock or other securities of Meadow or any of its Subsidiaries; or (ii) outstanding security, instrument or obligation that is or may become convertible into or exchangeable for any shares of the capital stock or other securities of Meadow or any of its Subsidiaries. There are no outstanding or authorized stock appreciation, phantom stock, profit participation or other similar rights with respect to Meadow or any of its Subsidiaries.

(f) All outstanding shares of Meadow Common Stock, the Meadow Options, the Meadow Warrants and other securities of Meadow have been issued and granted in material compliance with (i) all applicable securities Laws and other applicable Laws, and (ii) all requirements set forth in applicable Contracts. No Meadow Options have an exercise price that has been or may be less than the fair market value of the underlying stock as of the date such Meadow Option was granted or has any feature for the deferral of compensation that could render the grant subject to Section 409A of the Code.

#### 4.4. Authority; Binding Nature of Agreement.

(a) Each of Meadow and Merger Sub has all requisite corporate power and authority to execute and deliver this Agreement, to perform its obligations hereunder and, subject, with respect to Meadow, to receipt of the Meadow Stockholder Approval, with respect to Merger Sub, the adoption of this Agreement by Meadow in its capacity as sole stockholder of Merger Sub, to consummate the Contemplated Transactions. The Meadow Board has adopted resolutions, by vote at a meeting duly called, (i) determining that the Contemplated Transactions, including the Merger and the issuance of shares of Meadow Common Stock pursuant to this Agreement (the "**Meadow Share Issuance**"), are advisable and in the best interests of Meadow and its stockholders, (ii) approving and declaring advisable this Agreement and the Contemplated Transactions, and (iii) resolved to make the Meadow Board Recommendation. As of the date of this Agreement, such resolutions have not been amended or withdrawn. This Agreement has been duly executed and delivered by Meadow and Merger Sub and, assuming the due authorization, execution and delivery by Iris, constitutes the valid and binding obligation of Meadow and Merger Sub, enforceable against each of Meadow and Merger Sub in accordance with its terms, except, in each case, as enforcement may be limited by the Bankruptcy and Equity Exception.

(b) Except for the approval of the Meadow Share Issuance by the affirmative vote of the holders of Meadow's capital stock entitled to vote thereon by a majority of the votes cast (such approval, the "**Meadow Stockholder Approval**"), no other corporate proceedings on the part of the Meadow stockholders are necessary to authorize, adopt or approve, as applicable, this Agreement or the Contemplated Transactions. Except for the adoption of this Agreement by the sole stockholder of Merger Sub, no other corporate proceedings on the part of the Merger Sub stockholders are necessary to authorize, adopt or approve, as applicable, this Agreement.

#### 4.5. Non-Contravention; Consents.

(a) Subject to (I) obtaining the Meadow Stockholder Approval, (II) the filing of the Certificate of Merger required by the DGCL, (III) (A) the filing with the SEC of the Joint Proxy Statement/Prospectus in

## Table of Contents

definitive form, (B) the filing with the SEC, and declaration of effectiveness under the Securities Act of the Registration Statement, and (C) the filing with the SEC of such reports and other filings under, and such other compliance with, the Exchange Act and the Securities Act, and the rules and regulations thereunder, as may be required in connection with this Agreement, and the Contemplated Transactions, (IV) such Consents, registrations, declarations, notices or filings as are required to be made or obtained under the securities or “blue sky” laws of various states in connection with the issuance of the shares of Meadow Common Stock to be issued as the Merger Consideration and (V) such filings with and approvals of Nasdaq as are required to permit the consummation of the Merger and the listing of the shares of Meadow Common Stock to be issued as the Merger Consideration, neither (x) the execution, delivery or performance of this Agreement by Iris nor (y) the consummation by Meadow of the Contemplated Transactions, will (with or without notice or lapse of time):

(i) result in a violation or breach of any of the provisions of the Organizational Documents of Meadow or any of its Subsidiaries;

(ii) result in a violation or breach of, or give any Governmental Entity the right to exercise any remedy or obtain any relief under, any Law or any order, writ, injunction, judgment or decree to which Meadow or any of its Subsidiaries, or any of the assets owned by Meadow or any of its Subsidiaries, is subject;

(iii) result in a violation or breach of any of the terms or requirements of, or give any Governmental Entity the right to revoke, withdraw, suspend, cancel, terminate or modify, any Governmental Authorization that is held by Meadow or its Subsidiaries;

(iv) result in a violation or breach of, or result in a default under, any provision of any Meadow Material Contract, or give any Person the right to: (i) declare a default or exercise any remedy under any Meadow Material Contract; (ii) any material payment, rebate, chargeback, penalty or change in delivery schedule under any Meadow Material Contract; (iii) accelerate the maturity or performance of any Meadow Material Contract; or (iv) cancel, terminate or modify any term of any Meadow Material Contract; or

(v) result in the imposition or creation of any Lien upon or with respect to any asset owned or used by Meadow or any of its Subsidiaries (except for Permitted Liens);

except in the case of clauses (ii), (iii), (iv) and (v) of this Section 4.5(a) for any such violations, remedies, relief, revocations, withdrawals, suspensions, cancellations, termination, modifications, breaches, defaults, payments, rebates, chargebacks, penalties, changes, accelerations or Liens that would not have a Meadow Material Adverse Effect.

(b) Except for (i) the filing of the Certificate of Merger with the Secretary of State of the State of Delaware pursuant to the DGCL, (ii) (A) the filing with the SEC of the Joint Proxy Statement/Prospectus in definitive form, (B) the filing with the SEC, and declaration of effectiveness under the Securities Act of the Registration Statement, and (C) the filing with the SEC of such reports and other filings under, and such other compliance with, the Exchange Act and the Securities Act, and the rules and regulations thereunder, as may be required in connection with this Agreement, and the Contemplated Transactions, (iii) such filings with and approvals of Nasdaq as are required to permit the consummation of the Merger and the listing of the shares of Meadow Common Stock to be issued as the Merger Consideration and (iv) such consents, waivers, approvals, orders, authorizations, registrations, declarations and filings as may be required under applicable federal and state securities Laws, neither Meadow nor any of its Subsidiaries is or will be required to make any filing with or give any notice to, or to obtain any Consent from, any Governmental Entity in connection with (x) the execution, delivery or performance by Meadow of this Agreement, or (y) the consummation by Meadow of the Contemplated Transactions, which if individually or in the aggregate were not given or obtained, would reasonably be expected to prevent or materially delay the ability of Meadow to consummate the Contemplated Transactions or that would have a Meadow Material Adverse Effect. Assuming the accuracy of the representation set forth in Section 3.23, the Meadow Board has taken all actions necessary to ensure that the restrictions applicable to business combinations contained in Section 203 of the DGCL are, and will be, inapplicable to the

## Table of Contents

execution, delivery and performance of this Agreement and to the consummation of the Contemplated Transactions. To Meadow's Knowledge, no other takeover statute or similar Law applies or purports to apply to the Merger, this Agreement, or any of the Contemplated Transactions.

### 4.6. SEC Filings; Financial Statements.

(a) Other than such documents that can be obtained on the SEC's website at [www.sec.gov](http://www.sec.gov), Meadow has made available to Iris accurate and complete copies of all registration statements, proxy statements, Meadow Certifications (as defined below) and other statements, reports, schedules, forms and other documents filed by Meadow with the SEC between January 1, 2020 and the date hereof (the "**Meadow SEC Documents**"). Since the date of the Meadow Balance Sheet, all material statements, reports, schedules, forms and other documents required to have been filed by Meadow or its officers with the SEC have been so filed on a timely basis. As of the time it was filed with the SEC (or, if amended or superseded by a filing prior to the date of this Agreement, then on the date of such filing), each of the Meadow SEC Documents complied in all material respects with the applicable requirements of the Securities Act or the Exchange Act (as the case may be) and, as of the time they were filed, none of the Meadow SEC Documents contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading (or, in the case of a Meadow SEC Document that is a registration statement, as amended or supplemented, if applicable, filed pursuant to the Securities Act, as of the date such registration statement or amendment became effective, contained any untrue statement of a material fact or omitted to state any material fact required to be stated therein or necessary to make the statements made therein not misleading); provided, however, that no representation is made as to the accuracy of any financial projections or forward-looking statements or the completeness of any information furnished by Meadow to the SEC solely for the purposes of complying with Regulation FD promulgated under the Exchange Act. The certifications and statements required by (i) Rule 13a-14 under the Exchange Act and (ii) 18 U.S.C. §1350 (Section 906 of the Sarbanes-Oxley Act) relating to the Meadow SEC Documents (collectively, the "**Meadow Certifications**") are accurate and complete in all material respects and comply as to form and content in all material respects with all applicable Laws. As used in this Section 4.6, the term "file" and variations thereof shall be broadly construed to include any manner in which a document or information is furnished, supplied or otherwise made available to the SEC.

(b) The financial statements (including any related notes) contained or incorporated by reference in the Meadow SEC Documents: (i) complied as to form in all material respects with the published rules and regulations of the SEC applicable thereto; (ii) were prepared in accordance with GAAP (except as may be indicated in the notes to such financial statements or, in the case of unaudited financial statements, except as permitted by the SEC on Form 10-Q under the Exchange Act, and except that the unaudited financial statements may not contain footnotes and are subject to normal and recurring year-end adjustments) applied on a consistent basis unless otherwise noted therein throughout the periods indicated; and (iii) fairly present, in all material respects, the financial position of Meadow and its consolidated Subsidiaries as of the respective dates thereof and the results of operations and cash flows of Meadow and its consolidated Subsidiaries for the periods covered thereby. Other than as expressly disclosed in the Meadow SEC Documents filed between January 1, 2020 and the date hereof there has been no material change in Meadow's accounting methods or principles that would be required to be disclosed in Meadow's financial statements in accordance with GAAP.

(c) As of the date of this Agreement, Meadow is in compliance in all material respects with the applicable current listing and governance rules and regulations of Nasdaq.

(d) Meadow maintains a system of internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) that is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP and to provide reasonable assurance (i) that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, (ii) that receipts and expenditures are made only in

## Table of Contents

accordance with authorizations of management and the Meadow Board and (iii) regarding prevention or timely detection of the unauthorized acquisition, use or disposition of Meadow's assets that could have a material effect on Meadow's financial statements. Meadow has evaluated the effectiveness of Meadow's system of internal control over financial reporting as of December 31, 2021, and, to the extent required by applicable Law, presented in any applicable Meadow SEC Document that is a report on Form 10-K or Form 10-Q (or any amendment thereto) its conclusions about the effectiveness of the internal control over financial reporting as of the end of the period covered by such report or amendment based on such evaluation. Meadow has disclosed, based on its most recent evaluation of internal control over financial reporting, to Meadow's auditors and audit committee (and made available to Iris a summary of the significant aspects of such disclosure) (A) all significant deficiencies, if any, in the design or operation of internal control over financial reporting that are reasonably likely to adversely affect Meadow's ability to record, process, summarize and report financial information and (B) any known fraud that involves management or other employees who have a significant role in Meadow's internal control over financial reporting. Meadow has not identified, based on its most recent evaluation of internal control over financial reporting, any material weaknesses in the design or operation of Meadow's internal control over financial reporting.

(e) Meadow maintains "disclosure controls and procedures" (as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act) that are reasonably designed to ensure that information required to be disclosed by Meadow in the periodic reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the required time periods, and that all such information is accumulated and communicated to Meadow's management as appropriate to allow timely decisions regarding required disclosure and to make the Meadow Certifications.

4.7. Absence of Changes. Except (a) for reasonable and good faith actions or omissions taken to comply with applicable Law or guidance by Governmental Entity in connection with the COVID-19 pandemic or (b) as contemplated or permitted by or in connection with the execution and delivery of this Agreement, between the date of Meadow's latest consolidated unaudited balance sheet (the "**Meadow Balance Sheet**") and the date of this Agreement, Meadow has conducted its business in the Ordinary Course of Business in all material respects (except for the execution and performance of this Agreement and the discussions, negotiations and transactions related thereto, including the Contemplated Transactions) and there has not been any (i) Meadow Material Adverse Effect (disregarding for purposes of this Section 4.7 clause (2) of the definition thereof) or (ii) action, event or occurrence that would have required the consent of Iris pursuant to Section 5.1(b) (other than paragraphs (ii), (vi) and (xi) of Section 5.1(b) and paragraph (xiv) as it relates to paragraphs (ii), (vi) and (xi) of Section 5.1(b)) had such action, event or occurrence taken place after the execution and delivery of this Agreement.

4.8. Absence of Undisclosed Liabilities. As of the date of this Agreement and other than as contemplated by this Agreement, neither Meadow nor any of its Subsidiaries has any liability, debt or obligation, individually or in the aggregate, of a type required to be recorded or reflected on Meadow's balance sheet or disclosed in the footnotes thereto under GAAP except for liabilities, debts or obligations: (a) disclosed, reflected or reserved against in the Meadow Balance Sheet or disclosed in the notes thereto included in the Meadow SEC Documents; (b) that have been incurred by Meadow or any of its Subsidiaries since the date of the Meadow Balance Sheet in the Ordinary Course of Business; (c) for performance of obligations of Meadow or any of its Subsidiaries under the Meadow Material Contracts which have not resulted from a breach of such Meadow Material Contracts, breach of warranty, tort, infringement or violation of Law; (d) incurred in connection with the Contemplated Transactions; (e) that would not have a Meadow Material Adverse Effect; and (f) described in Section 4.8 of the Meadow Disclosure Schedule.

4.9. Title to Assets. Meadow and each of its Subsidiaries owns, and has good and valid title to, or, in the case of leased properties and assets, valid leasehold interests in, all material tangible properties or material tangible assets and material equipment used or held for use in its business or operations or purported to be owned by it, including: (a) all material tangible assets reflected on the Meadow Balance Sheet; and (b) all other material

## Table of Contents

tangible assets reflected in the books and records of Meadow or any of its Subsidiaries as being owned by Meadow or such Subsidiary. All of such assets are owned or, in the case of leased assets, leased by Meadow or its applicable Subsidiary free and clear of any Liens, other than Permitted Liens.

### 4.10. Legal Proceedings; Orders.

(a) As of the date of this Agreement, to Meadow's Knowledge, there is no pending Legal Proceeding and no Person has threatened in writing to commence any Legal Proceeding: (i) that involves (A) Meadow, (B) any of its Subsidiaries, (C) any Meadow Associate (in his or her capacity as such) or (D) any of the material assets owned or used by Meadow or its Subsidiaries; or (ii) that challenges, or that may have the effect of preventing, delaying, making illegal or otherwise interfering with, the Contemplated Transactions.

(b) Between January 1, 2020 and the date hereof, no Legal Proceeding has been pending against Meadow or any of its Subsidiaries that resulted in any liability that is material to Meadow and its Subsidiaries, taken as a whole.

(c) There is no material order, writ, injunction, judgment or decree to which Meadow or any of its Subsidiaries, or any of the material assets owned or used by Meadow or any of its Subsidiaries, is subject. To Meadow's Knowledge, as of the date hereof no officer or employee of Meadow or any of its Subsidiaries is subject to any order, writ, injunction, judgment or decree that prohibits such officer or employee from engaging in or continuing any conduct, activity or practice relating to the business of Meadow or any of its Subsidiaries or to any material assets owned or used by Meadow or any of its Subsidiaries.

### 4.11. Contracts.

(a) Section 4.11(a) of the Meadow Disclosure Schedule lists the following Meadow Contracts in effect as of the date of this Agreement (other than any Meadow Benefit Plan) under which Meadow or any of its Subsidiaries has any remaining material rights or obligations (each, a "**Meadow Material Contract**"):

(i) a material contract as defined in Item 601(b)(10) of Regulation S-K as promulgated under the Securities Act;

(ii) each Contract that is material to the business or operations of Meadow and its Subsidiaries, taken as a whole, containing (A) any covenant limiting the freedom of Meadow or any of its Subsidiaries to engage in any line of business or compete with any Person, (B) any "most-favored nations" pricing provisions or marketing or distribution rights related to any products or territory, (C) any exclusivity provision or (D) any agreement to purchase minimum quantity of goods or services;

(iii) each Contract relating to capital expenditures and requiring payments after the date of this Agreement in excess of \$100,000 pursuant to its express terms and not cancelable without penalty;

(iv) each Contract relating to the disposition or acquisition of material assets or any ownership interest in any entity;

(v) each Contract providing for the creation of any mortgages, indentures, loans, notes or credit agreements, security agreements or other agreements or instruments providing for the creation of material Indebtedness of Meadow or any of its Subsidiaries or creating any material Liens with respect to any material assets of Meadow or any of its Subsidiaries;

(vi) each Contract requiring payment by or to Meadow or any of its Subsidiaries after the date of this Agreement in excess of \$500,000 pursuant to its express terms relating to: (A) any distribution agreement (identifying any that contain exclusivity provisions); (B) any agreement involving provision of services or

## Table of Contents

products with respect to any pre-clinical or clinical development activities of Meadow or any of its Subsidiaries; (C) any dealer, distributor, joint marketing, alliance, joint venture, cooperation, development or other agreement currently in force under which Meadow or any of its Subsidiaries has continuing obligations to develop or market any product, technology or service, or any agreement pursuant to which Meadow or any of its Subsidiaries has continuing obligations to develop any Intellectual Property Rights that will not be owned, in whole or in part, by Meadow or any of its Subsidiaries; or (D) any Contract to license any third party to manufacture or produce any product, service or technology of Meadow or any of its Subsidiaries or any Contract to sell, distribute or commercialize any products or service of Meadow or any of its Subsidiaries, in each case, except for Contracts entered into in the Ordinary Course of Business;

(vii) each Meadow Real Estate Lease;

(viii) each Contract with any Governmental Entity, other than clinical trial agreements, sponsored research agreements or material transfer agreements entered into in the Ordinary Course of Business;

(ix) each Meadow Out-bound License and Meadow In-bound License;

(x) each Contract that is material to the business or operations of Meadow and its Subsidiaries, taken as a whole, containing any royalty, dividend or similar arrangement based on the revenues or profits of Meadow or any of its Subsidiaries;

(xi) each Contract that is not terminable at will with 60 days' prior notice (with no penalty or payment) by Meadow or its Subsidiaries, as applicable, and which involves payment or receipt by Meadow or its Subsidiaries after the date of this Agreement under any such Contract of more than \$100,000 in the aggregate, or obligations after the date of this Agreement in excess of \$100,000 in the aggregate;

(xii) each collective bargaining agreement or other similar Contract with any labor organization, union, group or association covering employees of Meadow; or

(xiii) each Contract (A) for the employment or engagement of any employee, consultant or independent contractor providing such Person with annual compensation or fees in excess of \$250,000, (B) providing for the payment of any cash or other compensation or benefits upon the consummation of the Merger, (C) restricting Meadow's ability to terminate the employment or services of any employee, consultant or independent contractor thereof at any time for any lawful reason or for no reason without penalty, or (D) providing for severance or similar termination payments, retention or change in control payments, or for the acceleration of vesting or grant of any incentive equity or similar compensation.

(b) Meadow has made available to Iris accurate and complete copies of all Meadow Material Contracts, including all material amendments thereto, in each case in effect on the date hereof but excluding any purchase orders and/or work orders issued under a Meadow Material Contract in the Ordinary Course of Business. There are no Meadow Material Contracts that are not in written form. As of the date of this Agreement, none of Meadow, any of its Subsidiaries or, to Meadow's Knowledge, any other party to a Meadow Material Contract, has breached, violated or defaulted under, or received notice that it breached, violated or defaulted under, any of the terms or conditions of, or Laws applicable to, any Meadow Material Contract in such manner as would permit any other party to cancel or terminate any such Meadow Material Contract, or would permit any other party to seek damages or pursue other legal remedies which would reasonably be expected to be material to Meadow and its Subsidiaries, taken as a whole. As to Meadow and its Subsidiaries, as of the date of this Agreement, each Meadow Material Contract is valid, binding, enforceable and in full force and effect, subject to the Bankruptcy and Equity Exception. Between the date of the Meadow Balance Sheet and the date hereof, no counterparty to a Meadow Material Contract has notified Meadow in writing (or, to the Knowledge of Meadow, otherwise) that it intends to terminate or not renew a Meadow Material Contract.



4.12. Employee and Labor Matters: Benefits Plans.

(a) Section 4.12(a) of Meadow Disclosure Schedule is a list of all Meadow Benefit Plans in effect on the date of this Agreement, including each such Meadow Benefit Plan that provides for retirement, change in control, stay or retention deferred compensation, incentive compensation, severance or retiree medical or life insurance benefits.

(b) As applicable with respect to each Meadow Benefit Plan, Meadow has made available to Iris, true and complete copies of (i) each Meadow Benefit Plan, including all amendments thereto, and in the case of an unwritten material Meadow Benefit Plan, a written description thereof, (ii) all current trust documents, investment management contracts, custodial agreements, administrative services agreements and insurance and annuity contracts relating thereto, (iii) the current summary plan description and each summary of material modifications thereto, (iv) the most recently filed annual reports with any Governmental Entity (e.g., Form 5500 and all schedules thereto), (v) the most recent IRS determination, opinion or advisory letter, (vi) the most recent summary annual reports, nondiscrimination testing reports, actuarial reports, financial statements and trustee reports, (vii) all non-routine correspondence received from or provided to the DOL the Pension Benefit Guaranty Corporation, the IRS or any other Governmental Entity between January 1, 2020 and the date hereof and (viii) all notices and filings concerning IRS or DOL or other Governmental Entity audits or investigations, including with respect to “prohibited transactions” within the meaning of Section 406 of ERISA or Section 4975 of the Code, between January 1, 2020 and the date of this Agreement.

(c) Each Meadow Benefit Plan has been established, maintained, operated, funded and administered in compliance in all material respects with its terms and any related documents or agreements and the applicable provisions of ERISA, the Code and all other applicable Laws.

(d) The Meadow Benefit Plans which are “employee pension benefit plans” within the meaning of Section 3(2) of ERISA and which are intended to meet the qualification requirements of Section 401(a) of the Code have received determination or opinion letters from the IRS on which they may currently rely to the effect that such plans are qualified under Section 401(a) of the Code and the related trusts are exempt from federal income Taxes under Section 501(a) of the Code, respectively, or are covered by advisory or opinion letters with respect to a volume submitter or prototype plan, and, to Meadow’s Knowledge, nothing has occurred that would reasonably be expected to materially adversely affect the qualification of such Meadow Benefit Plan or the tax exempt status of the related trust.

(e) None of Meadow, any of its Subsidiaries or any Meadow ERISA Affiliate has maintained, contributed to, been required to contribute to, or had any actual or contingent liability with respect to, (i) any “employee pension benefit plan” (within the meaning of Section 3(2) of ERISA) that is subject to Title IV or Section 302 of ERISA or Section 412 of the Code, (ii) any “multiemployer plan” (within the meaning of Section 3(37) of ERISA), (iii) any “multiple employer plan” (within the meaning of Section 413 of the Code), (iv) any “multiple employer welfare arrangement” (within the meaning of Section 3(40) of ERISA) or (v) any “voluntary employees beneficiary association” within the meaning of Section 501(c)(9) of the Code. The obligations of all Meadow Benefit Plans that provide health, welfare or similar insurance are fully insured by bona fide third-party insurers. No Meadow Benefit Plan is maintained through a human resources or benefit outsourcing entity, professional employer organization or other similar provider.

(f) As of the date of this Agreement, there are no pending audits or investigations by any Governmental Entity involving any Meadow Benefit Plan, and no pending or, to Meadow’s Knowledge, threatened claims (except for individual claims for benefits payable in the normal operation of the Meadow Benefit Plans), suits or proceedings involving any Meadow Benefit Plan, any fiduciary thereof or service provider thereto. To Meadow’s Knowledge, there have been no “prohibited transactions” (as that term shall have the meaning specified in Section 406 of ERISA or Section 4975 of the Code) involving any Meadow Benefit Plan, any fiduciary thereof or service provider thereto. Since January 1, 2020, all material contributions and premium payments required to have been timely made under any of the Meadow Benefit Plans or by applicable Law (without regard to any waivers granted under Section 412 of the Code), have been timely made and neither Meadow nor any of its



## Table of Contents

Subsidiaries has any liability for any such unpaid contributions with respect to any Meadow Benefit Plan, all benefits accrued under any unfunded Meadow Benefit Plan have been paid, accrued or otherwise adequately reserved in accordance with GAAP, and all reports, returns and similar documents required to be filed with any Governmental Entity or distributed to any plan participant have been timely filed or distributed.

(g) None of Meadow or any of its Subsidiaries, or, to Meadow's Knowledge, any fiduciary, trustee or administrator of any Meadow Benefit Plan, has engaged in, or in connection with the Contemplated Transactions will engage in, any transaction with respect to any Meadow Benefit Plan which would subject any such Meadow Benefit Plan, Meadow or any of its Subsidiaries to a material Tax, penalty or liability for a "prohibited transaction" under Section 406 of ERISA or Section 4975 of the Code.

(h) No Meadow Benefit Plan provides death, medical, dental, vision, life insurance or other welfare benefits beyond termination of service or retirement, other than coverage mandated by Law or at the participant or beneficiary's sole expense or, as described in Section 4.12(h) of the Meadow Disclosure Schedule, as provided with respect to continuation health coverage as part of severance, and none of Meadow or any of its Subsidiaries has any obligation to provide (whether under a Meadow Benefit Plan or otherwise) nor has made a written or oral representation promising the same.

(i) Neither the execution of this Agreement, nor the consummation of the Contemplated Transactions will either alone or in connection with any other event(s) (i) result in any payment (whether of severance pay or otherwise) becoming due to or forgiveness of indebtedness for any current or former employee, director, officer, independent contractor or other service provider of Meadow or any of its Subsidiaries, (ii) increase any amount of compensation or benefits otherwise payable to any current or former employee, director, officer, independent contractor or other service provider of Meadow or any of its Subsidiaries, (iii) result in the acceleration of the time of payment, funding or vesting of any benefits under any Meadow Benefit Plan, (iv) require any contribution or payment to fund any obligation under any Meadow Benefit Plan or (v) limit the right to merge, amend or terminate any Meadow Benefit Plan (or result in adverse consequences for so doing).

(j) Neither the execution of this Agreement, nor the consummation of the Contemplated Transactions (either alone or when combined with the occurrence of any other event, including a termination of employment) will result in the receipt or retention by any person who is a "disqualified individual" (within the meaning of Section 280G of the Code) with respect to Meadow and its Subsidiaries of any payment or benefit that is characterized as a "parachute payment" (within the meaning of Section 280G of the Code), determined without regard to the application of Section 280G(b)(5) of the Code.

(k) Each Meadow Benefit Plan providing for deferred compensation that constitutes a "nonqualified deferred compensation plan" (as defined in Section 409A(d)(1) of the Code and the regulations promulgated thereunder) is, and has been, established, administered and maintained in material compliance in both form and operation with the requirements of Section 409A of the Code and the regulations promulgated thereunder. Meadow does not have any liability for nonreporting or underreporting of income subject to Section 409A of the Code.

(l) No Person has any "gross up" agreements with Meadow or any of its Subsidiaries or other assurance of reimbursement by Meadow or any of its Subsidiaries for any Taxes imposed under Section 409A or Section 4999 of the Code.

(m) There are, and since January 1, 2020, there have been, no actual, threatened or pending negotiations, strikes, labor disputes, work stoppages, requests for representation, pickets, work slow-downs due to labor disagreements or any Proceedings or arbitrations that involve the labor or employment relations of Meadow or any of its Subsidiaries. Neither Meadow nor any of its Subsidiaries is a party to or bound by, or has a duty to bargain under, any collective bargaining agreement or other Contract with a labor union or labor organization representing any of its employees, and there is no labor union or labor organization representing or,

## Table of Contents

to Meadow's Knowledge, purporting to represent or seeking to represent any employees of Meadow or its Subsidiaries, including through the filing of a petition for representation election.

(n) Meadow and each of its Subsidiaries is, and since January 1, 2020 has been, in material compliance with all applicable Laws respecting labor, employment, employment practices, and terms and conditions of employment, including worker classification, discrimination, wrongful termination, harassment and retaliation, equal employment opportunities, fair employment practices, meal and rest periods, immigration and I-9, reasonable accommodation, disability rights or benefits, child labor, working conditions, meal and break periods, privacy, employee safety and health, wages (including overtime wages), unemployment and workers' compensation, leaves of absence, hours of work and orders, regulations, ordinances and guidelines by any Governmental Entity regarding COVID-19 (including any "stay at home" orders or other similar orders, regulations or guidelines). Except as would not be reasonably likely to result in a liability that is material to Meadow and its Subsidiaries, taken as a whole, with respect to employees of Meadow or any of its Subsidiaries, each of Meadow and its Subsidiaries, since January 1, 2020: (i) has withheld and reported all amounts required by Law or by agreement to be withheld and reported with respect to wages, salaries and other payments, benefits, or compensation to employees, (ii) is not liable for any arrears of wages (including overtime wages), premiums, commissions, paid time off, on-call payments, bonus, benefits, severance pay or any Taxes or any penalty for failure to comply with any of the foregoing, and (iii) is not liable for any payment to any trust or other fund governed by or maintained by or on behalf of any Governmental Entity, with respect to unemployment compensation benefits, disability, social security or other benefits or obligations for employees (other than routine payments to be made in the Ordinary Course of Business). As of the date of this Agreement, there are no actions, suits, claims, charges, demands, lawsuits, investigations, audits or administrative matters pending or, to Meadow's Knowledge, threatened or reasonably anticipated against Meadow or any of its Subsidiaries or Meadow Associates (in his or her capacity as such), relating to any current or former employee, applicant for employment, consultant, employment agreement or Meadow Benefit Plan (other than routine claims for benefits). All U.S. based employees of Meadow and its Subsidiaries are employed "at-will" and their employment can be terminated without advance notice or payment of severance in excess of sixty (60) days.

(o) Except as would not be reasonably likely to result in a liability that is material to Meadow and its Subsidiaries, taken as a whole, with respect to each individual who currently renders services to Meadow or any of its Subsidiaries, Meadow and each of its Subsidiaries has accurately classified each such individual as an employee, independent contractor, or otherwise under all applicable Laws and, for each individual classified as an employee, Meadow has accurately classified him or her as overtime eligible or overtime ineligible under all applicable Laws. Neither Meadow nor any of its Subsidiaries has any material liability with respect to any misclassification of: (a) any Person as an independent contractor rather than as an employee, (b) any employee leased from another employer, or (c) any employee currently or formerly classified as exempt from overtime wages. No employees are employed on a work visa or work permit.

(p) There is not and has not been since January 1, 2020, nor, to Meadow's Knowledge, is there or has there been since January 1, 2020 any threat of, any strike, slowdown, work stoppage, lockout, union election petition, demand for recognition, or any similar activity or dispute, or, to Meadow's Knowledge, any union organizing activity, against Meadow or any of its Subsidiaries. No event has occurred, and, to Meadow's Knowledge, no condition or circumstance exists, that would reasonably be expected directly or indirectly to give rise to or provide a basis for the commencement of any such strike, slowdown, work stoppage, lockout, union election petition, demand for recognition, or any similar activity or dispute.

(q) Neither Meadow nor any of its Subsidiaries has failed to comply in all material respects with ERISA Sections 601 to 608 and Code Section 4980B and Meadow has, for any relevant period, offered the requisite number of "full-time employees" group health coverage that is "affordable" and of "minimum value" (as such terms are defined by the employer shared responsibility provisions of the Patient Protection and Affordable Care Act).

## Table of Contents

(r) No Meadow Benefit Plan is or has been maintained outside the jurisdiction of the United States, or covers or covered any employee permanently residing or working outside the United States.

(s) Since January 1, 2020, neither Meadow nor its Subsidiaries has caused (i) a plant closing as defined in the WARN Act affecting any single site of employment of Meadow or its Subsidiaries or one or more operating units within any site of employment of Meadow or its Subsidiaries or (ii) a mass layoff as defined in the WARN Act, nor has Meadow or its Subsidiaries been affected by any transaction or engaged in layoffs or employment terminations sufficient in number to trigger application of any similar foreign, state or local Law. No employee of Meadow or its Subsidiaries has suffered an employment loss, as defined in the WARN Act, within the 90-day period ending on the Closing Date. Since January 1, 2020, neither Meadow nor its Subsidiaries has implemented any material workplace changes such as layoffs, furloughs, permanent office closures, or reductions in compensation, benefits or hours.

(t) No Legal Proceedings are as of the date of this Agreement open and pending (or between January 1, 2020 and the date hereof have been settled or otherwise closed) against Meadow or any of its Subsidiaries with respect to the employment of, or failure to employ, any individual, including any brought with or by the Equal Employment Opportunity Commission, the Office of Federal Contract Compliance Programs, or other Governmental Entity regulating the employment or compensation of individuals (or, with respect to discrimination, unlawful harassment, retaliation, or similar wrongdoing, pursuant to internal complaint procedures), and no employee of Meadow or any of its Subsidiaries has made, between January 1, 2020 and the date hereof, a written complaint of discrimination, unlawful harassment, retaliation, or other similar wrongdoing or, to the Knowledge of Meadow, between January 1, 2022 and the date hereof, an oral complaint. Between January 1, 2020 and the date hereof, neither Meadow nor any of its Subsidiaries has received any requests for, or conducted, an internal investigation of any officer, manager, or supervisor of Meadow or any of its Subsidiaries with respect to any claims with respect to discrimination, unlawful harassment, retaliation, or other similar wrongdoing. Neither Meadow nor any of its Subsidiaries is a party to any settlement agreement with a current or former officer, manager, employee, or contractor of any of them resolving allegations of sexual or other unlawful harassment, discrimination, or retaliation by any current or former officer, manager, employee, or contractor of Meadow or any of its Subsidiaries. Meadow and its Subsidiaries have promptly, thoroughly and impartially investigated all employment discrimination, sexual or other unlawful harassment, and retaliation allegations of, or against, any employee in accordance with applicable Law. With respect to each such allegation with potential merit, the applicable employer has taken prompt corrective action reasonably calculated to prevent further discrimination and harassment or retaliation, and neither Meadow nor any of its Subsidiaries reasonably expects to incur any material Liability with respect to any such allegation.

4.13. Environmental Matters. Meadow and each of its Subsidiaries are in compliance, and, to Meadow's Knowledge, since January 1, 2020 have complied with all applicable Environmental Laws, which compliance includes the possession by Meadow and its Subsidiaries of all permits and other Governmental Authorizations required under applicable Environmental Laws and compliance with the terms and conditions thereof, except for any failure to be in such compliance that, either individually or in the aggregate, would not reasonably be expected to be material to Meadow and its Subsidiaries, taken as a whole. Neither Meadow nor any of its Subsidiaries has received between January 1, 2020 and the date hereof, any written notice or other communication (in writing or otherwise), whether from a Governmental Entity or other Person, that alleges that Meadow or any of its Subsidiaries is not in compliance with or has liability pursuant to any Environmental Law, except where such failure to comply would not reasonably be expected to be material to Meadow and its Subsidiaries, taken as a whole. To Meadow's Knowledge, no current or (during the time a prior property was leased or controlled by Meadow or any of its Subsidiaries) prior property leased or controlled by Meadow or any of its Subsidiaries has had a release of or exposure to Hazardous Materials in material violation of or as would reasonably be expected to result in any material liability of Meadow or any of its Subsidiaries pursuant to Environmental Law.

4.14. Taxes.

(a) Meadow and each of its Subsidiaries have timely filed all income Tax Returns and other material Tax Returns that they were required to file under applicable Law. All such Tax Returns are correct and complete in all material respects and have been prepared in substantial compliance with all applicable Law. No written claim has ever been made prior to the date hereof by any Governmental Entity in any jurisdiction where Meadow or any of its Subsidiaries does not file a particular Tax Return or pay a particular Tax that Meadow or such Subsidiary is subject to taxation by that jurisdiction.

(b) All income Taxes and any other material Taxes due and owing by Meadow or any of its Subsidiaries on or before the date hereof (whether or not shown on any Tax Return) have been fully paid. The unpaid Taxes of Meadow and its Subsidiaries did not, as of the date of the Meadow Balance Sheet, materially exceed the reserve for Tax liability (excluding any reserve for deferred Taxes established to reflect timing differences between book and Tax items) set forth on the face of the Meadow Balance Sheet.

(c) All Taxes that Meadow or any of its Subsidiaries are or were required by Law to withhold or collect have been duly and timely withheld or collected in all material respects on behalf of its respective employees, independent contractors, stockholders, lenders, customers or other third parties and, have been timely paid to the proper Governmental Entity or other Person or properly set aside in accounts for this purpose.

(d) There are no Liens for material Taxes (other than Taxes not yet due and payable) upon any of the assets of Meadow or any of its Subsidiaries.

(e) No outstanding deficiencies for income Taxes or other material Taxes with respect to Meadow or any of its Subsidiaries have been claimed, proposed or assessed by any Governmental Entity in writing. There are no pending or ongoing, nor, to Meadow's Knowledge, threatened audits, assessments or other actions for or relating to any liability in respect of a material amount of Taxes of Meadow or any of its Subsidiaries. Neither Meadow nor any of its Subsidiaries (nor any of their predecessors) has waived any statute of limitations in respect of any income Taxes or other material Taxes or agreed to any extension of time with respect to any income Tax or other material Tax assessment or deficiency, which waiver or extension is still in effect.

(f) Neither Meadow nor any of its Subsidiaries has been a United States real property holding corporation within the meaning of Section 897(c)(2) of the Code during the applicable period specified in Section 897(c)(1)(A)(ii) of the Code.

(g) Neither Meadow nor any of its Subsidiaries is a party to any material Tax allocation agreement, Tax sharing agreement, Tax indemnity agreement, or similar agreement or arrangement, other than customary commercial contracts entered into in the Ordinary Course of Business the principal subject matter of which is not the allocation of Taxes.

(h) Neither Meadow nor any of its Subsidiaries will be required to include any material item of income in, or exclude any material item of deduction from, taxable income for any Tax period (or portion thereof) ending after the Closing Date as a result of any: (i) change in method of accounting for Tax purposes made on or prior to the Closing Date; (ii) use of an improper method of accounting for a Tax period (or portion thereof) ending on or prior to the Closing Date; (iii) "closing agreement" as described in Section 7121 of the Code (or any similar provision of state, local or foreign Law) executed on or prior to the Closing Date; (iv) installment sale or open transaction disposition made on or prior to the Closing Date; (v) prepaid amount received or deferred revenue accrued on or prior to the Closing Date; or (vi) application of Section 367(d) of the Code to any transfer of intangible property on or prior to the Closing Date. Meadow has not made any election under Section 965(h) of the Code.

(i) Neither Meadow nor any of its Subsidiaries has ever been (i) a member of a consolidated, combined or unitary Tax group (other than such a group the common parent of which is Meadow) or (ii) a party to any joint venture, partnership, or other arrangement that is treated as a partnership for U.S. federal income Tax purposes. Neither Meadow nor any of its Subsidiaries has any liability for any material Taxes of any Person (other than

## Table of Contents

Meadow and any of its Subsidiaries) under Treasury Regulations Section 1.1502-6 (or any similar provision of state, local, or foreign Law), as a transferee or successor, or otherwise.

(j) Neither Meadow nor any of its Subsidiaries (i) is a “passive foreign investment company” within the meaning of Section 1297 of the Code; or (ii) has ever had a permanent establishment (within the meaning of an applicable Tax treaty) or otherwise had an office or fixed place of business in a country other than the country in which it is organized.

(k) Neither Meadow nor any of its Subsidiaries has participated in or been a party to a transaction that, as of the date of this Agreement, constitutes a “listed transaction” that is required to be reported to the IRS pursuant to Section 6011 of the Code and applicable Treasury Regulations thereunder.

(l) Neither Meadow nor any of its Subsidiaries has taken or agreed to take any action or knows of any fact that could reasonably be expected to prevent the Merger from qualifying for the Intended Tax Treatment.

(m) Neither Meadow nor any of its Subsidiaries has availed itself of any Tax relief pursuant to any pandemic response laws (including the CARES Act) that could reasonably be expected to materially impact the Tax payment and/or Tax reporting obligations of Meadow and its Affiliates (including Iris and its Subsidiaries) after the Closing Date.

(n) For purposes of this Section 4.14, each reference to Meadow or any of its Subsidiaries shall be deemed to include any Person that was liquidated into, merged with, or is otherwise a predecessor to, Meadow of any of its Subsidiaries.

### 4.15. Intellectual Property.

(a) Section 4.15(a) of the Meadow Disclosure Schedule identifies (i) the name of the applicant/registrant, (ii) the jurisdiction of application/registration, (iii) the grant application or registration number and (iv) any other co-owners, for each item of Registered IP within the Meadow IP (the “**Meadow Registered IP**”). Each of the patents and patent applications included in the Meadow Registered IP within the Meadow Owned IP properly identifies by name each and every inventor of the inventions claimed therein as determined in accordance with applicable Laws of the United States and, to Meadow’s Knowledge, each of the patents and patent applications included in the Meadow Registered IP within the Meadow Licensed IP properly identifies by name each and every inventor of the inventions claimed therein as determined in accordance with applicable Laws of the United States. As of the date of this Agreement, no interference, opposition, reissue, reexamination or other proceeding of any nature (other than ex parte initial or continuing examination proceedings in front of a government agency) is pending or threatened in writing, in which the scope, validity, enforceability or ownership of any Meadow Owned IP within the Meadow Registered IP is being or has been contested or challenged and, to Meadow’s Knowledge, no interference, opposition, reissue, reexamination or other proceeding of any nature (other than ex parte initial or continuing examination proceedings in front of a government agency) is pending or threatened in writing, in which the scope, validity, enforceability or ownership of any Meadow Licensed IP within the Meadow Registered IP is being or has been contested or challenged. To Meadow’s Knowledge, all Meadow Registered IP is in effect, valid, subsisting and enforceable.

(b) Meadow or its Subsidiaries solely and exclusively owns or has rights to all right, title and interest in and to all material Meadow Owned IP, free and clear of all Liens other than Permitted Liens, except as would not have a Meadow Material Adverse Effect. Each Meadow Associate involved in the creation or development of any material Meadow Owned IP, pursuant to such Meadow Associate’s activities on behalf of Meadow or its Subsidiaries, has signed a valid, enforceable written agreement containing a present assignment of all such Meadow Associate’s rights in such material Meadow Owned IP to Meadow or its Subsidiaries (without further payment being owed to any such Meadow Associate and without any restrictions or obligations on Meadow’s or its Subsidiaries’ ownership or use thereof) and confidentiality provisions protecting the Meadow Owned IP, which, to Meadow’s Knowledge, has not been materially breached by such Meadow Associate.

## Table of Contents

(c) No funding, facilities or personnel of any Governmental Entity or any university, college, research institute or other educational or academic institution has been used, in whole or in part, to create any Meadow Owned IP, except for any such funding or use of facilities or personnel that does not result in such Governmental Entity or institution obtaining ownership or other rights (including any “march in” rights or a right to direct the location of manufacturing of products) to such Meadow Owned IP or the right to receive royalties or other consideration for the practice of such Meadow Owned IP.

(d) Section 4.15(d) of the Meadow Disclosure Schedule sets forth each license agreement pursuant to which Meadow or any of its Subsidiaries (i) is granted a license under any material Intellectual Property Right owned by any third party that is used by Meadow or any of its Subsidiaries in its business as currently conducted (each a “**Meadow In-bound License**”) or (ii) grants to any third party a license under any material Meadow IP or any material Intellectual Property Right licensed to Meadow or any of its Subsidiaries under a Meadow In-bound License (each a “**Meadow Out-bound License**”) (provided, that, the Meadow In-bound Licenses shall not include clinical trial agreements, services agreements, non-disclosure agreements, commercially available software-as-a-service offerings, off-the-shelf software licenses or generally available patent license agreements entered into in the Ordinary Course of Business on a non-exclusive basis; and the Meadow Out-bound Licenses shall not include clinical trial agreements, services agreements, non-disclosure agreements, or non-exclusive outbound licenses entered into in the Ordinary Course of Business on a non-exclusive basis and that do not grant any commercial rights to any products or services of Meadow or any of its Subsidiaries).

(e) To Meadow’s Knowledge, the Meadow Products and the operation of the businesses of Meadow and its Subsidiaries as currently conducted do not infringe any valid and enforceable patent of an Intellectual Property Right of any other Person, that is not licensed to Meadow or any of its Subsidiaries under a Meadow In-bound License, or misappropriate or otherwise violate any other Intellectual Property Right owned by any other Person, and no other Person is infringing, misappropriating or otherwise violating any Meadow IP or any material Intellectual Property Rights exclusively licensed to Meadow or any of its Subsidiaries (“**Meadow In-Licensed IP**”). As of the date of this Agreement, no Legal Proceeding is pending (or is threatened in writing) (A) against Meadow or any of its Subsidiaries alleging that the operation of the businesses of Meadow or its Subsidiaries infringes or constitutes the misappropriation or other violation of any Intellectual Property Rights of another Person or (B) by Meadow or any of its Subsidiaries alleging that another Person has infringed, misappropriated or otherwise violated any of the Meadow IP or any Meadow In-Licensed IP. Between January 1, 2020 and the date hereof, neither Meadow nor any of its Subsidiaries has received any written notice or other written communication alleging that the operation of the businesses of Meadow or any of its Subsidiaries infringes or constitutes the misappropriation or other violation of any Intellectual Property Right of another Person.

(f) None of the Meadow IP or, to Meadow’s Knowledge, any Meadow In-Licensed IP is subject to any pending or outstanding injunction, directive, order, judgment or other disposition of dispute that adversely and materially restricts the use, transfer, registration or licensing by Meadow or any of its Subsidiaries of any such Meadow IP or Meadow In-Licensed IP.

(g) None of Meadow or its Subsidiaries is now or has ever been a member or promoter of, or a contributor to, any industry standards body or any similar organization that would reasonably be expected to require or obligate Meadow or any of its Subsidiaries to grant or offer to any other Person any license or right to any Meadow IP.

(h) The operation of Meadow’s and its Subsidiaries’ business are in substantial compliance with all applicable Laws pertaining to data privacy and data security of any personally identifiable information and sensitive business information (collectively, “**Meadow Sensitive Data**”), except to the extent that such noncompliance has not and would not have a Meadow Material Adverse Effect. Since January 1, 2020, there have been (i) no material losses or thefts of data or security breaches relating to Meadow Sensitive Data used in the business of Meadow or its Subsidiaries, (ii) no violations of any security policy of Meadow or its Subsidiaries

## Table of Contents

regarding any such Meadow Sensitive Data, (iii) no unauthorized access or unauthorized use of any Meadow Sensitive Data used in the business of Meadow or its Subsidiaries and (iv) no unintended or improper disclosure of any personally identifiable information in the possession, custody or control of Meadow or its Subsidiaries or a contractor or agent acting on behalf of Meadow or its Subsidiaries, in each case of (i) through (iv), except as would not have a Meadow Material Adverse Effect.

(i) Each of Meadow and its Subsidiaries has complied, and continues to comply, with the Data Protection Legislation, including with the principles relating to processing Personal Data under Article 5 of the GDPR, with requirements to process Personal Data lawfully under Articles 6 and 9 of the GDPR, to provide processing information regarding the processing of Personal Data under Articles 13 and 14 of the GDPR, to engage data processors under Article 28 of the GDPR, to maintain a record of processing activities under Article 30 of the GDPR, to protect Personal Data under Article 32 of the GDPR, to notify supervisory authorities or data subjects under Articles 33 and 34 of the GDPR, to conduct data protection impact assessments under Articles 35 and 36 of the GDPR, to transfer Personal Data under Chapter V of the GDPR, except, in each case, as would not have a Meadow Material Adverse Effect.

(j) Each of Meadow and its Subsidiaries has implemented, and regularly assessed its implementation of, appropriate technical and organisational measures necessary to ensure that Personal Data is protected against loss, destruction and damage, unauthorised access, use, modification, disclosure or other misuse, except as would not have a Meadow Material Adverse Effect.

(k) (i) None of Meadow or its Subsidiaries transfers Personal Data outside of the European Economic Area and/or United Kingdom unless Iris or such Subsidiary, as applicable, has ensured that the recipient has adequate safeguards to protect such Personal Data including, but not solely depending on, the execution of standard contractual clauses in the form approved by the European Commission from time to time or equivalent data transfer agreements or arrangements (including binding corporate rules) in compliance with applicable provisions of Data Protection Legislation; (ii) where any transfers of Personal Data formerly relied-upon the EU-US or Swiss-US Privacy Shield framework, Meadow or such Subsidiary, as applicable, has ensured that the Personal Data transfers are lawful through an alternative mechanism or derogation in accordance with the GDPR; (iii) where reasonably required, Meadow or such Subsidiary, as applicable, has conducted a risk assessment regarding the transfer of Personal Data pursuant to standard contractual clauses or binding corporate rules and has concluded that such transfers are adequately protected; and (iv) none of Meadow or its Subsidiaries has suspended or terminated a transfer of Personal Data or notified a supervisory authority of any concerns regarding a transfer of Personal Data pursuant to standard contractual clauses or binding corporate rules and nor are there circumstances which reasonably justify such a notification, except, in each case of clauses (i), (ii), (iii) and (iv), as would not have a Meadow Material Adverse Effect.

(l) Between January 1, 2020 and the date hereof, none of Meadow or its Subsidiaries has become aware of a Personal Data Breach affecting the processing of Personal Data (whether by Meadow or any of its Subsidiaries or any data processor engaged directly or indirectly to process Personal Data).

(m) Between January 1, 2020 and the date hereof, none of Meadow or its Subsidiaries has received a written notice or allegation, or is aware, of any actual or alleged or threatened unlawful access, loss, destruction, restriction, anonymization and/or deletion of Personal Data or other incident prejudicing or revealing a material weakness in, the security of the Personal Data or any other breach of the Data Protection Legislation relating to Personal Data while in its possession or under its control.

(n) Between January 1, 2020 and the date hereof, none of Meadow or its Subsidiaries has received a written claim, complaint, allegation or other notice of a concern (whether directly or indirectly) from or on behalf of a Data Subject regarding its Personal Data processing activities.

(o) Between January 1, 2020 and the date hereof, none of Meadow or its Subsidiaries has received a written notice from any supervisory authority of any investigation, enquiry, request for information and/or for co-operation regarding its Personal Data processing activities.



4.16. Regulatory Matters.

(a) Meadow and each of its Subsidiaries are, and since January 1, 2020 have been, in compliance in all respects with all applicable Laws, including the FDCA and any other similar Laws administered or promulgated by the FDA or other comparable Governmental Entity, except for any noncompliance which would not have a Meadow Material Adverse Effect. Without limiting the foregoing, all Meadow Products have been manufactured, packaged, labeled, tested, stored, shipped, handled, warehoused, and distributed in accordance with all applicable Laws and Meadow Permits (as defined below), commensurate with the Meadow Products' stage of development, and are not and have not been adulterated, misbranded, or prohibited from introduction into interstate commerce under applicable Law. To Meadow's Knowledge, as of the date hereof, no investigation, inspection, claim, suit, proceeding, audit or other action by any Governmental Entity is pending or threatened against Meadow or any of its Subsidiaries.

(b) There is no agreement, judgment, injunction, order or decree binding upon Meadow or any of its Subsidiaries which (i) has or would reasonably be expected to have the effect of prohibiting or materially impairing any material business practice of Meadow or any of its Subsidiaries, any acquisition of material property by Meadow or any of its Subsidiaries or the conduct of any material portion of the business by Meadow or any of its Subsidiaries as currently conducted, (ii) is reasonably likely to have a material adverse effect on Meadow's ability to comply with or perform any covenant or obligation under this Agreement, or (iii) is reasonably likely to have the effect of preventing, materially delaying, making illegal or otherwise materially interfering with the Contemplated Transactions.

(c) Meadow and its Subsidiaries have at all times since January 1, 2020 held and have operated in compliance with all Governmental Authorizations that are necessary for the conduct of the business of Meadow and its Subsidiaries as currently being conducted (the "**Meadow Permits**"), except where such failures to hold or remain so in compliance would not have a Meadow Material Adverse Effect. All such Meadow Permits are valid and are in full force and effect, and assuming the notices, filings or other Consents listed on Section 4.16(c) of the Meadow Disclosure Schedule have been made or obtained, will continue to be so upon consummation of the Contemplated Transactions, except as would not have a Meadow Material Adverse Effect.

(d) Section 4.16(d) of the Meadow Disclosure Schedule identifies each Meadow Permit. Meadow and its Subsidiaries hold all right, title and interest in and to all the Meadow Permits free and clear of any Lien. All fees and charges with respect to such Meadow Permits, as of the date hereof, have been paid in full and all filing, reporting and maintenance obligations have been completely and timely satisfied, except as would not have a Meadow Material Adverse Effect. Meadow and each of its Subsidiaries are in material compliance with the terms of the Meadow Permits. To Meadow's Knowledge, as of the date hereof no Legal Proceeding is pending or threatened, which seeks to revoke, limit, suspend, or materially modify any Meadow Permit.

(e) To Meadow's Knowledge, as of the date hereof there are no proceedings pending or threatened with respect to an alleged material violation by Meadow or any of its Subsidiaries of the FDCA or any other similar Law administered or promulgated by any comparable Governmental Entity. As of the date hereof, neither Meadow, any of its Subsidiaries nor to Meadow's Knowledge, any Person providing services to Meadow or any of its Subsidiaries with respect to Meadow's product candidates zandelisib, voruciclib or ME-344 and currently contemplated uses (the "**Meadow Products**") has received any written notice, including any warning letter, untitled letter, cyber letter, FDA Form-483, Establishment Inspection Report, written notice of other adverse finding, notice of integrity review, notice of investigation, request for corrective or remedial action, or notice of deficiency or violation, or similar written communication from the FDA or any other Governmental Entity alleging that Meadow or its Subsidiaries, their respective operations, or the Meadow Products are in material violation of any applicable Law or Meadow Permits.

(f) No Meadow Product has been or has been requested by a Governmental Authority or other Person to be recalled, withdrawn, removed, suspended, seized, the subject of a corrective action, or discontinued



## Table of Contents

(whether voluntarily or otherwise). Neither Meadow, nor, to Meadow's Knowledge, any Governmental Authority or other Person, has sought, is seeking, or, to Meadow's Knowledge, has or is currently threatening or contemplating any Recall of a Meadow Product.

(g) As required under applicable Law or pursuant to a Governmental Authorization, Meadow and its Subsidiaries have maintained, filed, or furnished to the applicable Governmental Entities or Person all filings, documents, claims, reports, notices, and other submissions (the "**Meadow Reports**"), required to be maintained, filed, or furnished on a timely basis, and, at the time of maintenance, filing, or furnishing all such Meadow Reports were complete and accurate when submitted, or were subsequently updated, changed, corrected, or modified, except where the failures to so maintain, file, furnish, update, change, correct or modify would not have a Meadow Material Adverse Effect.

(h) Neither Meadow, its Subsidiaries, nor to Meadow's Knowledge, any Person providing services to Meadow or its Subsidiaries has made an untrue statement of a material fact or fraudulent statement to the FDA or a Governmental Entity, failed to disclose a material fact required to be disclosed to the FDA or a Governmental Entity, or made a statement, or failed to make a statement that, would reasonably be expected to provide a basis for the FDA to invoke the FDA Ethics Policy. Neither Meadow, its Subsidiaries, nor to Meadow's Knowledge, any Person providing services to Meadow or its Subsidiaries has ever been investigated by the FDA or other Governmental Entity for data or healthcare program fraud. Neither Meadow, its Subsidiaries, nor to Meadow's Knowledge, any Person providing services to Meadow or its Subsidiaries is the subject of any pending or, to Meadow's Knowledge, threatened investigation pursuant to the FDA Ethics Policy, or resulting from any other untrue or false statement or omission.

(i) As of the date hereof, neither Meadow, its Subsidiaries, nor any Person providing services to Meadow or its Subsidiaries, nor their respective officers, directors, partners, employees, or agents have been:

(i) debarred or suspended pursuant to 21 U.S.C. § 335a;

(ii) excluded under 42 U.S.C. § 1320a-7 or any similar law, rule or regulation of any Governmental Entity;

(iii) excluded, debarred, suspended or deemed ineligible to participate in federal procurement and non-procurement programs, including those produced by the U.S. General Services Administration;

(iv) charged, named in a complaint, convicted, or otherwise found liable in any Legal Proceeding that falls within the ambit of 21 U.S.C. § 331, 21 U.S.C. § 333, 21 U.S.C. § 334, 21 U.S.C. § 335a, 21 U.S.C. § 335b, 42 U.S.C. § 1320a—7, 31 U.S.C. §§ 3729 – 3733, 42 U.S.C. § 1320a-7a, or any other applicable Law;

(v) disqualified or deemed ineligible pursuant to 21 C.F.R. Parts 312, 511, or 812, or otherwise restricted, in whole or in part, or subject to an assurance; or

(vi) had a pending Legal Proceeding, or otherwise received any written notice from any Governmental Entity or any Person threatening, investigating, or pursuing (i)-(v) above.

(j) Meadow has not been restrained by a Governmental Authority nor other Person in its ability to conduct or have conducted the manufacturing, operation, storage, import, export, distribution, warehousing, packaging, labeling, handling, shipping, and/or nonclinical, clinical, or other testing of the Meadow Products.

(k) All clinical, pre-clinical and other studies and tests conducted by or on behalf of, or sponsored by, Meadow or any of its Subsidiaries, or in which Meadow or any of its Subsidiaries or the Meadow Products have participated, were and, if still pending, are being conducted in compliance in all material respects with all applicable Laws and regulations enforced by the FDA or any comparable Governmental Entity, including, to the extent applicable, 21 C.F.R. Parts 50, 54, 56, 58, 312 and 812. The study reports, protocols, and statistical

## Table of Contents

analysis plans for all such studies and tests accurately, completely, and fairly reflect the results from such studies and tests. Meadow has not received written notice of any complaints, information, or adverse drug experience reports related to a Meadow Product that would have a Meadow Material Adverse Effect.

(l) As of the date hereof, neither Meadow, its Subsidiaries, nor to Meadow's Knowledge, any Person providing services to Meadow or its Subsidiaries has received any written notice, correspondence, or other written communications from the FDA, any other Governmental Entity, any IRB or other Person or board, such as, but not limited to, a data safety monitoring board, responsible for the oversight of the conduct of any study conducted by or on behalf of, or sponsored by, Meadow or any of its Subsidiaries, or in which Meadow or any of the Meadow Products are participating, requiring or threatening the termination, hold, material adverse modification or suspension of any clinical study that is being or is proposed to be conducted. All clinical studies conducted or sponsored by or on behalf of Meadow or its Subsidiaries were and, if still pending, are being conducted in all material respects in accordance with all applicable Laws, the protocols, procedures and controls designed and approved for such studies, and in accordance with any requirement of an IRB or other Person or board responsible for review or oversight of such studies.

### 4.17. Insurance; Real Estate.

(a) Meadow has made available to Iris accurate and complete copies of all material insurance policies and all material self-insurance programs and arrangements relating to the business, assets, liabilities and operations of Meadow and each of its Subsidiaries in effect on the date hereof. Each of such insurance policies is in full force and effect and Meadow and each of its Subsidiaries are in compliance in all material respects with the terms thereof. Other than customary end of policy notifications from insurance carriers, between January 1, 2020 and the date hereof, neither Meadow nor any of its Subsidiaries has received any written notice or other written communication regarding any actual or possible: (i) cancellation or invalidation of any insurance policy; or (ii) refusal or denial of any coverage, reservation of rights or rejection of any material claim under any insurance policy. Meadow and each of its Subsidiaries have provided timely written notice to the appropriate insurance carrier(s) of each Legal Proceeding that is currently pending against Meadow or any of its Subsidiaries for which Meadow or such Subsidiary has insurance coverage, and no such carrier has issued a denial of coverage or a reservation of rights with respect to any such Legal Proceeding or informed Meadow or any of its Subsidiaries of its intent to do so.

(b) Neither Meadow nor any of its Subsidiaries owns, or has ever owned, any real property. Section 4.17(b) of the Meadow Disclosure Schedule sets forth a true and complete list of all real properties with respect to which Meadow or any of its Subsidiaries directly or indirectly holds a valid leasehold interest as well as any other real estate that is in the possession of or leased by Meadow or any of its Subsidiaries (the "**Meadow Leased Real Property**"), and a true and complete list of all leases under which any such real property is leased or possessed (the "**Meadow Real Estate Leases**"), each of which is in full force and effect, with no existing material default by Meadow thereunder. Meadow's or its applicable Subsidiary's use and operation of each such Meadow Leased Real Property conforms to all applicable Laws in all material respects, and Meadow or its applicable Subsidiary has exclusive possession of each such Meadow Leased Real Property and has not granted any occupancy rights to tenants or licensees with respect to such Meadow Leased Real Property. Neither Meadow nor any of its Subsidiaries has assigned, transferred or pledged any interest in any of the Meadow Real Estate Leases. In addition, each of Meadow and its applicable Subsidiary has a valid leasehold interest in (or a valid right to use and occupy) the Meadow Leased Real Property, free and clear of all Liens other than Permitted Liens. To Meadow's Knowledge, neither the whole nor any part of the Meadow Leased Real Property is subject to any pending suit for condemnation or other taking by any Governmental Entity, and no such condemnation or other taking is threatened or contemplated. The Meadow Leased Real Property comprises all of the real property used in, and is necessary for, the operation of the business of Meadow and its Subsidiaries as currently conducted. All structures and buildings on the Meadow Leased Real Property are adequately maintained and are in good operating condition and repair for the requirements of the business of the Meadow and its Subsidiaries as currently conducted.

## Table of Contents

4.18. Registration Statement and Joint Proxy Statement/Prospectus. None of the information supplied or to be supplied by Meadow in writing for inclusion or incorporation by reference in (a) the Registration Statement will, at the time the Registration Statement or any amendment or supplement thereto is declared effective under the Securities Act, contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein not misleading in any material respect or (b) the Joint Proxy Statement/Prospectus will, at the date it is first mailed to each of Meadow's stockholders and Iris's stockholders or at the time of the Meadow Stockholders Meeting, contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they are made, not misleading in any material respect. The Joint Proxy Statement/Prospectus will comply as to form in all material respects with the requirements of the Exchange Act and the rules and regulations thereunder, except that no representation is made by Meadow with respect to statements made or incorporated by reference therein based on information supplied Iris for inclusion or incorporation by reference therein.

4.19. Transactions with Affiliates. Since October 27, 2022, no event has occurred as of the date hereof that would be required to be reported by Meadow pursuant to Item 404 of Regulation S-K as promulgated under the Securities Act.

4.20. Brokers and Finders. Except for Torrey Partners, no broker, finder or investment banker is entitled to any brokerage fee, finder's fee, opinion fee, success fee, transaction fee or other fee or commission in connection with the Contemplated Transactions based upon arrangements made by or on behalf of Meadow or any of its Subsidiaries, including Merger Sub.

4.21. Opinion of Financial Advisor. As of the date of this Agreement, the Meadow Board has received the opinion, that will subsequently be provided in writing, of Torrey Partners that, as of the date of such opinion and based upon and subject to the various qualifications, assumptions, limitations and other matters set forth therein, the Exchange Ratio is fair, from a financial point of view, to Meadow. Meadow shall, promptly following the execution of this Agreement by all Parties, furnish a copy of each such written opinion to Iris solely for informational purposes (it being agreed that none of Iris, nor any of its Affiliates or Representatives, shall have the right to rely on such opinion).

4.22. Anti-Bribery. None of Meadow, any of its Subsidiaries or any of their respective directors, officers, employees or, to Meadow's Knowledge, agents or any other Person acting on their behalf has directly or indirectly made any bribes, rebates, payoffs, influence payments, kickbacks, illegal payments, illegal political contributions, or other payments, in the form of cash, gifts, or otherwise, or taken any other action or made or failed to make any other statement, in violation of Anti-Bribery Laws except, in each case, as would not be material to Meadow's business or operations. Neither Meadow nor any of its Subsidiaries nor any of their respective officers, employees or agents is or has been, in any capacity relating to Meadow or such Subsidiary, the subject of any debarment or exclusionary claims, actions, proceedings, or, to Meadow's Knowledge, investigation by any Governmental Entity with respect to potential violations of Anti-Bribery Laws except, in each case, as would not be material to Meadow's business or operations. None of Meadow, any of its Subsidiaries or any of their respective officers, employees or, to Meadow's Knowledge, agents is or has been subject to mandatory or permissive debarment for any basis specified at 21 U.S.C. 335a, and none of Meadow, any of its Subsidiaries or any of their respective principals (as defined at 48 C.F.R. 52.209-5(a)(2)) would be required to certify affirmatively to any element of the certification at 48 C.F.R. 52.209-5.

4.23. Ownership and Operations of Merger Sub. Meadow, directly or indirectly, owns beneficially all of the outstanding shares of common stock of Merger Sub. Merger Sub was formed solely for the purpose of engaging in the Merger, has engaged in no other business activities, and has incurred no liabilities or obligations other than as contemplated hereby or as otherwise required or incidental to negotiate, execute, deliver and effect the Contemplated Transactions. The authorized shares of common stock of Merger Sub consist of 1,000 shares, all of which are validly issued and outstanding. All of the issued and outstanding shares of Merger Sub are directly

## Table of Contents

owned by Meadow, free and clear of any Liens other than Liens imposed under any federal or state securities Laws.

4.24. Ownership of Iris Common Stock. Since January 1, 2020, neither Meadow nor any of its Subsidiaries has “owned” (as such term is defined in Section 203(c) of the DGCL), directly or indirectly, any shares of Iris Common Stock or other securities convertible into, exchangeable into or exercisable for shares of Iris Common Stock. There are no voting trusts or other agreements or understandings to which Meadow or any its Subsidiaries is a party with respect to the voting of the capital stock or other equity interest of Iris or any of its Subsidiaries.

## ARTICLE V COVENANTS

### 5.1. Interim Operations.

(a) Conduct of Business by Iris. Except (i) for matters set forth in Section 5.1(a) of the Iris Disclosure Schedule, (ii) as expressly permitted by or required in accordance this Agreement, (iii) as required by applicable Law, (iv) in connection with the COVID-19 pandemic, to the extent reasonably necessary, (A) to protect the health and safety of Iris’s or any of its Subsidiaries’ employees, (B) to respond to third party supply or service disruptions caused by the COVID-19 pandemic or (C) as required by any applicable Law, directive or guideline from any Governmental Entity arising out of, or otherwise related to, the COVID-19 pandemic (including any response to COVID-19) (collectively, “**COVID-19 Measures and Responses**”), or (v) as may be consented to in writing by Meadow (which consent shall not be unreasonably withheld, delayed or conditioned), from the date of this Agreement to the Effective Time, or, if earlier, the termination of this Agreement in accordance with its terms (such time, the “**Pre-Closing Period**”), Iris shall, and shall cause each of its Subsidiaries to, use commercially reasonable efforts to conduct its business in the Ordinary Course of Business. In addition, and without limiting the generality of the foregoing, except for matters set forth in the Iris Disclosure Schedule or otherwise expressly permitted or expressly contemplated by this Agreement or required by applicable Law or with the prior written consent of Meadow (which shall not be unreasonably withheld, conditioned or delayed), during the Pre-Closing Period, Iris shall not, and shall not permit any of its Subsidiaries to, do any of the following (provided that no such consent of Meadow shall be required to the extent Iris reasonably believes, based on its outside counsel’s advice, that obtaining such consent constitutes a violation of any applicable Laws):

(i) declare, accrue, set aside or pay any dividend or make any other distribution in respect of any shares of its capital stock or repurchase, redeem or otherwise reacquire any shares of its capital stock or other securities (except repurchases from terminated employees, directors or consultants of Iris or in connection with the payment of the exercise price and/or withholding Taxes incurred upon the exercise, settlement or vesting of any award or purchase rights granted under the Iris Stock Incentive Plans or Iris Inducement Grants in accordance with the terms of such award in effect on the date of this Agreement);

(ii) sell, issue, grant, modify, reprice, pledge or otherwise dispose of or encumber or authorize: (A) any capital stock or other security of Iris or any of its Subsidiaries (except for shares of Iris Common Stock issued upon the valid exercise or conversion of outstanding Iris Options, ESPP Options or settlement of Iris RSUs); (B) any option, warrant or right to acquire any capital stock or any other security; or (C) any instrument convertible into or exchangeable for any capital stock or other security of Iris or any of its Subsidiaries;

(iii) except as required to give effect to anything in contemplation of the Closing, amend any of Iris’s or its Subsidiaries’ Organizational Documents, or effect or be a party to any merger, consolidation, share exchange, business combination, recapitalization, reclassification of shares, stock split, reverse stock split or similar transaction except for the Contemplated Transactions;

(iv) form any Subsidiary or acquire any equity interest or other interest in any other entity or enter into a joint venture with any other entity;

## [Table of Contents](#)

(v) (A) lend money to any Person (except for the advancement of expenses to employees, directors and consultants in the Ordinary Course of Business), (B) incur or guarantee any indebtedness for borrowed money, (C) guarantee any debt securities of others, or (D) other than the incurrence or payment of Transaction Expenses, make any capital expenditure in excess of 110% of the budgeted capital expenditure amounts set forth in Iris's operating budget delivered to Meadow concurrently with the execution of this Agreement (the "**Iris Budget**");

(vi) other than as required by applicable Law or the terms of any Iris Benefit Plan as in effect on the date of this Agreement: (A) adopt, terminate, establish or enter into any Iris Benefit Plan, other than in the Ordinary Course of Business; (B) cause or permit any Iris Benefit Plan to be amended in any material respect, other than in the Ordinary Course of Business, other than discretionary accelerated vesting of some or all of the Iris RSUs to facilitate pre-Closing tax withholding; (C) increase or modify the amount or form of the wages, salary, commissions, or bonus compensation payable to any of its directors, officers or employees, including for the avoidance of doubt, the 2022 annual bonuses paid pursuant to the Iris Contingent Cash Compensation program, other than increases in base salary and annual cash bonus opportunities and payments made in the Ordinary Course of Business or (D) hire any officer or employee (other than ordinary course replacement of departed employees or officers in the positions set forth on Section 5.1(a)(vi) of the Iris Disclosure Schedule during the Pre-Closing Period);

(vii) recognize any labor union or labor organization, except as otherwise required by applicable Law;

(viii) acquire any material asset or sell, lease or otherwise irrevocably dispose of any of its material assets or properties, or grant any Lien with respect to such assets or properties, except in the Ordinary Course of Business;

(ix) sell, assign, transfer, license, sublicense or otherwise dispose of any material Iris IP (other than pursuant to non-exclusive licenses in the Ordinary Course of Business);

(x) make, change or revoke any material Tax election, fail to pay any income Tax or other material Tax as such Tax becomes due and payable, file any amendment making any material change to any Tax Return, settle or compromise any income Tax or other material Tax liability or submit any voluntary disclosure application, enter into any Tax allocation, sharing, indemnification or other similar agreement or arrangement (other than customary commercial contracts entered into in the Ordinary Course of Business the principal subject matter of which is not the allocation of Taxes), request or consent to any extension or waiver of any limitation period with respect to any claim or assessment for any income Tax or other material Taxes (other than pursuant to an extension of time to file any Tax Return granted in the Ordinary Course of Business of not more than seven months), or adopt or change any material accounting method in respect of Taxes;

(xi) enter into, materially amend or terminate any Iris Material Contract, or enter into any Contract that would be considered an Iris Material Contract if in effect on the date hereof;

(xii) other than as required by Law or GAAP, take any action to change accounting policies or procedures;

(xiii) initiate or settle any Legal Proceeding;

(xiv) enter into or amend any Contract for the purpose of preventing or materially impeding, interfering with, hindering or delaying the consummation of the Contemplated Transactions; or

(xv) agree, resolve or commit to do any of the foregoing.

## Table of Contents

(b) Conduct of Business by Meadow. Except (i) for matters set forth in Section 5.1(b) of the Meadow Disclosure Schedule, (ii) as expressly permitted by or required in accordance this Agreement, (iii) as required by applicable Law, (iv) for COVID-19 Measures and Responses, or (v) as may be consented to in writing by Iris (which consent shall not be unreasonably withheld, delayed or conditioned), during the Pre-Closing Period, Meadow shall, and shall cause each of its Subsidiaries to, use commercially reasonable efforts to conduct its business in the Ordinary Course of Business. In addition, and without limiting the generality of the foregoing, except for matters set forth in the Meadow Disclosure Schedule or otherwise expressly permitted or expressly contemplated by this Agreement or required by applicable Law or with the prior written consent of Iris (which shall not be unreasonably withheld, conditioned or delayed), during the Pre-Closing Period, Meadow shall not, and shall not permit any of its Subsidiaries to, do any of the following (provided that no such consent of Iris shall be required to the extent Meadow reasonably believes, based on its outside counsel's advice, that obtaining such consent constitutes a violation of any applicable Laws):

(i) declare, accrue, set aside or pay any dividend or make any other distribution in respect of any shares of its capital stock or repurchase, redeem or otherwise reacquire any shares of its capital stock or other securities (except repurchases from terminated employees, directors or consultants of Meadow or in connection with the payment of the exercise price and/or withholding Taxes incurred upon the exercise, settlement or vesting of any award or purchase rights granted under the Meadow Stock Plans in accordance with the terms of such award in effect on the date of this Agreement);

(ii) sell, issue, grant, modify, reprice, pledge or otherwise dispose of or encumber or authorize: (A) any capital stock or other security of Meadow, any of its Subsidiaries or Merger Sub (except for shares of Meadow Common Stock issued upon the valid exercise or conversion of outstanding Meadow Options or Meadow Warrants); (B) any option, warrant or right to acquire any capital stock or any other security; or (C) any instrument convertible into or exchangeable for any capital stock or other security of Meadow, any of its Subsidiaries or Merger Sub;

(iii) except as required to give effect to anything in contemplation of the Closing, amend any of Meadow's or its Subsidiaries' Organizational Documents, or effect or be a party to any merger, consolidation, share exchange, business combination, recapitalization, reclassification of shares, stock split, reverse stock split or similar transaction except for the Contemplated Transactions;

(iv) other than Merger Sub, form any Subsidiary or acquire any equity interest or other interest in any other entity or enter into a joint venture with any other entity;

(v) (A) lend money to any Person (except for the advancement of expenses to employees, directors and consultants in the Ordinary Course of Business), (B) incur or guarantee any indebtedness for borrowed money, (C) guarantee any debt securities of others, or (D) other than the incurrence or payment of Transaction Expenses, make any capital expenditure in excess of 110% of the budgeted capital expenditure amounts set forth in Meadow's operating budget delivered to Iris concurrently with the execution of this Agreement (the "**Meadow Budget**");

(vi) other than as required by applicable Law or the terms of any Meadow Benefit Plan as in effect on the date of this Agreement: (A) adopt, terminate, establish or enter into any Meadow Benefit Plan, other than in the Ordinary Course of Business; (B) cause or permit any Meadow Benefit Plan to be amended in any material respect, other than in the Ordinary Course of Business; (C) increase or modify the amount or form of the wages, salary, commissions, or bonus compensation payable to any of its directors, officers or employees, other than increases in base salary and annual cash bonus opportunities and payments made in the Ordinary Course of Business or (D) hire any officer or employee (other than ordinary course replacement of departed employees or officers in the positions set forth on Section 5.1(b)(vi) of the Meadow Disclosure Schedule during the Pre-Closing Period);

## Table of Contents

(vii) recognize any labor union or labor organization, except as otherwise required by applicable Law;

(viii) acquire any material asset or sell, lease or otherwise irrevocably dispose of any of its material assets or properties, or grant any Lien with respect to such assets or properties, except in the Ordinary Course of Business;

(ix) sell, assign, transfer, license, sublicense or otherwise dispose of any material Intellectual Property Rights that are owned or purported to be owned by Meadow or its Subsidiaries, or exclusively licensed or purported to be exclusively licensed to Meadow or its Subsidiaries;

(x) make, change or revoke any material Tax election, fail to pay any income Tax or other material Tax as such Tax becomes due and payable, file any amendment making any material change to any Tax Return, settle or compromise any income Tax or other material Tax liability or submit any voluntary disclosure application, enter into any Tax allocation, sharing, indemnification or other similar agreement or arrangement (other than customary commercial contracts entered into in the Ordinary Course of Business the principal subject matter of which is not the allocation of Taxes), request or consent to any extension or waiver of any limitation period with respect to any claim or assessment for any income Tax or other material Taxes (other than pursuant to an extension of time to file any Tax Return granted in the Ordinary Course of Business of not more than seven months), or adopt or change any material accounting method in respect of Taxes;

(xi) enter into, materially amend or terminate any Meadow Material Contract, or enter into any Contract that would be considered a Meadow Material Contract if in effect on the date hereof;

(xii) other than as required by Law or GAAP, take any action to change accounting policies or procedures;

(xiii) initiate or settle any Legal Proceeding;

(xiv) enter into or amend any Contract for the purpose of preventing or materially impeding, interfering with, hindering or delaying the consummation of the Contemplated Transactions; or

(xv) agree, resolve or commit to do any of the foregoing.

(c) Notice of Material Events. During the Pre-Closing Period, each Party shall promptly notify the other Party in writing upon becoming aware of any event, condition, fact or circumstance that would reasonably be expected to make the satisfaction of any of the conditions set forth in Article VI impossible or unlikely. Without limiting the generality of the foregoing, a Party shall promptly advise the other Party in writing upon becoming aware of (i) any claim asserted or Legal Proceeding commenced, or, to the Party's knowledge, either: (A) with respect to a Governmental Entity, overtly threatened; or (B) with respect to any other Person, threatened in writing, in each case against, relating to, involving or otherwise affecting any of the Contemplated Transactions; (ii) any knowledge of any notice from any Person alleging that the consent of such Person is or may be required in connection with the Merger or any of the other Contemplated Transactions; and (iii) any other material Legal Proceeding or material claim threatened, commenced or asserted against or with respect to any Party or its respective Subsidiaries. No notification given pursuant to this Section 5.1(c) shall limit or otherwise affect any of the representations, warranties, covenants or obligations of such Party contained in this Agreement.

(d) All notices, requests, instructions, communications or other documents to be given in connection with any consultation or approval required pursuant to this Section 5.1 shall be in writing and shall be deemed given as provided for in Section 8.7, and, in each case, shall be addressed to such individuals as the Parties shall designate in writing from time to time.



5.2. Iris Acquisition Proposals; Iris Change in Recommendation.

(a) No Solicitation or Negotiation. During the Pre-Closing Period, except as expressly permitted by this Section 5.2, Iris shall not, and Iris shall cause its and its Subsidiaries' directors, officers and employees not to, and shall cause its and their respective investment bankers, attorneys, accountants and other advisors, agents or representatives (collectively, along with such directors, officers and employees, "**Representatives**") not to, directly or indirectly:

- (i) solicit, initiate, induce, encourage or facilitate (including by way of granting a waiver under Section 203 of the DGCL), any inquiries or the making of any proposal or offer that constitutes, or could reasonably be expected to lead to, an Iris Acquisition Proposal;
- (ii) participate in any discussions or negotiations or cooperate in any way with any Person regarding any Iris Acquisition Proposal or any inquiry, proposal or offer that could reasonably be expected to lead to an Iris Acquisition Proposal;
- (iii) provide any non-public information or data concerning Iris or any of its Subsidiaries to any Person in connection with any Iris Acquisition Proposal or any inquiry, proposal or offer that could reasonably be expected to lead to an Iris Acquisition Proposal or for the purpose of soliciting, initiating, inducing, encouraging or facilitating an Iris Acquisition Proposal;
- (iv) enter into any binding or nonbinding letter of intent, term sheet, memorandum of understanding, merger agreement, acquisition agreement, agreement in principle, option agreement, joint venture agreement, partnership agreement, lease agreement or other similar agreement with respect to an Iris Acquisition Proposal;
- (v) adopt, approve or recommend or make any public statement approving or recommending any inquiry, proposal or offer that constitutes, or could reasonably be expected to lead to, an Iris Acquisition Proposal (including by approving any transaction, or approving any Person becoming an "interested stockholder," for purposes of Section 203 of the DGCL);
- (vi) take any action or exempt any Person (other than Meadow and its Subsidiaries) from the restriction on "business combinations" or any similar provision contained in applicable takeover laws or Iris's organizational or other governing documents; or
- (vii) publicly propose, resolve or agree to do any of the foregoing.

Iris shall, and shall cause its Subsidiaries and Representatives to, immediately cease and cause to be terminated any solicitation, encouragement, discussions and negotiations with any Person conducted heretofore with respect to any Iris Acquisition Proposal, or inquiry, proposal or offer that could reasonably be expected to lead to an Iris Acquisition Proposal and shall promptly terminate access by any such Person to any physical or electronic data rooms relating to any such Iris Acquisition Proposal. As soon as reasonably practicable after the date of this Agreement, Iris shall deliver a written notice to each Person that entered into a confidentiality agreement in anticipation of potentially making an Iris Acquisition Proposal within the last 12 months, to the effect that Iris is ending all discussions and negotiations with such Person with respect to any such Iris Acquisition Proposal effective as of the date hereof and requesting the prompt return or destruction of all confidential information previously furnished to such Person. Iris shall take all actions necessary to enforce its rights under the provisions of any "standstill" agreement between Iris and any Person (other than Meadow), and shall not grant any waiver of, or agree to any amendment or modification to, any such agreement, to permit such Person to submit an Iris Acquisition Proposal, unless in any such case the Iris Board shall have determined, in good faith, after consultation with outside legal counsel, that such actions would reasonably be expected to be inconsistent with the directors' fiduciary duties under applicable Law.

(b) Fiduciary Exception to No Solicitation Provision. Notwithstanding anything to the contrary in Section 5.2(a), prior to the time, but not after, the Iris Stockholder Approval is obtained, Iris may, in response to



## Table of Contents

an unsolicited, bona fide written Iris Acquisition Proposal (which Iris Acquisition Proposal was made after the date of this Agreement and has not been withdrawn) which did not result from a breach of this Section 5.2 and so long as at least three Business Days prior it has provided written notice to Meadow of the identity of such Person or group making the Iris Acquisition Proposal, the material terms and conditions of such Iris Acquisition Proposal (including, if applicable, copies of any material written communications) and its intention to engage or participate in any discussions or negotiations with any such Person or group, (i) provide access to non-public information regarding Iris or any of its Subsidiaries to the Person or group making the Iris Acquisition Proposal *provided that* such information has previously been made available to Meadow or is provided to Meadow substantially concurrently with the making of such information available to such Person or group and that, prior to furnishing any such non-public information, Iris receives from the Person or group making such Iris Acquisition Proposal an executed confidentiality agreement with terms at least as restrictive in all material respects (including with respect to confidentiality and restrictions on use) on such Person(s) as the Confidentiality Agreement's terms are on Meadow (it being understood that such confidentiality agreement need not prohibit the making or amending of an Iris Acquisition Proposal), and (ii) engage or participate in any discussions or negotiations with any such Person or group regarding such Iris Acquisition Proposal if, and only if, prior to taking any action described in clause (i) or (ii) above, the Iris Board determines in good faith after consultation with outside financial advisors and outside legal counsel that (x) such Iris Acquisition Proposal either constitutes an Iris Superior Proposal or would reasonably be expected to result in an Iris Superior Proposal and (y) the failure to take such action would reasonably be expected to be inconsistent with the directors' fiduciary duties under applicable Law.

(c) Notice. Iris shall promptly (and, in any event, within 24 hours) notify Meadow (orally and in writing) if (i) any written or other inquiries, proposals or offers with respect to an Iris Acquisition Proposal or any inquiries, proposals, offers or requests for information relating to or that could reasonably be expected to lead to an Iris Acquisition Proposal are received by Iris, (ii) any Person requests non-public information from Iris in connection with any Iris Acquisition Proposal (provided that Iris shall only be required to provide notice once per Person under this clause (ii)) or (iii) any discussions or negotiations with respect to or that could reasonably be expected to lead to an Iris Acquisition Proposal are sought to be initiated with Iris, indicating, in connection with such notice, the name of such Person and the material terms and conditions of any proposals or offers (including, if applicable, copies of any written requests, proposals or offers, including proposed agreements and other material written communications or, if oral, a summary of the material terms and conditions of such proposal or offer), and thereafter shall keep Meadow informed, on a current basis (and in any event within 24 hours), of the status and terms of any such proposals or offers (including any amendments thereto) and the status of any such discussions or negotiations, including by promptly providing copies of any additional requests, proposals or offers, including any drafts of proposed agreements and any amendments thereto and other information set forth above. Iris agrees that it and its Subsidiaries will not enter into any confidentiality agreement with any Person subsequent to the date of this Agreement which prohibits Iris from providing any information to Meadow in accordance with this Section 5.2 or otherwise prohibits Iris from complying with its obligations under this Section 5.2. Iris further agrees that it will not provide information to any Person pursuant to any confidentiality agreement entered into prior to the date of this Agreement unless such Person agrees prior to receipt of such information to waive any provision that would prohibit Iris from providing any information to Meadow in accordance with this Section 5.2 or otherwise prohibit Iris from complying with its obligations under this Section 5.2.

(d) Definitions. For purposes of this Agreement:

“**Iris Acquisition Proposal**” means any proposal (other than a proposal or offer by Meadow or any of its Affiliates) for (i) any merger, consolidation, share exchange, business combination, issuance of securities, direct or indirect acquisition of securities, recapitalization, tender offer, exchange offer or other similar transaction in which a Person or “group” (as defined in the Exchange Act and the rules promulgated thereunder) of Persons directly or indirectly acquires, or if consummated in accordance with its terms would acquire, beneficial or record ownership of securities representing more than 15% of the outstanding shares of any class of voting

## Table of Contents

securities of Iris; (ii) issuance or acquisition of securities representing more than 15% of the outstanding shares of any class of voting securities of Iris; (iii) any direct or indirect sale, lease, exchange, transfer, acquisition or disposition of any assets of Iris and of the subsidiaries of Iris that constitute or account for (A) more than 15% of the consolidated net revenues of Iris, consolidated net income of Iris or consolidated book value of Iris; or (B) more than 15% of the fair market value of the consolidated assets of Iris; or (iv) any liquidation or dissolution of Iris.

“**Iris Intervening Event**” means any Effect that is material to Iris and its Subsidiaries taken as a whole, occurring or arising after the date of this Agreement that (i) was not known to, or reasonably foreseeable by, the Iris Board (or if known, the effect of which was not known to, or reasonably foreseeable by, the Iris Board prior to the receipt of the Iris Stockholder Approval and (ii) does not relate to (A) an Iris Acquisition Proposal or (B) (1) any changes in the market price or trading volume of Iris or Meadow, (2) Iris or Meadow meeting, failing to meet or exceeding published or unpublished revenue or earnings projections, in each case in and of itself, (3) any events or developments relating to Meadow or any of the Meadow Affiliates, (4) any event or development generally affecting the industries in which Iris or Meadow operate or in the economy generally or other general business, financial, market or political conditions, including changes in interest rates in the United States or any other country or region in the world and changes in exchange rates for the currencies of any countries and any suspension of trading in securities (whether equity, debt, derivative or hybrid securities) generally on any securities exchange or over-the-counter market operating in the United States or any other country or region in the world, (5) any change in any applicable Law or other legal or regulatory conditions or changes in GAAP or other accounting standards, (6) any event or development to the extent directly resulting from the announcement or pendency of, or any actions required to be taken by Iris or Meadow (or refrained to be taken by Iris or Meadow) pursuant to the Agreement or the consummation of the Contemplated Transactions, (7) earthquakes, hurricanes, tsunamis, tornadoes, floods, mudslides, wild fires or other natural disasters, weather conditions and other force majeure events or (8) any Legal Proceedings made or brought by any of the current or former stockholders of Iris or Meadow (on their own behalf or on behalf of Iris or Meadow) against Iris or Meadow, including Legal Proceedings arising out of the Contemplated Transactions.

“**Iris Superior Proposal**” means any bona fide, written Iris Acquisition Proposal on terms which the Iris Board determines in its good faith judgment, after consultation with outside financial advisors and outside legal counsel, would reasonably be expected to be consummated in accordance with its terms, taking into account all legal, financial and regulatory aspects of the proposal and the Person or group of Persons making the proposal, and, if consummated, would result in a transaction more favorable to Iris’s stockholders from a financial point of view than the Merger (after taking into account any revisions to the terms of the Contemplated Transactions pursuant to Section 5.2(f) of this Agreement and the time likely to be required to consummate such Iris Acquisition Proposal); provided that for purposes of the definition of “Iris Superior Proposal”, the references to “15%” in the definition of Iris Acquisition Proposal shall be deemed to be references to “50%.”

(e) No Iris Change in Recommendation or Iris Alternative Acquisition Agreement. Except as provided in Section 5.2(f) and Section 5.2(g), the Iris Board and each committee of the Iris Board shall not (i) withhold, withdraw, qualify or modify (or publicly propose or resolve to withhold, withdraw, qualify or modify), in a manner adverse to Meadow, the Iris Board Recommendation or approve, recommend or otherwise declare advisable (or publicly propose or resolve to approve, recommend or otherwise declare advisable) any Iris Acquisition Proposal or make or authorize the making of any public statement (oral or written) that has the substantive effect of such a withdrawal, qualification or modification, or remove the Iris Board Recommendation from or fail to include the Iris Board Recommendation in the Joint Proxy Statement/Prospectus (each, an “**Iris Change in Recommendation**”) or (ii) cause or permit Iris or any of its Subsidiaries to enter into any letter of intent, term sheet, memorandum of understanding, agreement in principle, acquisition agreement, merger agreement, option agreement, joint venture agreement, partnership agreement, lease agreement or other similar agreement (other than a confidentiality agreement referred to in Section 5.2(b) entered into in compliance with Section 5.2(a)) relating to or that could reasonably be expected to lead to any Iris Acquisition Proposal or

## Table of Contents

requiring Iris (or that would require or could reasonably be expected to require Iris) to abandon, terminate, or fail to consummate the Merger or any other transaction contemplated by this Agreement or that would otherwise materially impede, interfere with or be inconsistent with, the Contemplated Transactions (an “**Iris Alternative Acquisition Agreement**”).

(f) Iris Change in Recommendation Due to Superior Proposal. Notwithstanding anything to the contrary set forth in Section 5.2(e), following receipt of an unsolicited, bona fide written Iris Acquisition Proposal by Iris after the date of this Agreement that did not result from a breach of this Section 5.2 and with respect to which Iris has received a written, definitive form of Iris Alternative Acquisition Agreement that has not been withdrawn, and the Iris Board determining in good faith, after consultation with outside financial advisors and outside legal counsel, that such Iris Acquisition Proposal constitutes an Iris Superior Proposal, the Iris Board may, at any time prior to the time the Iris Stockholder Approval is obtained, make an Iris Change in Recommendation, if all of the following conditions are met:

(i) Iris shall have complied in all material respects with the provisions of this Section 5.2 with respect to such Iris Acquisition Proposal and shall have (A) provided to Meadow four Business Days’ prior written notice, which shall state expressly (1) that it has received a written Iris Acquisition Proposal that constitutes an Iris Superior Proposal, (2) the material terms and conditions of the Iris Acquisition Proposal (including the consideration offered therein and the identity of the Person or group making the Iris Acquisition Proposal), including an unredacted copy of the Iris Alternative Acquisition Agreement and all other written documents and a summary of the material terms of oral communications related to the Iris Superior Proposal (it being understood and agreed that any amendment to the financial terms or any other material term or condition of such Iris Superior Proposal shall require a new notice and an additional two Business Day period) and (3) that, subject to clause (ii) below, the Iris Board has determined to effect an Iris Change in Recommendation, and (B) prior to making such an Iris Change in Recommendation, (x) engaged in good faith negotiations with Meadow (to the extent Meadow wishes to engage) during such notice period to consider adjustments to the terms and conditions of this Agreement that may be proposed in writing by Meadow such that the Iris Alternative Acquisition Agreement ceases to constitute an Iris Superior Proposal, and (y) in determining whether to make an Iris Change in Recommendation, the Iris Board shall take into account any changes to the terms of this Agreement proposed in writing by Meadow; and

(ii) the Iris Board shall have determined, in good faith, after consultation with outside financial advisors and outside legal counsel, that, in light of such Iris Superior Proposal and taking into account any revised terms proposed in writing by Meadow, such Iris Superior Proposal continues to constitute an Iris Superior Proposal and, after consultation with outside legal counsel, that the failure to make such Iris Change in Recommendation would reasonably be expected to be inconsistent with the directors’ fiduciary duties under applicable Law.

(g) Iris Change in Recommendation Due to Iris Intervening Event. Notwithstanding anything to the contrary set forth in Section 5.2(e), upon the occurrence of any Iris Intervening Event, the Iris Board may, at any time prior to the time the Iris Stockholder Approval is obtained, make an Iris Change in Recommendation, if all of the following conditions are met:

(i) Iris shall have (A) provided to Meadow four Business Days’ prior written notice, which shall (1) set forth in reasonable detail information describing the Iris Intervening Event and the rationale for the Iris Change in Recommendation (it being understood and agreed that any amendment to the facts and circumstances relating to the Iris Intervening Event shall require a new notice and an additional two Business Day period), and (2) state expressly that, subject to clause (ii) below, the Iris Board has determined to effect an Iris Change in Recommendation and (B) prior to making such an Iris Change in Recommendation, engaged in good faith negotiations with Meadow (to the extent Meadow wishes to engage) during such four Business Day period to consider adjustments to the terms and conditions of this Agreement that may be proposed in writing by Meadow in such a manner that the failure of the Iris Board to make an Iris Change in Recommendation in response to the Iris Intervening Event in accordance with clause (ii) below would no longer reasonably be expected to be inconsistent with the directors’ fiduciary duties under applicable Law; and

## Table of Contents

(ii) the Iris Board shall have determined in good faith, after consultation with outside financial advisors and outside legal counsel, that in light of such Iris Intervening Event and taking into account any revised terms proposed in writing by Meadow, the failure to make an Iris Change in Recommendation, would reasonably be expected to be inconsistent with the directors' fiduciary duties under applicable Law.

(h) Certain Permitted Disclosure. Nothing contained in this Section 5.2 shall be deemed to prohibit Iris from complying with its disclosure obligations under applicable U.S. federal or state Law with regard to an Iris Acquisition Proposal; *provided* that any "stop look and listen" communication to its stockholders of the nature contemplated by Rule 14d-9 under the Exchange Act shall include an affirmative statement to the effect that the recommendation of the Iris Board is affirmed or remains unchanged; *provided, further*, that this Section 5.2(h) shall not be deemed to permit Iris or the Iris Board to effect an Iris Change in Recommendation except in accordance with Sections 5.2(f) or 5.2(g). Iris shall not submit to the vote of its stockholders any Iris Acquisition Proposal or Iris Superior Proposal prior to the termination of this Agreement.

### 5.3. Meadow Acquisition Proposals; Meadow Change in Recommendation.

(a) No Solicitation or Negotiation. During the Pre-Closing Period, except as expressly permitted by this Section 5.3, Meadow shall not, and Meadow shall cause its and its Subsidiaries' directors, officers and employees not to, and shall cause its and their respective Representatives not to, directly or indirectly:

(i) solicit, initiate, induce, encourage or facilitate (including by way of granting a waiver under Section 203 of the DGCL), any inquiries or the making of any proposal or offer that constitutes, or could reasonably be expected to lead to, a Meadow Acquisition Proposal;

(ii) participate in any discussions or negotiations or cooperate in any way with any Person regarding any Meadow Acquisition Proposal or any inquiry, proposal or offer that could reasonably be expected to lead to a Meadow Acquisition Proposal;

(iii) provide any non-public information or data concerning Meadow or any of its Subsidiaries to any Person in connection with any Meadow Acquisition Proposal or any inquiry, proposal or offer that could reasonably be expected to lead to a Meadow Acquisition Proposal or for the purpose of soliciting, initiating, inducing, encouraging or facilitating a Meadow Acquisition Proposal;

(iv) enter into any binding or nonbinding letter of intent, term sheet, memorandum of understanding, merger agreement, acquisition agreement, agreement in principle, option agreement, joint venture agreement, partnership agreement, lease agreement or other similar agreement with respect to a Meadow Acquisition Proposal;

(v) adopt, approve or recommend or make any public statement approving or recommending any inquiry, proposal or offer that constitutes, or could reasonably be expected to lead to, a Meadow Acquisition Proposal (including by approving any transaction, or approving any Person becoming an "interested stockholder," for purposes of Section 203 of the DGCL);

(vi) take any action or exempt any Person (other than Iris and its Subsidiaries) from the restriction on "business combinations" or any similar provision contained in applicable takeover laws or the Meadow's organizational or other governing documents; or

(vii) publicly propose, resolve or agree to do any of the foregoing.

Meadow shall, and shall cause its Subsidiaries and Representatives to, immediately cease and cause to be terminated any solicitation, encouragement, discussions and negotiations with any Person conducted heretofore with respect to any Meadow Acquisition Proposal, or inquiry, proposal or offer that could reasonably be expected

## Table of Contents

to lead to a Meadow Acquisition Proposal and shall promptly terminate access by any such Person to any physical or electronic data rooms relating to any such Meadow Acquisition Proposal. As soon as reasonably practicable after the date of this Agreement, Meadow shall deliver a written notice to each Person that entered into a confidentiality agreement in anticipation of potentially making a Meadow Acquisition Proposal within the last 12 months, to the effect that Meadow is ending all discussions and negotiations with such Person with respect to any such Meadow Acquisition Proposal effective as of the date hereof and requesting the prompt return or destruction of all confidential information previously furnished to such Person. Meadow shall take all actions necessary to enforce its rights under the provisions of any “standstill” agreement between Meadow and any Person (other than Iris), and shall not grant any waiver of, or agree to any amendment or modification to, any such agreement, to permit such Person to submit a Meadow Acquisition Proposal, unless in any such case the Meadow Board shall have determined, in good faith, after consultation with outside legal counsel, that such actions would reasonably be expected to be inconsistent with the directors’ fiduciary duties under applicable Law.

(b) Fiduciary Exception to No Solicitation Provision. Notwithstanding anything to the contrary in Section 5.3(a), prior to the time, but not after, the Meadow Stockholder Approval is obtained, Meadow may, in response to an unsolicited, bona fide written Meadow Acquisition Proposal (which Meadow Acquisition Proposal was made after the date of this Agreement and has not been withdrawn) which did not result from a breach of this Section 5.3 and so long as at least three Business Days prior it has provided written notice to Iris of the identity of such Person or group making the Meadow Acquisition Proposal, the material terms and conditions of such Meadow Acquisition Proposal (including, if applicable, copies of any material written communications) and its intention to engage or participate in any discussions or negotiations with any such Person or group, (i) provide access to non-public information regarding Meadow or any of its Subsidiaries to the Person or group making the Meadow Acquisition Proposal; *provided that* such information has previously been made available to Iris or is provided to Iris substantially concurrently with the making of such information available to such Person or group and that, prior to furnishing any such non-public information, Meadow receives from the Person or group making such Meadow Acquisition Proposal an executed confidentiality agreement with terms at least as restrictive in all material respects (including with respect to confidentiality and restrictions on use) on such Person(s) as the Confidentiality Agreement’s terms are on Iris (it being understood that such confidentiality agreement need not prohibit the making or amending of a Meadow Acquisition Proposal), and (ii) engage or participate in any discussions or negotiations with any such Person or group regarding such Meadow Acquisition Proposal if, and only if, prior to taking any action described in clause (i) or (ii) above, the Meadow Board determines in good faith after consultation with outside financial advisors and outside legal counsel that (x) such Meadow Acquisition Proposal either constitutes a Meadow Superior Proposal or would reasonably be expected to result in a Meadow Superior Proposal and (y) the failure to take such action would reasonably be expected to be inconsistent with the directors’ fiduciary duties under applicable Law.

(c) Notice. Meadow shall promptly (and, in any event, within 24 hours) notify Iris (orally and in writing) if (i) any written or other inquiries, proposals or offers with respect to a Meadow Acquisition Proposal or any inquiries, proposals, offers or requests for information relating to or that could reasonably be expected to lead to an Meadow Acquisition Proposal are received by Meadow, (ii) any Person requests non-public information from Meadow in connection with any Meadow Acquisition Proposal (provided that Meadow shall only be required to provide notice once per Person under this clause (ii)) or (iii) any discussions or negotiations with respect to or that could reasonably be expected to lead to a Meadow Acquisition Proposal are sought to be initiated with Meadow, indicating, in connection with such notice, the name of such Person and the material terms and conditions of any proposals or offers (including, if applicable, copies of any written requests, proposals or offers, including proposed agreements and other material written communications or, if oral, a summary of the material terms and conditions of such proposal or offer), and thereafter shall keep Iris reasonably informed, on a current basis (and in any event within 24 hours), of the status and terms of any such proposals or offers (including any amendments thereto) and the status of any such discussions or negotiations, including by promptly providing copies of any additional requests, proposals or offers, including any drafts of proposed agreements and any amendments thereto and other information set forth above. Meadow agrees that it and its Subsidiaries will

## [Table of Contents](#)

not enter into any confidentiality agreement with any Person subsequent to the date of this Agreement which prohibits Meadow from providing any information to Iris in accordance with this [Section 5.3](#) or otherwise prohibits Meadow from complying with its obligations under this [Section 5.3](#). Meadow further agrees that it will not provide information to any Person pursuant to any confidentiality agreement entered into prior to the date of this Agreement unless such Person agrees prior to receipt of such information to waive any provision that would prohibit Meadow from providing any information to Iris in accordance with this [Section 5.3](#) or otherwise prohibit Meadow from complying with its obligations under this [Section 5.3](#).

(d) [Definitions](#). For purposes of this Agreement:

“**Meadow Acquisition Proposal**” means any proposal (other than a proposal or offer by Iris or any of its Affiliates) for (i) any merger, consolidation, share exchange, business combination, issuance of securities, direct or indirect acquisition of securities, recapitalization, tender offer, exchange offer or other similar transaction in which a Person or “group” (as defined in the Exchange Act and the rules promulgated thereunder) of Persons directly or indirectly acquires, or if consummated in accordance with its terms would acquire, beneficial or record ownership of securities representing more than 15% of the outstanding shares of any class of voting securities of Meadow; (ii) issuance or acquisition of securities representing more than 15% of the outstanding shares of any class of voting securities of Meadow; (iii) any direct or indirect sale, lease, exchange, transfer, acquisition or disposition of any assets of Meadow and of the subsidiaries of Meadow that constitute or account for (A) more than 15% of the consolidated net revenues of Meadow, consolidated net income of Meadow or consolidated book value of Meadow; or (B) more than 15% of the fair market value of the consolidated assets of Meadow; or (iv) any liquidation or dissolution of Meadow.

“**Meadow Intervening Event**” means any Effect that is material to Meadow and its Subsidiaries taken as a whole, occurring or arising after the date of this Agreement that (i) was not known to, or reasonably foreseeable by, the Meadow Board prior to the execution of this Agreement, which Effect becomes known to, or reasonably foreseeable by, the Meadow Board (or if known, the effect of which was not known to, or reasonably foreseeable) prior to the receipt of the Meadow Stockholder Approval and (ii) does not relate to (A) a Meadow Acquisition Proposal or (B) (1) any changes in the market price or trading volume of Meadow or Iris, (2) Meadow or Iris meeting, failing to meet or exceeding published or unpublished revenue or earnings projections, in each case in and of itself, (3) any events or developments relating to Iris or any of the Iris Affiliates, (4) any event or development generally affecting the industries in which Meadow or Iris operate or in the economy generally or other general business, financial, market or political conditions, including changes in interest rates in the United States or any other country or region in the world and changes in exchange rates for the currencies of any countries and any suspension of trading in securities (whether equity, debt, derivative or hybrid securities) generally on any securities exchange or over-the-counter market operating in the United States or any other country or region in the world, (5) any change in any applicable Law or other legal or regulatory conditions or changes in GAAP or other accounting standards, (6) any event or development to the extent directly resulting from the announcement or pendency of, or any actions required to be taken by Meadow or Iris (or refrained to be taken by Meadow or Iris) pursuant to the Agreement or the consummation of the Contemplated Transactions, (7) earthquakes, hurricanes, tsunamis, tornadoes, floods, mudslides, wild fires or other natural disasters, weather conditions and other force majeure events or (8) any Legal Proceedings made or brought by any of the current or former stockholders of Meadow or Iris (on their own behalf or on behalf of Meadow or Iris) against Meadow or Iris, including Legal Proceedings arising out of the Contemplated Transactions.

“**Meadow Superior Proposal**” means any bona fide, written Meadow Acquisition Proposal on terms which the Meadow Board determines in its good faith judgment, after consultation with outside financial advisors and outside legal counsel, would reasonably be expected to be consummated in accordance with its terms, taking into account all legal, financial and regulatory aspects of the proposal and the Person or group of Persons making the proposal, and, if consummated, would result in a transaction more favorable to Meadow’s stockholders from a financial point of view than the Merger (after taking into account any revisions to the terms of the Contemplated



## Table of Contents

Transactions pursuant to Section 5.3(f) of this Agreement and the time likely to be required to consummate such Meadow Acquisition Proposal); provided that for purposes of the definition of “Meadow Superior Proposal”, the references to “15%” in the definition of Meadow Acquisition Proposal shall be deemed to be references to “50%.”

(e) No Meadow Change in Recommendation or Meadow Alternative Acquisition Agreement. Except as provided in Section 5.3(f) and Section 5.3(g), the Meadow Board and each committee of the Meadow Board shall not (i) withhold, withdraw, qualify or modify (or publicly propose or resolve to withhold, withdraw, qualify or modify), in a manner adverse to Iris, the Meadow Board Recommendation or approve, recommend or otherwise declare advisable (or publicly propose or resolve to approve, recommend or otherwise declare advisable) any Meadow Acquisition Proposal or make or authorize the making of any public statement (oral or written) that has the substantive effect of such a withdrawal, qualification or modification, or remove the Meadow Board Recommendation from or fail to include the Meadow Board Recommendation in the Joint Proxy Statement/Prospectus (each, a “**Meadow Change in Recommendation**”) or (ii) cause or permit Meadow or any of its Subsidiaries to enter into any letter of intent, term sheet, memorandum of understanding, agreement in principle, acquisition agreement, merger agreement, option agreement, joint venture agreement, partnership agreement, lease agreement or other similar agreement (other than a confidentiality agreement referred to in Section 5.3(b)) entered into in compliance with Section 5.3(a)) relating to or that could reasonably be expected to lead to any Meadow Acquisition Proposal or requiring Meadow (or that would require or could reasonably be expected to require Meadow) to abandon, terminate, or fail to consummate the Merger or any other transaction contemplated by this Agreement or that would otherwise materially impede, interfere with or be inconsistent with, the Contemplated Transactions (a “**Meadow Alternative Acquisition Agreement**”).

(f) Meadow Change in Recommendation Due to Superior Proposal. Notwithstanding anything to the contrary set forth in Section 5.3(e), following receipt of an unsolicited, bona fide written Meadow Acquisition Proposal by Meadow after the date of this Agreement that did not result from a breach of this Section 5.3 and with respect to which Meadow has received a written, definitive form of a Meadow Alternative Acquisition Agreement that has not been withdrawn, and the Meadow Board determining in good faith, after consultation with outside financial advisors and outside legal counsel, that such Meadow Acquisition Proposal constitutes a Meadow Superior Proposal, the Meadow Board may, at any time prior to the time the Meadow Stockholder Approval is obtained, make a Meadow Change in Recommendation, if all of the following conditions are met:

(i) Meadow shall have complied in all material respects with the provisions of this Section 5.3 with respect to such Meadow Acquisition Proposal and shall have (A) provided to Iris four Business Days’ prior written notice, which shall state expressly (1) that it has received a written Meadow Acquisition Proposal that constitutes a Meadow Superior Proposal, (2) the material terms and conditions of the Meadow Acquisition Proposal (including the consideration offered therein and the identity of the Person or group making the Meadow Acquisition Proposal), including an unredacted copy of the Meadow Alternative Acquisition Agreement and all other written documents and a summary of the material terms of oral communications related to the Meadow Superior Proposal (it being understood and agreed that any amendment to the financial terms or any other material term or condition of such Meadow Superior Proposal shall require a new notice and an additional two Business Day period) and (3) that, subject to clause (ii) below, the Meadow Board has determined to effect a Meadow Change in Recommendation, and (B) prior to making such a Meadow Change in Recommendation, (x) engaged in good faith negotiations with Iris (to the extent Iris wishes to engage) during such notice period to consider adjustments to the terms and conditions of this Agreement that may be proposed in writing by Iris such that the Meadow Alternative Acquisition Agreement ceases to constitute a Meadow Superior Proposal, and (y) in determining whether to make a Meadow Change in Recommendation, the Meadow Board shall take into account any changes to the terms of this Agreement proposed in writing by Iris; and

(ii) the Meadow Board shall have determined, in good faith, after consultation with outside financial advisors and outside legal counsel, that, in light of such Meadow Superior Proposal and taking into account any revised terms proposed in writing by Iris, such Meadow Superior Proposal continues to constitute a

## Table of Contents

Meadow Superior Proposal and, after consultation with outside legal counsel, that the failure to make such Meadow Change in Recommendation would reasonably be expected to be inconsistent with the directors' fiduciary duties under applicable Law.

(g) Meadow Change in Recommendation Due to Meadow Intervening Event. Notwithstanding anything to the contrary set forth in Section 5.3(e), upon the occurrence of any Meadow Intervening Event, the Meadow Board may, at any time prior to the time the Meadow Stockholder Approval is obtained, make a Meadow Change in Recommendation, if all of the following conditions are met:

(i) Meadow shall have (A) provided to Iris four Business Days' prior written notice, which shall (1) set forth in reasonable detail information describing the Meadow Intervening Event and the rationale for the Meadow Change in Recommendation (it being understood and agreed that any amendment to the facts and circumstances relating to the Meadow Intervening Event shall require a new notice and an additional two Business Day period), and (2) state expressly that, subject to clause (ii) below, the Meadow Board has determined to effect a Meadow Change in Recommendation and (B) prior to making such a Meadow Change in Recommendation, engaged in good faith negotiations with Iris (to the extent Iris wishes to engage) during such four Business Day period to consider adjustments to the terms and conditions of this Agreement that may be proposed in writing by Iris in such a manner that the failure of the Meadow Board to make a Meadow Change in Recommendation in response to the Meadow Intervening Event in accordance with clause (ii) below would no longer reasonably be expected to be inconsistent with the directors' fiduciary duties under applicable Law; and

(ii) the Meadow Board shall have determined in good faith, after consultation with outside financial advisors and outside legal counsel, that in light of such Meadow Intervening Event and taking into account any revised terms proposed in writing by Iris, the failure to make a Meadow Change in Recommendation, would reasonably be expected to be inconsistent with the directors' fiduciary duties under applicable Law.

(h) Certain Permitted Disclosure. Nothing contained in this Section 5.3 shall be deemed to prohibit Meadow from complying with its disclosure obligations under applicable U.S. federal or state Law with regard to a Meadow Acquisition Proposal; *provided* that any "stop look and listen" communication to its stockholders of the nature contemplated by Rule 14d-9 under the Exchange Act shall include an affirmative statement to the effect that the recommendation of the Meadow Board is affirmed or remains unchanged; *provided, further*, that this Section 5.3(h) shall not be deemed to permit the Meadow Board or Iris Board to effect an Iris Change in Recommendation except in accordance with Sections 5.3(f) or 5.3(g). Meadow shall not submit to the vote of its stockholders any Meadow Acquisition Proposal or Meadow Superior Proposal prior to the termination of this Agreement.

### 5.4. Information Supplied.

(a) Iris and Meadow shall jointly prepare and cause to be filed with the SEC a joint proxy statement (as amended or supplemented from time to time, the "**Joint Proxy Statement/Prospectus**") with respect to the Iris Stockholders Meeting and the Meadow Stockholders Meeting. As promptly as practicable following the date of this Agreement, Meadow shall prepare (with Iris's reasonable cooperation) and file with the SEC a registration statement on Form S-4 (as amended or supplemented from time to time, the "**Registration Statement**"), in which the Joint Proxy Statement/Prospectus will be included as a prospectus, in connection with the registration under the Securities Act of the shares of Meadow Common Stock to be issued in the Merger. Meadow shall use its reasonable best efforts to have the Registration Statement declared effective under the Securities Act as promptly as practicable after such filing and to keep the Registration Statement effective as long as is necessary to consummate the Merger and the other Contemplated Transactions. Meadow shall also take any action (other than qualifying to do business in any jurisdiction in which it is not now so qualified or filing a general consent to service of process) required to be taken under any applicable state securities or "blue sky" laws in connection with the issuance of shares of Meadow Common Stock in the Merger. Each of Iris and Meadow shall furnish all



## Table of Contents

information concerning Iris and the holders of Shares and Meadow and the holders of the capital stock of Meadow, as applicable, as may be reasonably requested in connection with any such action. Each of Iris and Meadow shall use reasonable best efforts to cause the Joint Proxy Statement/Prospectus to be mailed to Iris's stockholders and Meadow's stockholders, as applicable, as promptly as practicable after the Registration Statement is declared effective under the Securities Act.

(b) No filing of, or amendment or supplement to, the Registration Statement will be made by Meadow, and no filing of, or amendment or supplement to, the Joint Proxy Statement/Prospectus will be made by Iris or Meadow, in each case without providing the other Party a reasonable opportunity to review and comment thereon (other than, in each case, any filing, amendment or supplement in connection with an Iris Change in Recommendation or a Meadow Change in Recommendation, as applicable), and each Party shall consider in good faith and reflect all comments reasonably proposed by the other Party. Each of Iris and Meadow shall promptly provide the other with copies of all such filings, amendments or supplements to the extent not publicly available. Each of Iris and Meadow shall furnish all information concerning such Person and its Affiliates to the other and provide such other assistance as may be reasonably requested by such other Party to be included therein and shall otherwise reasonably assist and cooperate with the other in the preparation of the Registration Statement or Joint Proxy Statement/Prospectus, as applicable, and the resolution of any comments to either received from the SEC. If at any time prior to the receipt of the Iris Stockholder Approval or the Meadow Stockholder Approval, any information relating to Iris or Meadow, or any of their respective Affiliates, directors or officers, should be discovered by Iris or Meadow which is required to be set forth in an amendment or supplement to either the Registration Statement or the Joint Proxy Statement/Prospectus, so that either such document would not include any misstatement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading, the Party which discovers such information shall promptly notify the other Party and an appropriate amendment or supplement describing such information shall be promptly filed with the SEC and, to the extent required by applicable Law, disseminated to the stockholders of Iris or the stockholders of Meadow, as applicable. The Parties shall notify each other promptly of the receipt of any comments from the SEC or the staff of the SEC and of any request by the SEC or the staff of the SEC for amendments or supplements to the Registration Statement or the Joint Proxy Statement/Prospectus, or for additional information and shall supply each other with copies of (i) all correspondence between it or any of its Representatives, on the one hand, and the SEC or the staff of the SEC, on the other hand, with respect to the Registration Statement, Joint Proxy Statement/Prospectus or the Merger and (ii) all orders of the SEC relating to the Registration Statement. No response to any comments from the SEC or the staff of the SEC relating to the Joint Proxy Statement/Prospectus will be made by either Party without providing the other a reasonable opportunity to review and comment thereon unless pursuant to a telephone call initiated by the SEC, and each Party shall consider in good faith and reflect all comments reasonably proposed by the other Party. The Parties will cause the Registration Statement and Joint Proxy Statement/Prospectus to comply as to form in all material respects with the applicable provisions of the Securities Act and the Exchange Act and the rules and regulations thereunder.

### 5.5. Stockholder Meetings.

#### (a) Iris Stockholders Meeting.

(i) Iris will, as promptly as practicable in accordance with applicable Law and its certificate of incorporation and bylaws, establish a record date for, duly call and give notice of, and use its reasonable best efforts to convene a meeting of holders of Shares to consider and vote upon the adoption of this Agreement, which meeting shall in any event take place within 45 days after the declaration of the effectiveness of the Registration Statement (the "**Iris Stockholders Meeting**"). Iris shall use its reasonable best efforts to hold Iris Stockholders Meeting on the same day as the Meadow Stockholders Meeting as soon as practicable after the date on which the Registration Statement becomes effective. Subject to the provisions of Section 5.2, the Iris Board shall include the Iris Board Recommendation in the Joint Proxy Statement/Prospectus and recommend at the Iris Stockholders Meeting that the holders of Shares adopt this Agreement and shall use its reasonable best efforts to

## Table of Contents

obtain and solicit such adoption. Notwithstanding the foregoing, (A) if on or before the date on which the Iris Stockholders Meeting is scheduled, Iris reasonably believes that (1) it will not receive proxies representing the Iris Stockholder Approval, whether or not a quorum is present or (2) it will not have enough Shares represented to constitute a quorum necessary to conduct the business of the Iris Stockholders Meeting, Iris may (and, if requested by Meadow, Iris shall) postpone or adjourn, or make one or more successive postponements or adjournments of, the Iris Stockholders Meeting and (B) Iris may postpone or adjourn the Iris Stockholders Meeting to allow reasonable additional time for the filing or mailing of any supplemental or amended disclosure that Iris has determined, after consultation with outside legal counsel, is reasonably likely to be required under applicable Law and for such supplemental or amended disclosure to be disseminated and reviewed by stockholders of Iris prior to the Iris Stockholders Meeting, as long as the date of the Iris Stockholders Meeting is not postponed or adjourned more than an aggregate of 30 calendar days in connection with any such postponements or adjournments pursuant to either or both of the preceding clauses (A) and (B).

(ii) Notwithstanding any Iris Change in Recommendation, Iris shall submit this Agreement to the holders of Shares for adoption at the Iris Stockholders Meeting unless this Agreement is terminated in accordance with Article VII prior to the Iris Stockholders Meeting. Without the prior written consent of Meadow, the adoption of this Agreement shall be the only matter (other than matters of procedure and matters required by Law to be voted on by Iris's stockholders in connection with the adoption of this Agreement and the Contemplated Transactions) that Iris shall propose to be acted on by the stockholders of Iris at the Iris Stockholders Meeting.

### (b) Meadow Stockholders Meeting.

(i) Meadow will, as promptly as practicable in accordance with applicable Law and its certificate of incorporation and bylaws, establish a record date for, duly call and give notice of, and use its reasonable best efforts to convene a meeting of holders of Shares to consider and vote upon the adoption of this Agreement, which meeting shall in any event take place within 45 days after the declaration of the effectiveness of the Registration Statement (the "**Meadow Stockholders Meeting**"). Meadow shall use its reasonable best efforts to hold the Meadow Stockholders Meeting on the same day as the Iris Stockholders Meeting as soon as practicable after the date on which the Registration Statement becomes effective. Subject to the provisions of Section 5.3, the Meadow Board shall include the Meadow Board Recommendation in the Joint Proxy Statement/Prospectus that the holders of capital stock of Meadow approve the Meadow Share Issuance and shall use its reasonable best efforts to obtain and solicit such approval. Notwithstanding the foregoing, (A) if on or before the date on which the Meadow Stockholders Meeting is scheduled, Meadow reasonably believes that (1) it will not receive proxies representing the Meadow Stockholder Approval, whether or not a quorum is present or (2) it will not have enough shares of Meadow Common Stock represented to constitute a quorum necessary to conduct the business of the Meadow Stockholders Meeting, Meadow may (and, if requested by Iris, Meadow shall) postpone or adjourn, or make one or more successive postponements or adjournments of, the Meadow Stockholders Meeting and (B) Meadow may postpone or adjourn the Meadow Stockholders Meeting to allow reasonable additional time for the filing or mailing of any supplemental or amended disclosure that Meadow has determined, after consultation with outside legal counsel, is reasonably likely to be required under applicable Law and for such supplemental or amended disclosure to be disseminated and reviewed by stockholders of Meadow prior to the Meadow Stockholders Meeting, as long as the date of the Meadow Stockholders Meeting is not postponed or adjourned more than an aggregate of 30 calendar days in connection with any such postponements or adjournments pursuant to either or both of the preceding clauses (A) and (B).

(ii) Notwithstanding any Meadow Change in Recommendation, Meadow shall seek the Meadow Stockholder Approval at the Meadow Stockholders Meeting unless this Agreement is terminated in accordance with Article VII prior to the Meadow Stockholders Meeting. Without the prior written consent of Iris, the Meadow Share Issuance shall be the only matter (other than matters of procedure and matters required by Law to be voted on by Meadow's stockholders in connection with the Contemplated Transactions) that Meadow shall propose to be acted on by the stockholders of Meadow at the Meadow Stockholders Meeting.

5.6. Regulatory Approvals and Related Matters.

(a) Each of Iris and Meadow shall give the other Party prompt notice of the commencement or known threat of commencement of any Legal Proceeding by or before any Governmental Entity with respect to the Merger or any of the Contemplated Transactions, keep the other party reasonably informed as to the status of any such Legal Proceeding or threat, and in connection with any such Legal Proceeding, each of Iris or Meadow will permit authorized representatives of the other party to be present at each meeting or conference relating to any such Legal Proceeding and to have access to and be consulted in connection with any document, opinion or proposal made or submitted to any Governmental Entity in connection with any such Legal Proceeding.

(b) Subject to the immediately following sentence, Meadow and Iris shall use reasonable best efforts to take, or cause to be taken, all actions necessary to consummate the Merger and make effective the other Contemplated Transactions. Without limiting the generality of the foregoing, each Party to this Agreement: (i) shall make all filings (if any) and give all notices (if any) required to be made and given by such party in connection with the Merger and the other Contemplated Transactions; (ii) shall use reasonable best efforts to obtain each Consent (if any) required to be obtained (pursuant to any applicable Law) by such party in connection with the Merger or any of the other Contemplated Transactions; and (iii) shall use reasonable best efforts to lift any restraint, injunction or other legal bar to the Merger.

(c) Iris and Meadow each shall, upon request by the other, promptly furnish the other with all information concerning itself, its Subsidiaries, directors, officers and stockholders and such other matters as may be reasonably necessary or advisable in connection with the Registration Statement, Joint Proxy Statement/Prospectus and any other statement, filing, notice or application made by or on behalf of Meadow, Iris or any of their respective Subsidiaries to any third party and/or any Governmental Entity in connection with the Contemplated Transactions.

(d) Iris and Meadow each shall promptly furnish the other with copies of notices or other communications received by Iris or Meadow, as the case may be, or any of their respective Subsidiaries from any third party and/or any Governmental Entity with respect to the Contemplated Transactions, other than immaterial communications.

5.7. Access; Consultation. Upon reasonable notice, and except as may otherwise be required by applicable Law, each of Iris and Meadow shall, and shall cause each of its Subsidiaries to, afford the other Party's Representatives reasonable access (at the requesting Party's cost) under the supervision of appropriate personnel of the other Party, during normal business hours during the period prior to the Effective Time, to the other Party's, and each of its Subsidiaries' properties, assets, books, records and contracts and, during such period, each of Iris and Meadow shall, and shall cause each of its Subsidiaries to, furnish promptly to the other all information concerning its or any of its Subsidiaries' capital stock, business and personnel as may reasonably be requested by the other; provided that no investigation pursuant to this Section 5.7 shall affect or be deemed to modify any representation or warranty made by Iris or Meadow; and provided, further that the foregoing shall require neither Iris nor Meadow to permit any invasive sampling or testing or to disclose any information pursuant to this Section 5.7 to the extent that (a) in the reasonable good faith judgment of such Party, any applicable Law requires such Party or its Subsidiaries to restrict or prohibit access to any such properties or information, (b) in the reasonable good faith judgment of such Party, the information is subject to confidentiality obligations to a third party or (c) disclosure of any such information or document would result in the loss of attorney-client privilege; provided, further that with respect to clauses (a) through (c) of this Section 5.7, Meadow or Iris, as applicable, shall use its commercially reasonable efforts to (i) obtain the required consent of any such third party to provide such inspection or disclosure, (ii) develop an alternative to providing such information so as to address such matters that is reasonably acceptable to Meadow and Iris and (iii) in the case of clauses (a) and (c), implement appropriate and mutually agreeable measures to permit the disclosure of such information in a manner to remove the basis for the objection, including by arrangement of appropriate clean room procedures, redaction or entry into a customary joint defense agreement with respect to any information to

## Table of Contents

be so provided, if the Parties determine that doing so would reasonably permit the disclosure of such information without violating applicable Law or jeopardizing such privilege. Any investigation pursuant to this Section 5.7 shall be conducted in such a manner as not to interfere unreasonably with the conduct of the business of the other Party. All requests for information made pursuant to this Section 5.7 shall be directed in writing to an executive officer of Iris or Meadow, as applicable, or such Person as may be designated by any such executive officer. Each Party shall take reasonable steps to ensure that any information it obtains regarding the other Party pursuant to this Section 5.7 shall be used solely in connection with, and in furtherance of effecting, the Contemplated Transactions.

5.8. Stock Exchange Listing, De-listing and De-registration. Meadow shall use reasonable best efforts to cause the shares of Meadow Common Stock to be issued in the Merger to be approved for listing on The Nasdaq Capital Market, subject to official notice of issuance, prior to the Effective Time. Iris shall take all actions necessary to permit the Shares and any other security issued by Iris or one of its Subsidiaries and listed on The Nasdaq Global Market to be de-listed and de-registered under the Exchange Act as soon as possible following the Effective Time.

[\*\*]

[\*\*]

5.11. Publicity. The initial press release with respect to the Merger and the other Contemplated Transactions shall be a joint press release approved by both Parties and thereafter Iris and Meadow shall consult with each other prior to issuing or making, and provide each other the reasonable opportunity to review and comment on, any press releases or other public announcements with respect to the Contemplated Transactions and any filings with any Governmental Entity (including any national securities exchange) with respect thereto, except (a) as may be required by applicable Law or by obligations pursuant to any listing agreement with or rules of any national securities exchange, (b) any consultation that would not be reasonably practicable as a result of requirements of applicable Law, (c) any press release or public statement that consists solely of information previously disclosed in all material respects in prior press releases issued or public statements made by a Party in compliance with this Section 5.11, (d) any internal announcements to employees regarding the Merger so long as such statements consist solely of information previously disclosed in all material respects in previous press releases issued or public disclosures or public statements made jointly by the Parties (or individually, if approved by the other Party) or (e) with respect to any Iris Change in Recommendation or Meadow Change in Recommendation made in accordance with this Agreement or, as applicable, Meadow's or Iris's response thereto.

5.12. Expenses. Except as otherwise provided in Sections 7.5 and 7.6, whether or not the Merger is consummated, all costs and expenses incurred in connection with this Agreement and the Contemplated Transactions shall be paid by the Party incurring such expense.

5.13. Indemnification; Directors' and Officers' Insurance.

(a) From and after the Effective Time, each of Meadow and the Surviving Company shall, jointly and severally, indemnify and hold harmless each Person who is now, or has been at any time prior to the date hereof, or who becomes prior to the Effective Time a director or officer of Iris or any of its Subsidiaries (each, an "**Indemnified Person**") against all expenses (including attorneys' fees), liabilities, losses, judgments, fines (including excise taxes and penalties arising under ERISA), and amounts paid in settlement, actually and reasonably incurred in connection with any threatened, pending or completed action, suit, proceeding or investigation, whether civil, criminal, administrative or investigative (other than an action by or in the right of Iris), arising out of or pertaining to the fact that the Indemnified Person is or was, or has agreed to become, a director or officer of Iris, or is or was serving, or has agreed to serve, at the request of Iris, as a director, officer,

## Table of Contents

partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise (including any employee benefit plan), whether asserted or claimed prior to, at or after the Effective Time, to the fullest extent that Iris would be required to indemnify such person under the DGCL, Iris's certificate of incorporation or bylaws (as in effect as of the date of this Agreement) or the D&O Indemnification Agreement with such person. Each Indemnified Person will be entitled to advancement of expenses (including attorneys' fees) incurred in the defense of any such action, suit or proceeding and any appeal therefrom from each of Meadow and the Surviving Company to the fullest extent that Iris would be required to advance expenses to such person under the certificate of incorporation or bylaws of Iris or the D&O Indemnification Agreement with such person, within 10 Business Days of receipt by Meadow or the Surviving Company from the Indemnified Person of a request therefor; provided, that any Indemnified Person to whom expenses are advanced provides an undertaking, to the extent required by the DGCL in the event that Iris was providing the advancement, to repay such advances if it is determined by a final determination of a court of competent jurisdiction (which determination is not subject to appeal) that such Indemnified Person is not entitled to indemnification under applicable Law.

(b) Meadow shall cause all rights to exculpation, indemnification and advancement by Iris and its Subsidiaries existing in favor of the Indemnified Persons for their acts and omissions as directors and officers of Iris or any of its Subsidiaries occurring prior to the Effective Time, as provided in Iris's or its applicable Subsidiary's Organizational Documents (as in effect as of the date of this Agreement) and as provided in any indemnification agreements between Iris and said Indemnified Persons (as such agreements are in effect as of the date of this Agreement) to survive the Merger and be observed by the Surviving Company to the fullest extent permitted by Delaware law for a period of six years from the date on which the Merger becomes effective, which provisions governing such rights shall not be amended, repealed, abrogated or otherwise modified in any manner that would adversely affect any Indemnified Persons.

(c) From and after the Effective Time, Meadow shall maintain directors' and officers' liability insurance policies, with an effective date as of the Closing Date, on commercially available terms and conditions and with coverage limits customary for U.S. public companies similarly situated to Meadow. Prior to the Effective Time, Iris shall purchase a six year "tail policy" for the existing policy of directors' and officers' liability insurance maintained by Iris as of the date of this Agreement in the form made available by Iris to Meadow prior to the date of this Agreement at an annualized premium not to exceed 300% of the annual premiums currently paid by Iris for such insurance. The costs of such tail policy will be split evenly between Iris and Meadow, and the portion paid for by Meadow will be treated as a Transaction Expense of Meadow hereunder.

(d) In the event Meadow or Iris or any of their respective successors or assigns (i) consolidates with or merges into any other Person and shall not be the continuing or surviving corporation or entity of such consolidation or merger, (ii) transfers all or substantially all of its properties and assets to any Person, (iii) consummates any division transaction or (iv) engages in any similar transaction, then, and in each such case, Meadow and any of its successors and assigns shall ensure that the successors and assigns of Meadow or the Surviving Company, as the case may be, shall assume the obligations set forth in this Section 5.13.

(e) If any Indemnified Person makes any claim for indemnification or advancement of expenses under this Section 5.13 that is denied by Meadow and/or Iris or the Surviving Company, and a court of competent jurisdiction determines that the Indemnified Person is entitled to such indemnification or advancement of expenses, then Meadow, Iris or the Surviving Company shall pay the Indemnified Person's costs and expenses, including reasonable legal fees and expenses, incurred by the Indemnified Person in connection with pursuing his or her claims to the fullest extent permitted by law.

(f) The provisions of this Section 5.13 are intended to be in addition to the rights otherwise available to any Indemnified Party by law, charter, statute, bylaw or agreement, and shall operate for the benefit of, and shall be enforceable by, each of the Indemnified Persons, their heirs and their representatives.

## Table of Contents

5.14. Takeover Statute. Iris and the Iris Board and Meadow and the Meadow Board shall use their respective reasonable best efforts to (a) take all action reasonably appropriate to ensure that no state takeover statute or similar statute or regulation is or becomes applicable to this Agreement or the Contemplated Transactions and (b) if any state takeover statute or similar statute or regulation becomes applicable to this Agreement or the Contemplated Transactions, take all action reasonably appropriate to ensure that the Contemplated Transactions may be consummated as promptly as practicable on the terms contemplated by this Agreement and otherwise to eliminate or minimize the effect of such statute or regulation on the Contemplated Transactions.

5.15. Control of Iris's or Meadow's Operations. Nothing contained in this Agreement shall give Meadow or Iris, directly or indirectly, rights to control or direct the operations of the other prior to the Effective Time. Prior to the Effective Time, each of Meadow and Iris shall exercise, consistent with the terms and conditions of this Agreement, complete control and supervision of its operations.

5.16. Directors and Officers; Post-Closing Company Headquarters and Name.

(a) The Parties shall use reasonable best efforts and take all necessary action so that immediately after the Effective Time, (i) the Meadow Board is comprised of 8 members, with 4 such members designated by Meadow, 3 such members designated by Iris (with the Person listed as chair of the Meadow Board in Exhibit D hereto designated by Iris as the chair of the Meadow Board) and 1 such member designated jointly by Meadow and Iris, with each such designee and the class of the Meadow classified board to which such designee is appointed set forth in Exhibit D as modified from time to time in accordance with this Section 5.16(a), and (ii) the Persons listed in Exhibit D hereto under the heading "Officers" are elected or appointed, as applicable, to the positions of officers of Meadow, as set forth therein, to serve in such positions effective as of the Effective Time until successors are duly appointed and qualified in accordance with applicable Law. If any Person listed in Exhibit D is unable or unwilling to serve as an officer of Meadow, as set forth therein, as of the Effective Time, the Parties shall mutually agree upon a successor. The Persons listed in Exhibit D under the heading "Board Designees – Meadow" shall be Meadow's designees pursuant to clause (i) of this Section 5.16(a) (which list may be changed by Meadow at any time prior to the Closing by written notice to Iris to include different board designees who are reasonably acceptable to Iris). The Persons listed in Exhibit D under the heading "Board Designees – Iris" shall be Iris's designees pursuant to clause (i) of this Section 5.16(a) (which list may be changed by Iris at any time prior to the Closing by written notice to Meadow to include different board designees who are reasonably acceptable to Meadow). The Person listed in Exhibit D under the heading "Board Designee – Joint" shall be the member of the Meadow Board jointly designated by Meadow and Iris pursuant to clause (i) of this Section 5.16(a) (which may be changed by mutual agreement of Meadow and Iris at any time prior to the Closing). Each Person listed in Exhibit D under the heading "Committee Chairs" shall be the chair of the committee of the Meadow Board set forth opposite such Person's name, in each case effective as of immediately after the Effective Time. At the Effective Time, the charter of each committee of the Meadow Board shall be amended to affirmatively state that, unless specifically reflected otherwise in the Certificate of Incorporation, the bylaws of Meadow or any other Organizational Document of Meadow, all authority is vested in the full Meadow Board.

(b) At and following the Effective Time, Meadow's principal executive offices shall be located in San Diego, CA.

(c) The name and the ticker symbol of Meadow at and following the Effective Time (which shall be distinct from the Parties' current names) shall be mutually determined by Meadow and Iris prior to filing the Proxy Statement/Prospectus.

5.17. Section 16(b). The board of directors of each of Iris and Meadow (or, in each case, a duly authorized committee thereof) shall, prior to the Effective Time, take all such actions within its control as may be necessary or appropriate to cause the Contemplated Transactions and any other dispositions of equity securities of Iris and acquisitions of equity securities of Meadow (including derivative securities) in connection with the Contemplated

## Table of Contents

Transactions by each individual who is a director or executive officer of Iris or is or may become a director or executive officer of Meadow in connection with the Contemplated Transactions to be exempt under Rule 16b-3 promulgated under the Exchange Act.

5.18. Approval by Sole Stockholder of Merger Sub. Immediately (and in any event with 24 hours) following the execution and delivery of this Agreement by the Parties, Meadow, as sole stockholder of Merger Sub, shall adopt this Agreement and approve the Merger, in accordance with Delaware Law, by written consent.

5.19. Stockholder Litigation. Each Party shall notify the other Party, in writing and promptly after acquiring knowledge thereof, of any litigation related to this Agreement, the Merger or the other Contemplated Transactions that is brought against or, to the Knowledge of Iris or Meadow, threatened against, either Party, either Party's Subsidiaries and/or any of their respective directors or officers and shall keep the other Party informed on a reasonably current basis with respect to the status thereof. Each Party shall provide the other Party (a) the opportunity to participate in the defense of any such Legal Proceedings and (b) the right to review and comment on all material filings or responses to be made by the Parties in connection with any such Legal Proceedings (and the Parties shall in good faith take such comments and other advice into consideration). The Parties agree to cooperate in the defense and settlement of any such litigation, and neither Party shall settle any such litigation without the prior written consent of the other Party (not to be unreasonably withheld, conditioned or delayed), except that such other Party will not be obligated to consent to any settlement that does not include a full release of the litigating Party and such Party's Affiliates or that imposes an injunction or other equitable relief upon the litigating Party or any of its Affiliates. Without limiting in any way the Parties' obligations under Section 5.6, each of Iris and Meadow shall, and shall cause their respective Subsidiaries to, cooperate in the defense or settlement of any litigation contemplated by this Section 5.19.

### 5.20. Tax Treatment.

(a) Each of Meadow and Merger Sub shall use its respective reasonable best efforts to, and cause each of their respective Subsidiaries to, cause the Merger to qualify for the Intended Tax Treatment. Neither Meadow nor Merger Sub shall take any action (or fail to take any action, including failing to use its reasonable best efforts to proscribe any of its respective Subsidiaries from taking any action) that could reasonably be expected to prevent or impede such qualification.

(b) Iris shall use its reasonable best efforts to, and cause its Subsidiaries to, cause the Merger to qualify for the Intended Tax Treatment. Iris shall not take any action (or fail to take any action, including failing to use its reasonable best efforts to proscribe any of its Subsidiaries from taking any action) that could reasonably be expected to prevent or impede such qualification.

(c) Unless otherwise required pursuant to a final "determination" within the meaning of Section 1313(a) of the Code or any analogous provision of applicable state, local or foreign Law, (i) each of the Parties shall report the Merger for U.S. federal income tax purposes as a "reorganization" within the meaning of Section 368(a) of the Code in all Tax Returns, and (ii) none of the Parties shall take any Tax reporting position inconsistent with the characterization of the Contemplated Transactions as a "reorganization" under Section 368(a) of the Code. The Parties to this Agreement adopt this Agreement as a "plan of reorganization" within the meaning of Treasury Regulations Section 1.368-2(g).

(d) If, in connection with the preparation and filing of the Joint Proxy Statement/Prospectus, the Registration Statement or any other filing required by applicable Law or the SEC's review thereof, the SEC requests or requires that a tax opinion with respect to the U.S. federal income tax consequences of the Merger and the Intended Tax Treatment be prepared and submitted (a "Tax Opinion"), (i) Meadow and Iris shall each use their respective reasonable best efforts to deliver to Wilmer Cutler Pickering Hale and Dorr LLP, counsel to Iris, and to Morgan, Lewis & Bockius LLP, counsel to Meadow, customary Tax representation letters satisfactory to each such counsel, dated and executed as of such date(s) as determined to be reasonably necessary by each



## Table of Contents

such counsel in connection with the preparation and filing of such Registration Statement or any other filing required by applicable Law, (ii) Iris shall use its reasonable best efforts to cause Wilmer Cutler Pickering Hale and Dorr LLP to furnish a Tax Opinion addressed to Iris, subject to customary assumptions and limitations, satisfactory to the SEC and (iii) Meadow shall use its reasonable best efforts to cause Morgan, Lewis & Bockius LLP to furnish a Tax Opinion addressed to Meadow, subject to customary assumptions and limitations, satisfactory to the SEC.

(e) Notwithstanding anything to the contrary contained herein, Meadow and Iris each shall pay 50% of all transfer, documentary, sales, use, stamp, registration, value added or other similar Taxes incurred in connection with the Merger, and the portion paid for by Meadow will be treated as a Transaction Expense of Meadow hereunder. The party responsible under applicable Law shall file any necessary Tax Returns with respect to all such Taxes, and, if required by applicable Law, each of Meadow, Iris and their respective Affiliates shall join in the execution of any such Tax Returns.

### 5.21. Employee Matters.

(a) For twelve (12) months following the Closing Date (or, if earlier, until the termination date of a Current Employee, as defined below), Meadow shall, or shall cause the Surviving Company to, maintain for each individual employed by Iris or any of its Subsidiaries at the Effective Time (each, a “**Current Employee**”), to the extent they continue to be employed by Meadow or the Surviving Company: (i) base salary or wage and cash incentive compensation opportunities at least as favorable, as to each element, as that provided to similarly situated employees of Meadow and (ii) benefits, including severance benefits, that are at least as favorable, in the aggregate, to those benefits maintained for and/or provided to similarly situated employees of Meadow.

(b) Meadow shall, and shall cause the Surviving Company to, cause service rendered by each Current Employee to Iris or any of its Subsidiaries (or its or their predecessors) prior to the Effective Time to be taken into account with respect to employee benefit plans of Meadow, any of its Subsidiaries and/or the Surviving Company for purposes of determining eligibility to participate, level of benefits and vesting, to the same extent as such service was taken into account under an Iris Benefit Plan immediately prior to the Effective Time; provided that the foregoing will not apply to the extent that its application would result in a duplication of benefits with respect to the same period of service. Without limiting the generality of the foregoing, for the plan year in which the Effective Time occurs, Meadow shall, or shall cause the Surviving Company to, use commercially reasonable efforts to waive for the Current Employees any eligibility requirements, waiting periods, actively-at-work requirements or pre-existing condition limitations under any health plan of Meadow, any of its Subsidiaries and/or the Surviving Company.

(c) If requested by Meadow, Iris shall, at least one (1) day prior to the Effective Time, (i) adopt written resolutions (or take other necessary and appropriate actions) to terminate each Iris Benefit Plan intended to be qualified under Section 401(a) of the Code (the “**Iris 401(k) Plan**”), (ii) adopt written resolutions (or take other necessary and appropriate actions) to amend the Iris 401(k) Plan to cease any new contributions or transfers to the Iris stock fund thereunder immediately prior to termination of the Iris 401(k) Plan, (iii) cease all contributions to the Iris 401(k) Plan for any compensation paid after such termination date, (iv) one hundred percent (100%) vest all participants under the Iris 401(k) Plan, with such termination, cessation and vesting to be effective no later than the day preceding the Effective Time and (v) provide Meadow with a copy of such resolutions for review and comment at least five (5) business days prior to the Effective Time.

(d) Without limiting the generality of this Section 5.21, no provision of this Agreement (i) prohibits Meadow, Iris or the Surviving Company from amending, modifying or terminating any Iris Benefit Plan or any other benefit or compensation plan, program, contract, agreement, policy or arrangement in a manner that does not conflict with or contravene the obligations of Meadow, Iris, the Surviving Company or any of their respective Affiliates under this Section 5.21, (ii) requires Meadow or the Surviving Company to keep any Person employed or otherwise providing services for any period of time, or (iii) constitutes or shall be construed to constitute the



## Table of Contents

establishment or adoption of, or amendment to, any Iris Benefit Plan or other benefit or compensation plan, program, contract, agreement, policy or arrangement. This Section 5.21 shall not confer upon any Current Employee or any other Person (including any beneficiary or dependent thereof) not a party to this Agreement any third-party beneficiary or similar rights or remedies.

5.22. Obligations of Merger Sub and Surviving Company. Meadow will take all action necessary to cause each of Merger Sub and the Surviving Company to perform their respective obligations under this Agreement before and after the Effective Time.

## **ARTICLE VI CONDITIONS**

6.1. Conditions to Each Party's Obligation to Effect the Merger. The respective obligation of each Party to effect the Merger is subject to the satisfaction or waiver at or prior to the Closing of each of the following conditions:

(a) Stockholder Approvals. (i) The Iris Stockholder Approval shall have been obtained in accordance with applicable Law and Iris's Organizational Documents and (ii) the Meadow Stockholder Approval shall have been obtained in accordance with applicable Law and Meadow's Organizational Documents.

(b) Law; Judgment. No Governmental Entity of competent jurisdiction shall have enacted, issued, promulgated, enforced or entered any Law or Judgment (whether temporary, preliminary or permanent) that is in effect and restrains, enjoins or otherwise prohibits consummation of the Merger.

(c) Registration Statement. The Registration Statement shall have been declared effective by the SEC under the Securities Act and no stop order suspending the effectiveness of the Registration Statement shall have been issued and no proceedings for that purpose shall have been initiated or threatened.

(d) Nasdaq Listing. The existing shares of Meadow Common Stock shall have been continually listed on Nasdaq as of and from the date of this Agreement through the Closing Date, and the shares of Meadow Common Stock issuable in connection with the Merger shall have been approved for listing on The Nasdaq Capital Market, subject to official notice of issuance.

6.2. Conditions to Obligations of Meadow and Merger Sub. The obligations of Meadow and Merger Sub to effect the Merger are also subject to the satisfaction or waiver by Meadow at or prior to the Closing of the following conditions:

(a) Representations and Warranties. The representations and warranties of Iris contained in this Agreement (except for the representations and warranties contained in Sections 3.2(a), 3.3, 3.4 and 3.20) shall be true and correct (without giving effect to any limitation as to "materiality" or "Iris Material Adverse Effect" set forth therein) at and as of the Closing Date as if made at and as of such time (except to the extent expressly made as of an earlier date, in which case as of such earlier date), except where the failure of such representations and warranties to be true and correct (without giving effect to any limitation as to "materiality" or "Iris Material Adverse Effect" set forth therein) would not have an Iris Material Adverse Effect (disregarding for purposes of this Section 6.2(a) clause (2) of the definition thereof); the representations and warranties of Iris contained in Sections 3.2(a), 3.3 (other than the first sentence of each of Section 3.3(a) and 3.3(e)), 3.4, and 3.20 shall be true and correct in all material respects at and as of the Closing Date as if made at and as of such time (except to the extent expressly made as of an earlier date, in which case as of such earlier date); and the representations and warranties of Iris contained in the first sentence of each of Section 3.3(a) and 3.3(e) shall be true and correct in all respects, except for *de minimis* inaccuracies at and as of the Closing Date as if made at and as of such time (except to the extent expressly made as of an earlier date, in which case as of such earlier date).

## Table of Contents

(b) Performance of Obligations of Iris. Iris shall have performed in all material respects all obligations required to be performed by it under this Agreement at or prior to the Closing.

(c) No Iris Material Adverse Effect. After the date of this Agreement, there shall not have occurred and be continuing an Iris Material Adverse Effect.

(d) Iris Certificates. Meadow shall have received at the Closing (1) a certificate signed on behalf of Iris by a senior executive officer of Iris to the effect that the conditions set forth in Sections 6.2(a), (b) and (c) have been satisfied and (2) a complete and duly executed certificate of Iris satisfying the requirements of Treasury Regulation section 1.1445-2(c)(3).

(e) Minimum Iris Net Cash. The Iris Final Net Cash shall have been determined in accordance with Section 2.6 to be greater than or equal to the Iris Minimum Net Cash.

6.3. Conditions to Obligation of Iris. The obligation of Iris to effect the Merger is also subject to the satisfaction or waiver by Iris at or prior to the Closing of the following conditions:

(a) Representations and Warranties. The representations and warranties of Meadow contained in this Agreement (except for the representations and warranties contained in Sections 4.2(a), 4.3, 4.4 and 4.20) shall be true and correct (without giving effect to any limitation as to “materiality” or “Meadow Material Adverse Effect” set forth therein) at and as of the Closing Date as if made at and as of such time (except to the extent expressly made as of an earlier date, in which case as of such earlier date), except where the failure of such representations and warranties to be true and correct (without giving effect to any limitation as to “materiality” or “Meadow Material Adverse Effect” set forth therein) would not have a Meadow Material Adverse Effect (disregarding for purposes of this Section 6.3(a) clause (2) of the definition thereof); the representations and warranties of Meadow contained in Sections 4.2(a), 4.3 (other than the first sentence of Section 4.3(a) and 4.3(e)), 4.4 and 4.20 shall be true and correct in all material respects at and as of the Closing Date as if made at and as of such time (except to the extent expressly made as of an earlier date, in which case as of such earlier date); and the representations and warranties of Meadow contained in the first sentence of Section 4.3(a) and 4.3(e) shall be true and correct in all respects, except for *de minimis* inaccuracies at and as of the Closing Date as if made at and as of such time (except to the extent expressly made as of an earlier date, in which case as of such earlier date).

(b) Performance of Obligations of Meadow and Merger Sub. Each of Meadow and Merger Sub shall have performed in all material respects all obligations required to be performed by it under this Agreement at or prior to the Closing.

(c) No Meadow Material Adverse Effect. After the date of this Agreement, there shall not have occurred and be continuing a Meadow Material Adverse Effect.

(d) Meadow Certificate. Iris shall have received at the Closing a certificate signed on behalf of Meadow by a senior executive officer of Meadow to the effect that the conditions set forth in Sections 6.3(a), (b) and (c) have been satisfied.

(e) Minimum Meadow Net Cash. The Meadow Final Net Cash shall have been determined in accordance with Section 2.5 to be greater than or equal to the Meadow Minimum Net Cash.

6.4. Frustration of Conditions. None of Iris, Meadow or Merger Sub may rely, either as a basis for not consummating the Merger or the other transactions or terminating this Agreement and abandoning the Merger, on the failure of any condition set forth in Sections 6.1, 6.2 or 6.3, as the case may be, to be satisfied if such failure was caused by such Party’s material breach of any provision of this Agreement.

## ARTICLE VII TERMINATION

7.1. Termination by Mutual Consent. This Agreement may be terminated and the Merger may be abandoned at any time prior to the Effective Time, whether before or after satisfaction of the condition referred to in Section 6.1(a), by mutual written consent of Iris and Meadow.

7.2. Termination by Either Meadow or Iris. This Agreement may be terminated and the Merger may be abandoned at any time prior to the Effective Time by either Meadow or Iris if:

(a) the Merger shall not have been consummated by 11:59 p.m. (Eastern Standard time) on August 31, 2023, (the “**Termination Date**”), provided, however, that the right to terminate this Agreement under this Section 7.2(a) shall not be available to any Party whose material breach of any provision of this Agreement has been the cause of, or resulted in, the failure of the Merger to be consummated by the Termination Date;

(b) the Iris Stockholder Approval shall not have been obtained at a meeting duly convened therefor or at any adjournment or postponement thereof at which a vote upon the adoption of this Agreement was taken; provided, however, that the right to terminate this Agreement under this Section 7.2(b) shall not be available to Iris if its material breach of any provision of this Agreement has been the cause of, or resulted in, the failure to obtain the Iris Stockholder Approval;

(c) the Meadow Stockholder Approval shall not have been obtained at a meeting duly convened therefor or at any adjournment or postponement thereof at which a vote upon the Meadow Stock Issuance was taken; provided, however, that the right to terminate this Agreement under this Section 7.2(c) shall not be available to Meadow if its material breach of any provision of this Agreement has been the cause of, or resulted in, the failure to obtain the Meadow Stockholder Approval; or

(d) any Law or Judgment permanently restraining, enjoining or otherwise prohibiting consummation of the Merger shall become final and non-appealable, whether before or after the satisfaction of the condition referred to in Section 6.1(a); provided, however, that the right to terminate this Agreement under this Section 7.2(d) shall not be available to any Party if its material breach of any provision of this Agreement has been the cause of, or resulted in, the failure of the Merger to be consummated.

7.3. Termination by Iris. This Agreement may be terminated and the Merger may be abandoned at any time prior to the Effective Time by Iris if:

(a) at any time prior to the Meadow Stockholder Approval having been obtained, (i) the Meadow Board shall have made a Meadow Change in Recommendation, (ii) Meadow shall have failed to include the Meadow Board Recommendation in the Joint Proxy Statement/Prospectus or (iii) Meadow shall have materially breached or shall have failed to perform in any material respect its obligations set forth in Section 5.2; provided that Iris’s right to terminate this Agreement pursuant to this Section 7.3(a) shall expire upon receipt of the Meadow Stockholder Approval; or

(b) at any time prior to the Effective Time, whether before or after the Iris Stockholder Approval referred to in Section 6.1(a) is obtained, if there has been a breach of any representation, warranty, covenant or agreement made by Meadow or Merger Sub in this Agreement, or any such representation and warranty shall have become untrue after the date of this Agreement, such that any condition set forth in Sections 6.3(a) or 6.3(b), as the case may be, would not be satisfied and such breach or failure to be true is not curable or, if curable, is not cured prior to the earlier of (i) 30 days following notice to Meadow from Iris of such breach or failure and (ii) the date that is one Business Day prior to the Termination Date; provided that Iris shall not have the right to terminate this Agreement pursuant to this Section 7.3(a) if Iris is then in material breach of any of its representations, warranties, covenants or agreements under this Agreement.

## Table of Contents

7.4. Termination by Meadow. This Agreement may be terminated and the Merger may be abandoned at any time prior to the Effective Time by Meadow if:

(a) at any time prior to the Iris Stockholder Approval having been obtained, (i) the Iris Board shall have made an Iris Change in Recommendation, (ii) Iris shall have failed to include the Iris Board Recommendation in the Joint Proxy Statement/Prospectus or (iii) Iris shall have materially breached or shall have failed to perform in any material respect its obligations set forth in Section 5.2; provided that Meadow's right to terminate this Agreement pursuant to this Section 7.4(a) shall expire upon receipt of the Iris Stockholder Approval;

(b) at any time prior to the Effective Time, whether before or after the Meadow Stockholder Approval referred to in Section 6.1(a) is obtained, if there has been a breach of any representation, warranty, covenant or agreement made by Iris in this Agreement, or any such representation and warranty shall have become untrue after the date of this Agreement, such that any condition set forth in Sections 6.2(a) or 6.2(b), as the case may be, would not be satisfied and such breach or failure to be true is not curable or, if curable, is not cured prior to the earlier of (i) 30 days following notice to Iris from Meadow of such breach or failure and (ii) the date that is one Business Day prior to the Termination Date; *provided that* Meadow shall not have the right to terminate this Agreement pursuant to this Section 7.4(b) if Meadow is then in material breach of any of its representations, warranties, covenants or agreements under this Agreement; or

(c) Either of the Clinical Milestones shall not have been completed by the Clinical Milestones Deadline.

### 7.5. Iris Termination Fee and Expense Reimbursement.

(a) In the event that (i) (A) after the date of this Agreement, an Iris Acquisition Proposal shall have been made to Iris and such Iris Acquisition Proposal becomes publicly known prior to the Iris Stockholders' Meeting and, in either case, such Iris Acquisition Proposal shall not have been withdrawn at the time of the Iris Stockholders Meeting, (B) this Agreement is terminated by Iris or Meadow pursuant to Section 7.2(a) or Section 7.2(b), or by Meadow pursuant to Section 7.4(b) and (C) within 12 months after such termination, Iris enters into an Iris Alternative Acquisition Agreement with respect to an Iris Acquisition Proposal or consummates an Iris Acquisition Proposal (solely for purposes of this Section 7.5(i), the references to "15%" in the definition of Iris Acquisition Proposal shall be deemed to be references to "50%"); or (ii) this Agreement is terminated by Meadow pursuant to Section 7.4(a); then Iris shall, within two Business Days after such termination in the case of clause (ii) or within one Business Day after the consummation of an Iris Acquisition Proposal, in the case of clause (i), pay Meadow the Iris Termination Fee. In no event shall Iris be required to pay the Iris Termination Fee on more than one occasion.

(b) If this Agreement is terminated by Meadow pursuant to Section 7.2(b), Section 7.4(a) or Section 7.4(b), Iris shall reimburse Meadow for all reasonable out of pocket fees and expenses incurred by Meadow in connection with this Agreement and the Contemplated Transactions, up to a maximum of \$1,000,000.00, by wire transfer of same day funds within five Business Days following the date on which Meadow submits to Iris true and correct copies of reasonable documentation supporting such expenses.

### 7.6. Meadow Termination Fee and Expense Reimbursement.

(a) In the event that (i) (A) after the date of this Agreement, a Meadow Acquisition Proposal shall have been made to Meadow and such Meadow Acquisition Proposal becomes publicly known prior to the Meadow Stockholders' Meeting and, in either case, such Meadow Acquisition Proposal shall not have been withdrawn at the time of the Meadow Stockholders Meeting, (B) this Agreement is terminated by Meadow or Iris pursuant to Section 7.2(a) or Section 7.2(c), or by Iris pursuant to Section 7.3(b) and (C) within 12 months after such termination, Meadow enters into a Meadow Alternative Acquisition Agreement with respect to a Meadow Acquisition Proposal or consummates a Meadow Acquisition Proposal (solely for purposes of this Section 7.6(i), the references to "15%" in the definition of Meadow Acquisition Proposal shall be deemed to be references to

## Table of Contents

“50%”); or (ii) this Agreement is terminated by Iris pursuant to Section 7.3(a); then Meadow shall, within two Business Days after such termination in the case of clause (ii) or within one Business Day after the consummation of an Meadow Acquisition Proposal in the case of clause (i), pay Iris the Meadow Termination Fee. In no event shall Meadow be required to pay the Meadow Termination Fee on more than one occasion.

(b) If this Agreement is terminated by Iris pursuant to Section 7.2(c), Section 7.3(a) or Section 7.3(b), Meadow shall reimburse Iris for all reasonable out of pocket fees and expenses incurred by Iris in connection with this Agreement and the Contemplated Transactions, up to a maximum of \$1,000,000.00, by wire transfer of same day funds within five Business Days following the date on which Iris submits to Meadow true and correct copies of reasonable documentation supporting such expenses.

7.7. Effect of Termination and Abandonment. In the event of termination of this Agreement and the abandonment of the Merger pursuant to this Article VII, this Agreement (other than as set forth in this Section 7.7 and in Section 8.1) shall become void and of no effect with no liability on the part of any Party (or of any of its respective Representatives); provided that no such termination shall relieve any Party (a) from any liability for Fraud or Willful Breach of this Agreement prior to such termination and (b) from any obligation to pay, if applicable, the Iris Termination Fee pursuant to Section 7.5 or the Meadow Termination Fee pursuant to Section 7.6, as applicable. For purposes of this Agreement, the term “**Willful Breach**” means a deliberate act or a deliberate failure to act, taken or not taken with the actual knowledge that such act or failure to act would, or would reasonably be expected to, result in or constitute a material breach of this Agreement, regardless of whether breaching was the object of the act or failure to act.

### 7.8. Remedies.

(a) Each Party acknowledges that the agreements contained in Sections 7.5 and 7.6 are an integral part of the Contemplated Transactions, and that, without these agreements, no Party would have entered into this Agreement; accordingly, if Iris fails to pay promptly the Iris Termination Fee pursuant to Section 7.5 or Meadow fails to pay promptly the Meadow Termination Fee pursuant to Section 7.6 (each, a “**Termination Fee**”), and, in order to obtain such Termination Fee, the Party entitled to receive such Termination Fee (the “**Recipient**”) commences a suit which results in a judgment against the Party obligated to pay such Termination Fee (the “**Payor**”), the Payor shall pay to the Recipient its costs and expenses (including attorneys’ fees) in connection with such suit, together with interest on such Termination Fee at the prime rate in effect on the date such Termination Fee was required to be paid through the date of full payment thereof.

(b) The Parties agree that the monetary remedies set forth in this and the specific performance remedies set forth in Section 8.13 shall be the sole and exclusive remedies of (i) Iris and its Subsidiaries against Meadow, Merger Sub and any of their respective former, current or future general or limited partners, shareholders, managers, members, Representatives or Affiliates for any loss suffered as a result of the failure of the Merger to be consummated except in the case of Fraud or a Willful Breach of any covenant, agreement or obligation (in which case only Meadow shall be liable for damages for such Fraud or Willful Breach), and upon payment of such amount, none of Meadow, Merger Sub or any of their respective former, current or future general or limited partners, shareholders, managers, members, Representatives or Affiliates shall have any further liability or obligation relating to or arising out of this Agreement or the Contemplated Transactions, except for the liability of Meadow in the case of Fraud or a Willful Breach of any covenant, agreement or obligation; and (ii) Meadow and Merger Sub against Iris and its Subsidiaries and any of their respective former, current or future general or limited partners, shareholders, managers, members, Representatives or Affiliates for any loss suffered as a result of the failure of the Contemplated Transactions to be consummated except in the case of Fraud or a Willful Breach of any covenant, agreement or obligation (in which case only Iris shall be liable for damages for such Fraud or Willful Breach), and upon payment of such amount, none of Iris and its Subsidiaries or any of their respective former, current or future general or limited partners, shareholders, managers, members, Representatives or Affiliates shall have any further liability or obligation relating to or arising out of this Agreement or the Contemplated Transactions, except for the liability of Iris in the case of Fraud or a Willful Breach of any covenant, agreement or obligation.

**ARTICLE VIII  
MISCELLANEOUS AND GENERAL**

8.1. Survival. This Article VIII and the agreements of Iris, Meadow and Merger Sub contained in Section 5.12, Section 5.13 and Section 5.20 shall survive the consummation of the Merger. This Article VIII (other than Section 8.2, Section 8.3 and Section 8.4) and the agreements of Iris, Meadow and Merger Sub contained in Section 5.12, Section 7.5, Section 7.6, Section 7.7, Section 7.8 and the Confidentiality Agreement shall survive the termination of this Agreement. All other representations, warranties, covenants and agreements in this Agreement and in any certificate or other writing delivered pursuant hereto shall not survive the consummation of the Merger or the termination of this Agreement. This Section 8.1 shall not limit any covenant or agreement of the Parties which by its terms contemplates performance after the Effective Time.

8.2. Amendment. This Agreement may be amended with the approval of Iris, Merger Sub and Meadow at any time (whether before or after obtaining the Iris Stockholder Approval or before or after obtaining the Meadow Stockholder Approval); provided, however, that after any such approval of this Agreement by a Party's stockholders, no amendment shall be made which by Law requires further approval of such stockholders without the further approval of such stockholders. This Agreement may not be amended except by an instrument in writing signed on behalf of each of Iris, Merger Sub and Meadow.

8.3. Assignability. This Agreement shall be binding upon, and shall be enforceable by and inure solely to the benefit of, the Parties and their respective successors and permitted assigns; provided, however, that neither this Agreement nor any of a Party's rights or obligations hereunder may be assigned or delegated by such Party without the prior written consent of the other Party, and any attempted assignment or delegation of this Agreement or any of such rights or obligations by such Party without the other Party's prior written consent shall be void and of no effect.

8.4. Waiver.

(a) No failure on the part of any Party to exercise any power, right, privilege or remedy under this Agreement, and no delay on the part of any Party in exercising any power, right, privilege or remedy under this Agreement, shall operate as a waiver of such power, right, privilege or remedy; and no single or partial exercise of any such power, right, privilege or remedy shall preclude any other or further exercise thereof or of any other power, right, privilege or remedy.

(b) No Party shall be deemed to have waived any claim arising out of this Agreement, or any power, right, privilege or remedy under this Agreement, unless the waiver of such claim, power, right, privilege or remedy is expressly set forth in a written instrument duly executed and delivered on behalf of such Party and any such waiver shall not be applicable or have any effect except in the specific instance in which it is given.

8.5. Entire Agreement; Counterparts; Exchanges by Electronic Transmission. This Agreement, the Iris Disclosure Schedule, the Meadow Disclosure Schedule and the other agreements referred to in this Agreement constitute the entire agreement and supersede all prior agreements and understandings, both written and oral, among or between any of the Parties with respect to the subject matter hereof and thereof; provided, however, that the Confidentiality Agreement shall not be superseded and shall remain in full force and effect in accordance with its terms. This Agreement may be executed in several counterparts, each of which shall be deemed an original and all of which shall constitute one and the same instrument. The exchange of a fully executed Agreement (in counterparts or otherwise) by all Parties by electronic transmission in .PDF format shall be sufficient to bind the Parties to the terms and conditions of this Agreement.

8.6. Governing Law and Venue; Waiver of Jury Trial. This Agreement shall be governed by, and construed in accordance with, the Laws of the State of Delaware, regardless of the Laws that might otherwise govern under

## Table of Contents

applicable principles of conflicts of laws. In any action or proceeding between any of the Parties arising out of or relating to this Agreement or any of the Contemplated Transactions, each of the Parties: (a) irrevocably and unconditionally consents and submits to the exclusive jurisdiction and venue of the Court of Chancery of the State of Delaware located in New Castle County or, to the extent such court does not have subject matter jurisdiction, the United States District Court for the District of Delaware or, to the extent that neither of the foregoing courts has jurisdiction, the Superior Court of the State of Delaware; (b) agrees that all claims in respect of such action or proceeding shall be heard and determined exclusively in accordance with clause (a) of this Section 8.6; (c) waives any objection to laying venue in any such action or proceeding in such courts; (d) waives any objection that such courts are an inconvenient forum or do not have jurisdiction over any Party; and (e) agrees that service of process upon such Party in any such action or proceeding shall be effective if notice is given in accordance with Section 8.7 of this Agreement. EACH PARTY ACKNOWLEDGES AND AGREES THAT ANY ACTION OR PROCEEDING WHICH MAY ARISE UNDER THIS AGREEMENT IS LIKELY TO INVOLVE COMPLICATED AND DIFFICULT ISSUES, AND THEREFORE IT HEREBY IRREVOCABLY AND UNCONDITIONALLY WAIVES ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN RESPECT OF ANY ACTION OR PROCEEDING DIRECTLY OR INDIRECTLY ARISING OUT OF OR RELATING TO THIS AGREEMENT AND ANY OF THE AGREEMENTS DELIVERED IN CONNECTION HERewith, OR THE TRANSACTIONS CONTEMPLATED HEREBY OR THEREBY. EACH PARTY CERTIFIES AND ACKNOWLEDGES THAT (I) NO REPRESENTATIVE, AGENT OR ATTORNEY OF ANY OTHER PARTY HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT SUCH OTHER PARTY WOULD NOT, IN THE EVENT OF ANY ACTION OR PROCEEDING, SEEK TO ENFORCE EITHER OF SUCH WAIVERS, (II) IT UNDERSTANDS AND HAS CONSIDERED THE IMPLICATIONS OF SUCH WAIVERS, (III) IT MAKES SUCH WAIVERS VOLUNTARILY AND (IV) IT HAS BEEN INDUCED TO ENTER INTO THIS AGREEMENT BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS SECTION 8.6.

8.7. Notices. All notices and other communications hereunder shall be in writing and shall be deemed to have been duly delivered and received hereunder (a) one (1) Business Day after being sent for next Business Day delivery, fees prepaid, via a reputable international overnight courier service, (b) upon delivery in the case of delivery by hand, or (c) on the date delivered in the place of delivery if sent by email (if no automated notice of delivery failure is received by the sender) prior to 5:00 p.m. New York time, otherwise on the next succeeding Business Day, in each case to the intended recipient as set forth below:

if to Meadow or Merger Sub

MEI Pharma, Inc.  
11455 El Camino Real Suite 250  
San Diego, CA 92130  
Attention: Daniel P. Gold and David M. Urso  
Email: dgold@meipharma.com; urso@meipharma.com

with copies to (which shall not constitute notice):

Morgan, Lewis & Bockius LLP  
101 Park Avenue  
New York, NY 10178  
Attention: Steven A. Navarro and Robert W. Dickey  
Email: steven.navarro@morganlewis.com; robert.dickey@morganlewis.com

if to Iris

Infinity Pharmaceuticals, Inc.  
1100 Massachusetts Avenue, Floor 4  
Cambridge, Massachusetts 02138  
Attention: General Counsel  
Email: Seth.Tasker@infi.com



## Table of Contents

with copies to (which shall not constitute notice):

WilmerHale LLP  
60 State Street  
Boston, MA 02109  
Attention: Hal J. Leibowitz, Cynthia Mazareas and Michael Gilligan  
Email: hal.leibowitz@wilmerhale.com; cynthia.mazareas@wilmerhale.com;  
michael.gilligan@wilmerhale.com

or to such other persons or addresses as may be designated in writing by the Party to receive such notice as provided above.

8.8. No Third Party Beneficiaries. This Agreement is not intended to, and does not, confer upon any Person other than Parties any rights or remedies hereunder, other than (a) the Indemnified Persons as provided in Section 5.13, (b) the right of Iris's stockholders to receive the Merger Consideration after the Closing and (c) the rights of Iris's other equityholders pursuant to Section 2.3.

8.9. Severability. Any term or provision of this Agreement that is invalid or unenforceable in any situation in any jurisdiction shall not affect the validity or enforceability of the remaining terms and provisions of this Agreement or the validity or enforceability of the offending term or provision in any other situation or in any other jurisdiction. If a final judgment of a court of competent jurisdiction declares that any term or provision of this Agreement is invalid or unenforceable, the Parties agree that the court making such determination shall have the power to limit such term or provision, to delete specific words or phrases or to replace such term or provision with a term or provision that is valid and enforceable and that comes closest to expressing the intention of the invalid or unenforceable term or provision, and this Agreement shall be valid and enforceable as so modified.

8.10. No Other Representations and Warranties.

(a) Except for the representations and warranties of Iris contained in Article III, Meadow and Merger Sub acknowledge that neither Iris nor any of its Subsidiaries is making and has not made, and no other Person is making or has made on behalf of Iris or any of its Subsidiaries, any express or implied representation or warranty in connection with this Agreement or the Contemplated Transactions. Neither Meadow nor Merger Sub is relying and neither Meadow nor Merger Sub has relied on any representations or warranties whatsoever regarding the subject matter of this Agreement, express or implied, except for the representations and warranties in Article III, including the Iris Disclosure Schedule. Such representations and warranties by Iris constitute the sole and exclusive representations and warranties of Iris and its Subsidiaries in connection with the Contemplated Transactions and each of Meadow and Merger Sub understands, acknowledges and agrees that all other representations and warranties of any kind or nature whether express, implied or statutory are specifically disclaimed by Iris and its Subsidiaries.

(b) Except for the representations and warranties of Meadow and Merger Sub contained in Article IV, Iris acknowledges that neither Meadow nor Merger Sub is making or has made, and no other Person is making or has made on behalf of the Meadow or Merger Sub, any express or implied representation or warranty in connection with this Agreement or the Contemplated Transactions. Iris is not relying and it has not relied on any representations or warranties whatsoever regarding the subject matter of this Agreement, express or implied, except for the representations and warranties in Article IV, including the Meadow Disclosure Schedule. Such representations and warranties by Meadow and Merger Sub constitute the sole and exclusive representations and warranties of Meadow and Merger Sub in connection with the Contemplated Transactions and Iris understands, acknowledges and agrees that all other representations and warranties of any kind or nature whether express, implied or statutory are specifically disclaimed by Meadow.



8.11. Construction.

(a) References to “cash,” “dollars” or “\$” are to U.S. dollars.

(b) For purposes of this Agreement, whenever the context requires: the singular shall include the plural, and vice versa; the masculine gender shall include the feminine and neuter genders; the feminine gender shall include the masculine and neuter genders; and the neuter gender shall include masculine and feminine genders.

(c) The Parties have participated jointly in the negotiating and drafting of this Agreement and agree that any rule of construction to the effect that ambiguities are to be resolved against the drafting Party shall not be applied in the construction or interpretation of this Agreement, and no presumption or burden of proof shall arise favoring or disfavoring any Party by virtue of the authorship of any provision of this Agreement.

(d) As used in this Agreement, the words “include” and “including,” and variations thereof, shall not be deemed to be terms of limitation, but rather shall be deemed to be followed by the words “without limitation.”

(e) The words “hereof,” “herein” and “hereunder” and words of similar import, when used in this Agreement, refer to this Agreement as a whole and not to any particular provision of this Agreement.

(f) References herein to a Person are also to such Person’s successors and permitted assigns.

(g) Unless otherwise specifically provided for herein, the term “or” will not be deemed to be exclusive.

(h) Except as otherwise indicated, all references in this Agreement to “Sections,” “Exhibits” and “Schedules” are intended to refer to Sections of this Agreement and Exhibits and Schedules to this Agreement, respectively. Any capitalized terms used in any Exhibits or Schedules but not otherwise defined therein have the meanings ascribed to such terms as in this Agreement.

(i) Any reference to legislation or to any provision of any legislation shall include any modification, amendment, re-enactment thereof, any legislative provision substituted therefore and all rules, regulations, and statutory instruments issued or related to such legislations.

(j) The headings and table of contents contained in this Agreement are for convenience of reference only, shall not be deemed to be a part of this Agreement and shall not be referred to in connection with the construction or interpretation of this Agreement.

(k) The Parties agree that each of the Iris Disclosure Schedule and the Meadow Disclosure Schedule shall be arranged in sections and subsections corresponding to the numbered and lettered sections and subsections contained in this Agreement. The disclosures in any section or subsection of the Iris Disclosure Schedule or the Meadow Disclosure Schedule shall qualify other sections and subsections in this Agreement to the extent it is readily apparent on its face from a reading of the disclosure that such disclosure is applicable to such other sections and subsections.

(l) The phrase “made available” means, with respect to any documentation, that (i) a copy of such material has been posted to and made available by a Party to the other Party and its Representatives in the electronic data room maintained by such disclosing Party prior to 11:59 p.m. (New York time) on the date that is one calendar day prior to the date of this Agreement, (ii) a copy of such material has been delivered directly to the other Party’s counsel or (iii) such material is disclosed in the Iris SEC Documents or the Meadow SEC Documents filed with the SEC prior to the date hereof and publicly made available on the SEC’s Electronic Data Gathering Analysis and Retrieval system.

(m) Whenever the last day for the exercise of any privilege or the discharge of any duty hereunder shall fall upon a day that is not a Business Day, the Party having such privilege or duty may exercise such privilege or discharge such duty on the next succeeding day which is a regular Business Day.

8.12. Certain Definitions: For the purposes of this Agreement:

(a) An “**Affiliate**” of any Person means another Person that directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with, such first Person. For purposes of this definition, “control,” when used with respect to any specified Person, means the power to direct or cause the direction of the management and policies of such Person, directly or indirectly, whether through ownership of voting securities or by Contract or otherwise, and the terms “controlling” and “controlled by” have correlative meanings to the foregoing.

(b) “**Anti-Bribery Laws**” means the FCPA, as amended, any rules or regulations thereunder, or any other applicable United States or foreign anti-corruption or anti-bribery laws or regulations.

(c) “**Business Day**” means any day other than a Saturday, Sunday or other day on which banks in New York, New York are authorized or obligated by Law to be closed.

(d) “**CARES Act**” means the Coronavirus Aid, Relief, and Economic Security Act and any similar or successor legislation in effect as of the Effective Time, including any presidential memoranda or executive orders, relating to the COVID-19 pandemic, as well as any applicable guidance (including IRS Notice 2020-65, 2020-38 IRB) issued thereunder or relating thereto.

(e) “**Confidentiality Agreement**” means the confidentiality agreement entered into between Iris and Meadow on October 4, 2022.

(f) “**Consent**” means consent, approval, ratification, permission, authorization, clearance, waiver, permit or order.

(g) “**Contemplated Transactions**” means the Merger, the Meadow Share Issuance and the other transactions and actions contemplated by this Agreement.

(h) “**Contract**” means any written, oral or other agreement, contract, subcontract, lease, instrument, note, option, warranty, purchase order, license, sublicense, insurance policy, benefit plan or legally binding commitment, understanding, arrangement or undertaking of any nature.

(i) “**Data Protection Legislation**” means the UK Data Protection Act 1998, the UK Data Protection Act 2018, the GDPR, PECR and all other data protection, data security and privacy laws.

(j) “**Data Subject**” means the meaning as provided under Article 4 of the GDPR.

(k) “**Effect**” means any effect, change, event or development.

(l) “**Environmental Laws**” means any Law concerning or relating to pollution or protection of the environment or natural resources, or protection of human health and safety as related to exposure to any harmful or deleterious substances.

(m) “**ERISA**” means the Employee Retirement Income Security Act of 1974, as amended.

(n) “**Exchange Act**” means the Securities Exchange Act of 1934, as amended.

(o) “**Exchange Ratio**” means 1.0449.

(p) “**FCPA**” means the Foreign Corrupt Practices Act of 1977, as amended.

(q) “**FDA**” means the U.S. Food and Drug Administration or any successor Governmental Entity thereto.

## Table of Contents

(r) “**FDCA**” means the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et seq.), as amended, and the regulations promulgated thereunder.

(s) “**Fraud**” means, with respect to a Party, an actual and intentional misrepresentation, deceit or concealment of fact made by such Party with respect to the making of the representations and warranties of such Party as expressly set forth in [Article III](#) or [Article IV](#), as applicable, of this Agreement, with the intent to induce the other Party to rely on such misrepresentation, deceit or concealment of fact and act or fail to act to such other Party’s detriment, on which such other Party justifiably relies and subsequently justifiably acts or fails to act in a manner that results in actual material losses to such other Party; provided that, actual and intentional misrepresentation, deceit or concealment of fact of a Party specifically excludes any misrepresentation, deceit or concealment of fact made negligently or recklessly.

(t) “**GAAP**” means United States generally accepted accounting principles.

(u) “**GDPR**” means the EU General Data Protection Regulation 2016/679 including the UK implementation of this Regulation under section 3 of the UK European Union (Withdrawal) Act 2018.

(v) “**Governmental Authorization**” means any: (i) permit, license, certificate, franchise, permission, variance, exception, exemption, approval, order, clearance, registration, qualification or authorization issued, granted, given or otherwise made available by or under the authority of any Governmental Entity or pursuant to any Law; or (ii) right under any Contract with any Governmental Entity.

(w) “**Governmental Entity**” means any (i) nation, state, commonwealth, province, territory, county, municipality, district or other jurisdiction of any nature; (ii) federal, state, local, municipal, foreign or other government; (iii) governmental or quasi-governmental authority of any nature (including any governmental division, department, agency, commission, bureau, instrumentality, official, ministry, fund, foundation, center, organization, unit, body or entity and any court or other tribunal, and for the avoidance of doubt, any taxing authority); or (iv) self-regulatory organization (including FINRA and Nasdaq).

(x) “**Hazardous Materials**” means any substance, material or waste that is listed, defined or otherwise characterized as “hazardous”, “toxic”, “radioactive” or a “pollutant”, or “contaminant” or terms of similar meaning or effect under any Environmental Law, including petroleum or its by-products, asbestos and polychlorinated biphenyls.

(y) “**Indebtedness**” means, with respect to any Person, without duplication, (i) all obligations of such Person for borrowed money, or with respect to deposits or advances of any kind to such Person, including related prepayment fees, final fees or other similar fees, (ii) all obligations of such Person evidenced by bonds, debentures, notes or similar instruments, (iii) all capitalized lease obligations of such Person or obligations of such Person to pay the deferred and unpaid purchase price of property and equipment, (iv) all obligations of such Person pursuant to securitization or factoring programs or arrangements, (v) all guarantees and arrangements having the economic effect of a guarantee of such Person of any debt of any other Person (other than any guarantee by a Party with respect to debt of such Party or any wholly owned Subsidiary of such Party), (vi) net cash payment obligations of such Person under swaps, options, derivatives and other hedging agreements or arrangements that will be payable upon termination thereof (assuming they were terminated on the date of determination), (vii) letters of credit, bank guarantees, and other similar contractual obligations entered into by or on behalf of such Person, (viii) obligations in respect of banker’s acceptances or (ix) obligations representing the balance deferred and unpaid of the purchase price of any property or services due more than one year after such property is acquired or such services are completed. In addition, the term “Indebtedness” includes all Indebtedness of others secured by a Lien on any asset of the specified Person (whether or not such Indebtedness is assumed by the specified Person) and, to the extent not otherwise included, the guarantee by the specified Person of any Indebtedness of any other Person. Indebtedness will be calculated without giving effect to the effects of Statement of Financial Accounting Standards No. 133 and related interpretations to the extent such

## Table of Contents

effects would otherwise increase or decrease an amount of Indebtedness for any purpose under the indenture as a result of accounting for any embedded derivatives created by the terms of such Indebtedness.

(z) “**Intellectual Property Rights**” means all rights of the following types, which may exist or be created under the laws of any jurisdiction in the world: (i) rights associated with works of authorship, including exclusive exploitation rights, copyrights, moral rights, software, databases, and mask works; (ii) trademarks, service marks, trade dress, logos, trade names and other source identifiers, domain names and URLs and similar rights and any goodwill associated therewith; (iii) rights associated with trade secrets, know how, inventions, invention disclosures, methods, processes, protocols, specifications, techniques and other forms of technology; (iv) patents and industrial property rights; (v) other proprietary rights in intellectual property of every kind and nature; (vi) rights of privacy and publicity; and (vii) all registrations, renewals, extensions, statutory invention registrations, provisionals, utility applications, continuations, continuations-in-part, divisionals, or reissues of, and applications for, any of the rights referred to in clauses “(i)” through “(vi)” above (whether or not in tangible form and including all tangible embodiments of any of the foregoing, such as samples, studies and summaries), along with all rights to prosecute and perfect the same through administrative prosecution, registration, recordation or other administrative proceeding, and all causes of action and rights to sue or seek other remedies arising from or relating to the foregoing.

(aa) “**Iris Affiliate**” means any Person under common control with any of Iris or any of its Subsidiaries within the meaning of Section 414(b), Section 414(c), Section 414(m) or Section 414(o) of the Code, and the regulations issued thereunder.

(bb) “**Iris Associate**” means any current or former officer, employee, independent contractor, consultant or director, of or to Iris or any of its Subsidiaries or any controlled Iris Affiliate.

(cc) “**Iris Benefit Plan**” means each (i) “employee benefit plan” as defined in Section 3(3) of ERISA and (ii) other pension, retirement, supplemental retirement, deferred compensation, excess benefit, profit sharing, bonus, stock option, stock purchase, stock ownership, restricted stock, incentive, equity or equity-based, phantom equity, employment, consulting, severance, change-of-control, retention, health, medical, life, disability, group insurance, paid-time off, holiday, welfare and fringe benefit plan, program, agreement, contract, or arrangement (whether written or unwritten, qualified or nonqualified, funded or unfunded and including any that have been frozen or terminated), in any case, sponsored, maintained, contributed to, or required to be contributed to, by Iris or any of its Subsidiaries for the benefit of any current or former employee, director, officer, consultant or independent contractor of Iris or any of its Subsidiaries or under which Iris or any of its Subsidiaries has any actual or contingent liability (including as to the result of it being treated as a single employer under Section 414 of the Code with any other Person).

(dd) “**Iris Capital Stock**” means Iris Common Stock, together with Iris Preferred Stock.

(ee) “**Iris Closing Price**” means the volume weighted average closing trading price of a share of Iris Common Stock for the five consecutive trading days ending five trading days immediately prior to the date upon which the Merger becomes effective.

(ff) “**Iris Contract**” means any Contract: (i) to which Iris or any of its Subsidiaries is a party; (ii) by which Iris or any of its Subsidiaries or any Iris IP or any other asset of Iris or its Subsidiaries is or may become bound or under which Iris or any of its Subsidiaries has, or may become subject to, any obligation; or (iii) under which Iris or any of its Subsidiaries has or may acquire any right or interest.

(gg) “**Iris ERISA Affiliate**” means any corporation or trade or business (whether or not incorporated) which is (or at any relevant time was) treated with Iris or any of its Subsidiaries as a single employer within the meaning of Section 414 of the Code.

(hh) “**Iris ESPP**” means the Iris 2013 Employee Stock Purchase Plan, as amended.

## Table of Contents

(ii) “**Iris Inducement Grant**” means any option to purchase Shares or any restricted stock unit made in the form of inducement awards pursuant to NASDAQ Stock Market Rule 5635(c)(4) outside of the Iris Stock Incentive Plans and not approved by security holders of Iris.

(jj) “**Iris IP**” means Iris Owned IP and Iris Licensed IP.

(kk) “**Iris Licensed IP**” means all Intellectual Property Rights that are exclusively licensed to Iris or any of its Subsidiaries and cover the Iris Products.

(ll) “**Iris Material Adverse Effect**” means any Effect that, individually or in the aggregate with all other Effects, (1) materially adversely affects or would reasonably be expected to materially adversely affect the business, financial condition or results of operations of Iris and its Subsidiaries, taken as a whole, or (2) would reasonably be expected to prevent the consummation of the Contemplated Transactions by Iris, excluding, in the case of clause (1), any Effect to the extent that, either alone or in combination, it results from or arises out of (i) general business or economic conditions generally affecting the industry in which Iris and its Subsidiaries operate, (ii) political conditions, acts of war, the outbreak or escalation of armed hostilities, acts of terrorism, earthquakes, wildfires, hurricanes, tsunamis, folds, mudslides, weather conditions, other natural disasters, man-made disasters, health and other emergencies, calamities, epidemics, pandemics (including COVID-19 and any evolutions or mutations thereof), disease outbreaks, other acts of God or force majeure events, (iii) changes in financial, banking or securities markets, including changes in interest rates in the United States or any other country or region in the world and changes in exchange rates for the currencies of any countries and any suspension of trading in securities (whether equity, debt, derivative or hybrid securities) generally on any securities exchange or over-the-counter market operating in the United States or any other country or region in the world, (iv) COVID-19 Measures and Responses, (v) any change in, or any compliance with or action taken for the purpose of complying with, any Law or GAAP (or interpretations of any Law or GAAP), (vi) any change in the stock price or trading volume of Iris Common Stock (it being understood, however, that any Effect causing or contributing to any change in stock price or trading volume of Iris Common Stock may be taken into account in determining whether an Iris Material Adverse Effect has occurred, unless such Effects are otherwise excepted from this definition), (vii) the failure of Iris to meet internal or analysts’ expectations or projections or the results of operations of Iris (it being understood, however, that any Effect causing or contributing to the failure of Iris to meet internal or analysts’ expectations or projections or the results of operations of Iris may be taken into account in determining whether an Iris Material Adverse Effect has occurred, unless such Effects are otherwise excepted from this definition), (viii) the announcement of this Agreement or the pendency of the Contemplated Transactions, including (A) the identity of Meadow, (B) the loss or departure of officers or other employees of Iris or any of its Subsidiaries directly or indirectly resulting from, arising out of, attributable to, or related to the Contemplated Transactions and (C) any other negative development (or potential negative development) in the relationships of Iris or any of its Subsidiaries with business partners, whether as a direct or indirect result of the loss or departure of officers or employees of Iris or any of its Subsidiaries or otherwise, directly or indirectly resulting from, arising out of, attributable to, or related to the Contemplated Transactions, (ix) any actions taken or failure to take action, in each case, to which Iris has provided its prior written consent; or compliance with the terms of, or the taking of any action required or contemplated by, this Agreement; or the failure to take any action prohibited by this Agreement, (x) any product candidate of Iris or any of its Subsidiaries, including any change, event, circumstance or development relating to the use or sale of any such product candidate, the suspension, rejection, refusal of, request to refile or any delay in obtaining or making any regulatory application or filing relating to any such product candidate, any other negative actions, requests, recommendations or decisions of the FDA or any other Governmental Entity relating to any such product candidate, any other regulatory development affecting any such product candidate, or the failure to conduct successful clinical trials on a timely basis for any such product candidate; (xi) any product or product candidate of any Person (other than Iris and its Subsidiaries), including the entry into the market of any product competitive with any product or product candidate of Iris or any of its Subsidiaries; (xii) any clinical trials or studies undertaken by any Person, and any negative publicity or unfavorable media attention resulting therefrom; (xiii) any fees or expenses incurred in connection with the Contemplated Transactions, or (xiv) any Legal Proceedings made or brought by

## Table of Contents

any of the current or former stockholders of Iris (on their own behalf or on behalf of Iris) against Iris, Merger Sub, Meadow or any of their directors or officers, including Legal Proceedings arising out of the Merger or in connection with any other Contemplated Transactions; except, in each case, with respect to clauses (i) through (v), to the extent disproportionately affecting Iris and its Subsidiaries, taken as a whole, relative to other similarly situated companies in the industries in which Iris and its Subsidiaries operate.

(mm) “**Iris Minimum Net Cash**” means (a) if the Closing occurs on or before June 30, 2023, \$4,000,000.00, (b) if the Closing occurs after June 30, 2023 but on or before July 31, 2023, \$3,000,000.00 and (c) if the Closing occurs after July 31, 2023 but on or before August 31, 2023, \$2,000,000.00.

(nn) “**Iris Option**” means any option to purchase Shares (whether granted under the Iris Stock Incentive Plans or as an Iris Inducement Grant, assumed by Iris in connection with any merger, acquisition or similar transaction or otherwise issued or granted), but excluding the options granted pursuant to the Iris ESPP.

(oo) “**Iris Owned IP**” means all Intellectual Property Rights that are owned by Iris or any of its Subsidiaries that cover the Iris Products.

(pp) “**Iris RSU**” means any Iris restricted stock unit (whether granted under the Iris Stock Incentive Plans or as an Iris Inducement Grant, assumed by Iris in connection with any merger, acquisition or similar transaction or otherwise issued or granted).

(qq) “**Iris Termination Fee**” means \$2,900,000.

(rr) “**Iris Warrant**” means any warrant to purchase shares of Iris Capital Stock.

(ss) “**Judgment**” means any judgment, order, injunction, ruling, writ award or decree of any Governmental Entity.

(tt) “**Knowledge**” of any Person means, in the case of Meadow, the actual knowledge of any of the Persons set forth on Section 8.12(tt) of the Meadow Disclosure Schedule after reasonable inquiry of such Person’s direct reports who would reasonably be expected to have information with respect to the subject matter thereof and, in the case of Iris, the actual knowledge of any of the Persons set forth on Section 8.12(tt) of the Iris Disclosure Schedule after reasonable inquiry of such Person’s direct reports who would reasonably be expected to have information with respect to the subject matter thereof.

(uu) “**Law**” means any federal, state, local, foreign or transnational law, statute, regulation, ordinance, common law, ruling, writ, award or decree of any Governmental Entity.

(vv) “**Legal Proceeding**” means any action, suit, litigation, arbitration, proceeding (including any civil, criminal, administrative, investigative or appellate proceeding), hearing, inquiry, audit, examination or investigation commenced, brought, conducted or heard by or before any court or other Governmental Entity or any arbitrator or arbitration panel.

(ww) “**Liens**” means pledges, liens, charges, mortgages, deeds of trust, encumbrances and security interests of any kind or nature whatsoever.

(xx) “**Meadow Affiliate**” means any Person under common control with the Meadow within the meaning of Section 414(b), Section 414(c), Section 414(m) or Section 414(o) of the Code, and the regulations issued thereunder.

(yy) “**Meadow Associate**” means any current or former officer, employee, independent contractor, consultant or director, of or to the Meadow or any of its Subsidiaries or any controlled Meadow Affiliate.

## Table of Contents

(zz) “**Meadow Benefit Plan**” means each (i) “employee benefit plan” as defined in Section 3(3) of ERISA and (ii) other pension, retirement, supplemental retirement, deferred compensation, excess benefit, profit sharing, bonus, stock option, stock purchase, stock ownership, restricted stock, incentive, equity or equity-based, phantom equity, employment consulting, severance, change-of-control, retention, health, medical, life, disability, group insurance, paid-time off, holiday, welfare and fringe benefit plan, program, agreement, contract, or arrangement (whether written or unwritten, qualified or nonqualified, funded or unfunded and including any that have been frozen or terminated), in any case, sponsored, maintained, contributed to, or required to be contributed to, by Meadow or any of its Subsidiaries for the benefit of any current or former employee, director, officer, consultant or independent contractor of Meadow or any of its Subsidiaries or under which Meadow or any of its Subsidiaries has any actual or contingent liability (including as to the result of it being treated as a single employer under Section 414 of the Code with any other Person).

(aaa) “**Meadow Closing Price**” means the volume weighted average closing trading price of a share of Meadow Common Stock for the five consecutive trading days ending five trading days immediately prior to the date upon which the Merger becomes effective.

(bbb) “**Meadow Contract**” means any Contract: (i) to which Meadow or any of its Subsidiaries is a party; (ii) by which Meadow or any of its Subsidiaries or any Meadow IP or any other asset of Meadow or its Subsidiaries is or may become bound or under which Meadow or any of its Subsidiaries has, or may become subject to, any obligation; or (iii) under which Meadow or any of its Subsidiaries has or may acquire any right or interest.

(ccc) “**Meadow ERISA Affiliate**” means any corporation or trade or business (whether or not incorporated) which is (or at any relevant time was) treated with Meadow or any of its Subsidiaries as a single employer within the meaning of Section 414 of the Code.

(ddd) “**Meadow IP**” means Meadow Owned IP and Meadow Licensed IP.

(eee) “**Meadow Licensed IP**” means all Intellectual Property Rights that are exclusively licensed to Meadow or any of its Subsidiaries and cover the Meadow Product.

(fff) “**Meadow Material Adverse Effect**” means any Effect that, individually or in the aggregate with all other Effects, (1) materially adversely affects or would reasonably be expected to materially adversely affect the business, financial condition or results of operations of Meadow and its Subsidiaries, taken as a whole, or (2) would reasonably be expected to prevent the consummation of the Contemplated Transactions by Meadow, excluding, in the case of Clause (1), any Effect to the extent that, either alone or in combination, it results from or arises out of (i) general business or economic conditions generally affecting the industry in which Meadow and its Subsidiaries operate, (ii) political conditions, acts of war, the outbreak or escalation of armed hostilities, acts of terrorism, earthquakes, wildfires, hurricanes, tsunamis, folds, mudslides, weather conditions, other natural disasters, man-made disasters, health and other emergencies, calamities, epidemics, pandemics (including COVID-19 and any evolutions or mutations thereof), disease outbreaks, other acts of God or force majeure events, (iii) changes in financial, banking or securities markets, including changes in interest rates in the United States or any other country or region in the world and changes in exchange rates for the currencies of any countries and any suspension of trading in securities (whether equity, debt, derivative or hybrid securities) generally on any securities exchange or over-the-counter market operating in the United States or any other country or region in the world, (iv) COVID-19 Measures and Responses, (v) any change in, or any compliance with or action taken for the purpose of complying with, any Law or GAAP (or interpretations of any Law or GAAP), (vi) any change in the stock price or trading volume of Meadow Common Stock (it being understood, however, that any Effect causing or contributing to any change in stock price or trading volume of Meadow Common Stock may be taken into account in determining whether a Meadow Material Adverse Effect has occurred, unless such Effects are otherwise excepted from this definition), (vii) the failure of Meadow to meet internal or analysts’ expectations or projections or the results of operations of Meadow (it being understood,



## Table of Contents

however, that any Effect causing or contributing to the failure of Meadow to meet internal or analysts' expectations or projections or the results of operations of Meadow may be taken into account in determining whether a Meadow Material Adverse Effect has occurred, unless such Effects are otherwise excepted from this definition), (viii) the announcement of this Agreement or the pendency of the Contemplated Transactions, including (A) the identity of Iris, (B) the loss or departure of officers or other employees of Meadow or any of its Subsidiaries directly or indirectly resulting from, arising out of, attributable to, or related to the Contemplated Transactions and (C) any other negative development (or potential negative development) in the relationships of Meadow or any of its Subsidiaries with business partners, whether as a direct or indirect result of the loss or departure of officers or employees of Meadow or any of its Subsidiaries or otherwise, directly or indirectly resulting from, arising out of, attributable to, or related to the Contemplated Transactions, (ix) any actions taken or failure to take action, in each case, to which Meadow has provided its prior written consent; or compliance with the terms of, or the taking of any action required or contemplated by, this Agreement; or the failure to take any action prohibited by this Agreement, (x) any product candidate of Meadow or any of its Subsidiaries, including any change, event, circumstance or development relating to the use or sale of any such product candidate, the suspension, rejection, refusal of, request to refile or any delay in obtaining or making any regulatory application or filing relating to any such product candidate, any other negative actions, requests, recommendations or decisions of the FDA or any other Governmental Entity relating to any such product candidate, any other regulatory development affecting any such product candidate, or the failure to conduct successful clinical trials on a timely basis for any such product candidate; (xi) any product or product candidate of any Person (other than Meadow and its Subsidiaries), including the entry into the market of any product competitive with any product or product candidate of Meadow or any of its Subsidiaries; (xii) any clinical trials or studies undertaken by any Person, and any negative publicity or unfavorable media attention resulting therefrom; (xiii) any fees or expenses incurred in connection with the Contemplated Transactions, or (xiv) any Legal Proceedings made or brought by any of the current or former stockholders of Meadow (on their own behalf or on behalf of Meadow) against Meadow, Merger Sub, Iris or any of their directors or officers, including Legal Proceedings arising out of the Merger or in connection with any other Contemplated Transactions; except, in each case, with respect to clauses (i) through (v), to the extent disproportionately affecting Meadow and its Subsidiaries, taken as a whole, relative to other similarly situated companies in the industries in which Meadow and its Subsidiaries operate.

(ggg) "**Meadow Minimum Net Cash**" means (a) if the Closing occurs on or before June 30, 2023, \$80,000,000.00, (b) if the Closing occurs after June 30, 2023 but on or before July 31, 2023, \$78,000,000.00 and (c) if the Closing occurs after July 31, 2023 but on or before August 31, 2023, \$76,000,000.00.

(hhh) "**Meadow Option**" means any option to purchase Meadow Common Stock (whether granted under any Meadow Stock Plan, assumed by the Meadow in connection with any merger, acquisition or similar transaction or otherwise issued or granted).

(iii) "**Meadow Owned IP**" means all Intellectual Property Rights that are owned by Meadow or any of its Subsidiaries that cover the Meadow Product.

(jjj) "**Meadow Termination Fee**" means \$4,000,000.

(kkk) "**Meadow Warrants**" means any warrants to purchase capital stock of Meadow including those listed on Section 4.3(a) of the Meadow Disclosure Schedule.

(lll) "**Nasdaq**" means the National Association of Securities Dealers Automatic Quotation System.

(mmm) "**Net Cash**" means with respect to each party as of the Cash Determination Time, (i) the sum of cash, cash equivalents and short term investments, *minus* (ii) the sum of short term liabilities, including accounts payable and accrued expenses, *minus* (iii) the amount of any Indebtedness, *minus* (iv) the amount of all fees and expenses incurred in connection with the Contemplated Transactions to the extent not paid as of the



## Table of Contents

Closing, *minus* (v) the cash cost of any unpaid change of control payments or severance, termination or similar payments pursuant to a Contract, plan or applicable Law that are or become due to any current or former employee, director or independent contractors, or any other third party, as a result of the of the Contemplated Transactions, *minus* (vi) with respect to Meadow, to the extent known as of the Cash Determination Time, all unpaid third party costs net of any reimbursements (including all amounts due, whether invoiced or not, from Kyowa Kirin Co., Ltd), associated with winding down Meadow's activities with respect to zandelisib, including research, development, marketing and commercialization costs, *minus* (vii) all payroll, employment or other withholding Taxes incurred in connection with any payment amounts set forth in clause (v), *plus* (viii) the amount of accounts receivable, *plus* (ix) the amount of prepaid expenses, *plus* (x) all third-party costs incurred for clinical research, contract manufacturing and consulting expenses related to ME-344 and voruciclib, in the case of Meadow, and eganelisib, in the case of Iris, from the date of this Agreement. Each component of Net Cash, to the extent applicable, shall be determined in a manner consistent with the manner in which such items were historically determined and in accordance with such party's audited financial statements. For the avoidance of doubt, no non-cash liabilities (e.g., warrant liability, deferred revenue and operating lease liability) shall be included in the calculation of Net Cash and no item that may fall within more than one category described above shall be counted more than once in the calculation of Net Cash. For illustrative purposes only, a sample statement of Net Cash as of the date described therein is set forth on Schedule II.

(nnn) "**Ordinary Course of Business**" means, in the case of each of Iris and Meadow, such actions taken in the ordinary course of its and its Subsidiaries' normal operations and consistent in all material respects with its and its Subsidiaries' past practices; provided that for purposes of this definition the normal operations of Meadow shall be deemed to be such actions as are required after giving effect to the winding down of Meadow's prior research and development activities (including the termination of ongoing contractual obligations relating to Meadow's current products or product candidates).

(ooo) "**Organizational Documents**" means, with respect to any Person (other than an individual), (i) the certificate or articles of association or incorporation or organization or limited partnership or limited liability company, and any joint venture, limited liability company, operating or partnership agreement and other similar documents adopted or filed in connection with the creation, formation or organization of such Person and (ii) all bylaws and similar documents or agreements relating to the organization or governance of such Person, in each case, as amended or supplemented.

(ppp) "**Permitted Liens**" means any (i) Lien (A) for Taxes or governmental assessments, charges or claims of payment (1) not yet due and payable or (2) being contested in good faith in appropriate proceedings, (B) which is a carriers', warehousemen's, mechanics', materialmen's, repairmen's, or other similar lien arising in the ordinary course of business, (C) with respect to zoning, planning, and other limitations and restrictions, including all rights of any Governmental Entity (but not violations thereof), (D) in the case of any Contract, Liens that are restrictions against the transfer or assignment thereof that are included in the terms of such Contract or any license of Intellectual Property Rights, (E) with respect to this Agreement and Liens created by the execution and delivery of this Agreement, (F) which is disclosed on the most recent consolidated balance sheet of Iris or Meadow, as applicable, or notes thereto which has been previously provided to Meadow or Iris, as applicable, or (G) for which adequate reserves have been established and (ii) non-exclusive licenses of Intellectual Property Rights in the ordinary course of business consistent with past practice.

(qqq) "**Person**" means any natural person, firm, corporation, partnership, company, limited liability company, trust, joint venture, association, Governmental Entity or other entity.

(rrr) "**Personal Data**" means the meaning as provided under Article 4 of the GDPR.

(sss) "**Personal Data Breach**" means the meaning as provided under Article 4 of the GDPR.

(ttt) "**Reference Date**" means February 21, 2023.

## Table of Contents

(uuu) “**Registered IP**” means all Intellectual Property Rights that are pending, granted, or registered with, by or under the authority of any Governmental Entity, including all patents, patent applications, registered copyrights, registered mask works and registered trademarks and all applications for any of the foregoing.

(vvv) “**SEC**” means the Securities and Exchange Commission.

(www) “**Securities Act**” means the Securities Act of 1933, as amended.

(xxx) “**Subsidiary**” means, with respect to any Person, another Person (i) of which such first Person owns or controls, directly or indirectly, securities or other ownership interests representing (A) more than 50% of the voting power of all outstanding stock or ownership interests of such second Person or (B) the right to receive more than 50% of the net assets available for distribution to the holders of outstanding stock or ownership interests upon a liquidation or dissolution, or (ii) of which such first Person is a general partner.

(yyy) “**Tax Return**” means all Tax returns, declarations, statements, reports, claims for refund, schedules, forms and information returns, any amended Tax return and any other document filed or required to be filed with a Governmental Entity relating to Taxes.

(zzz) “**Taxes**” means all income, profits, franchise, gross receipts, environmental, customs duty, capital stock, severance, stamp, payroll, sales, employment, Medicare, unemployment, disability, use, property, withholding, excise, production, value added, occupancy and any other taxes, duties or assessments in the nature of a tax imposed by any Governmental Entity, together with all interest, penalties and additions imposed with respect to such amounts and any interest in respect of such penalties and additions.

(aaaa) “**Transaction Expenses**” means with respect to each Party, all fees and expenses incurred by such party at or prior to the Effective Time in connection with this Agreement and the Contemplated Transactions, including (i) any fees and expenses of legal counsel and accountants, the maximum amount of fees and expenses payable to financial advisors, investment bankers, brokers, consultants, and other advisors of such party; (ii) fees paid to the SEC in connection with filing the Registration Statement, the Joint Proxy Statement/Prospectus, and any amendments and supplements thereto, with the SEC; (iii) any fees and expenses in connection with the printing, mailing and distribution of the Registration Statement, including any amendments and supplements thereto; and (iv) any fees associated with delisting or de-registering the Shares and any other security issued by Iris or one of its Subsidiaries from The Nasdaq Global Market under the Exchange Act.

8.13. Specific Performance. The Parties acknowledge and agree that irreparable damage would occur and that the Parties would not have any adequate remedy at law if any provision of this Agreement were not performed in accordance with its specific terms or were otherwise breached, and that monetary damages, even if available, would not be an adequate remedy therefor. It is accordingly agreed that the Parties shall be entitled to an injunction or injunctions, specific performance and other equitable relief to prevent breaches of this Agreement and to enforce specifically the performance of the terms and provisions hereof, without proof of actual damages (and each Party hereby waives any requirement for the security or posting of any bond in connection with such remedy), this being in addition to any other remedy to which they are entitled at Law or in equity. The Parties further agree not to assert that a remedy of specific enforcement is unenforceable, invalid, contrary to applicable Law or inequitable for any reason, and not to assert that a remedy of monetary damages would provide an adequate remedy for any such breach or that Iris or Meadow otherwise have an adequate remedy at law. The Parties acknowledge that the agreements contained in this Section 8.13 are an integral part of the transactions contemplated by this Agreement, and that, without these agreements, the Parties would not enter into this Agreement.

*[The remainder of this page is intentionally left blank.]*

[Table of Contents](#)

IN WITNESS WHEREOF, this Agreement has been duly executed and delivered by the duly authorized officers of the Parties hereto as of the date first written above.

MEI PHARMA, INC.

By: /s/ Daniel Gold

Name: Daniel Gold

Title: Chief Executive Officer

INFINITY PHARMACEUTICALS, INC.

By: /s/ Adelene Q. Perkins

Name: Adelene Q. Perkins

Title: Chief Executive Officer

MEADOW MERGER SUB, INC.

By: /s/ David Urso

Name: David Urso

Title: President and Secretary

[Signature Page to Agreement and Plan of Merger]

**EXHIBIT A**

**Form of Certificate of Merger**

(attached)

[Exhibit A to Agreement and Plan of Merger]

A-88

**CERTIFICATE OF MERGER**

**of**

**MEADOW MERGER SUB, INC., a Delaware corporation**

**with and into**

**INFINITY PHARMACEUTICALS, INC., a Delaware corporation**

---

Pursuant to Section 251 of the General Corporation Law of  
the State of Delaware

---

INFINITY PHARMACEUTICALS, INC. does hereby certify as follows:

**FIRST:** That the constituent corporations to the merger herein certified are Meadow Merger Sub, Inc. (“*Merger Sub*”), which is incorporated under the laws of the State of Delaware, and Infinity Pharmaceuticals, Inc. (the “*Company*”) which is incorporated under the laws of the State of Delaware.

**SECOND:** That an Agreement and Plan of Merger (as it may be amended from time to time in accordance with its terms, the “*Merger Agreement*”), made and entered into as of February 22, 2023, by and among Merger Sub, the Company, and MEI Pharma, Inc., a Delaware corporation and the parent of Merger Sub (“*Meadow*”), setting forth the terms and conditions of the merger of Merger Sub with and into the Company (the “*Merger*”), has been approved, adopted, executed and acknowledged by each of the constituent corporations in accordance with the requirements of Section 251(c) of the Delaware General Corporation Law (the “*DGCL*”) and, in the case of Merger Sub, Section 228 of the DGCL.

**THIRD:** That the Company shall be the surviving corporation after the Merger (the “*Surviving Company*”) and the name of the Surviving Company shall be “\_\_\_\_\_”.

**FOURTH:** That as of the effective time of the Merger, the Certificate of Incorporation of the Surviving Company shall be amended and restated in its entirety so as to read as set forth on [Exhibit A](#), and, as so amended and restated, shall constitute the Amended and Restated Certificate of Incorporation of the Surviving Company.

**FIFTH:** That an executed copy of the Merger Agreement is on file at the principal place of business of the Surviving Company at the following address:

Infinity Pharmaceuticals, Inc.  
Address

Attention:

**SIXTH:** That a copy of the Merger Agreement will be furnished by the Surviving Company, on request and without cost, to any stockholder of any constituent corporation.

**SEVENTH:** That the Merger shall become effective upon the filing of this Certificate of Merger with the Secretary of State of the State of Delaware.

*(Signature Page Follows)*

IN WITNESS WHEREOF, the Company has caused this Certificate of Merger to be executed in its corporate name as of this      day of

**INFINITY PHARMACEUTICALS, INC.**

By: \_\_\_\_\_  
Name:  
Title:

**EXHIBIT A**

**AMENDED AND RESTATED CERTIFICATE OF INCORPORATION**

A-91

**EXHIBIT B**

**Form of Certificate of Incorporation**

(attached)

[Exhibit B to Agreement and Plan of Merger]

A-92



AMENDED AND RESTATED CERTIFICATE OF INCORPORATION

OF

INFINITY PHARMACEUTICALS, INC.

FIRST: The name of the corporation is: Infinity Pharmaceuticals, Inc. (the “Corporation”)

SECOND: The address of the Corporation’s registered office in the State of Delaware is 1209 Orange Street, in the City of Wilmington, New Castle County, Delaware, 19801. The name of its registered agent at such address is The Corporation Trust Company.

THIRD: The nature of the business or purposes to be conducted or promoted by the Corporation is to engage in any lawful act or activity for which corporations may be organized under the Delaware General Corporate Law (“DGCL”).

FOURTH: The total number of shares of all classes of capital stock which the Corporation shall have authority to issue is 100 shares of Common Stock, \$0.001 par value per share.

The number of authorized shares of Common Stock may be increased or decreased (but not below the number of shares thereof then outstanding) by the affirmative vote of the holders of a majority of the stock of the Corporation entitled to vote, irrespective of the provisions of Section 242(b)(2) of the DGCL.

FIFTH: In furtherance of and not in limitation of powers conferred by statute, it is further provided:

1. The business and affairs of the Corporation shall be managed by or under the direction of the Board of Directors.
2. Election of directors need not be by written ballot.
3. The Board of Directors is expressly authorized to adopt, amend, alter or repeal the Amended and Restated Bylaws of the Corporation.

SIXTH: To the fullest extent permitted by the General Corporation Law of the State of Delaware, no director or officer of the Corporation shall be personally liable to the Corporation or its stockholders for monetary damages for any breach of fiduciary duty as a director or officer. No amendment, repeal or elimination of this provision shall apply to or have any effect on its application with respect to any act or omission of a director or officer occurring before such amendment, repeal or elimination. If the General Corporation Law of the State of Delaware is amended to permit further elimination or limitation of the personal liability of directors or officers to the Corporation or its stockholders, then the liability of a director or officer of the Corporation shall be eliminated or limited to the fullest extent permitted by the General Corporation Law of the State of Delaware as so amended.

SEVENTH:

(a) To the fullest extent permitted by applicable law, this corporation is authorized to provide indemnification of (and advancement of expenses to) directors, officers, employees and agents of this corporation (and any other persons to which the DGCL permits this corporation to provide indemnification) through Bylaw provisions, agreements with such persons, vote of stockholders or disinterested directors or otherwise, in excess of the indemnification and advancement otherwise permitted by Section 145 of the DGCL, subject only to limits

---

[Table of Contents](#)

created by applicable law (statutory or non-statutory), with respect to actions for breach of duty to this corporation, its stockholders, and others. Any amendment, repeal or modification of the foregoing provisions of this Article SEVENTH shall not adversely affect any right or protection of a director, officer, employee, agent or other person existing at the time of, or increase the liability of any such person with respect to any acts or omissions of such person occurring prior to, such amendment, repeal or modification.

(b) The Corporation may indemnify to the fullest extent permitted by law any person made or threatened to be made a party to an action or proceeding, whether criminal, civil, administrative or investigative, by reason of the fact that he, his testator or intestate is or was a director, officer, employee or agent of the Corporation or any predecessor of the Corporation or serves or served at any other enterprise as a director, officer or employee at the request of the Corporation or any predecessor Corporation.

EIGHTH: The Corporation reserves the right to amend, alter, change or repeal any provision contained in this Amended and Restated Certificate of Incorporation, in the manner now or hereafter prescribed by statute and this Amended and Restated Certificate of Incorporation, and all rights conferred upon stockholders herein are granted subject to this reservation.

**EXHIBIT C**

**Form of Bylaws**

(attached)

[Exhibit C to Agreement and Plan of Merger]

A-95

**AMENDED AND RESTATED BYLAWS  
OF  
INFINITY PHARMACEUTICALS, INC.**

A-96

**TABLE OF CONTENTS**

	Page
<b>ARTICLE I STOCKHOLDERS</b>	
1.1. Place of Meetings	A-99
1.2. Annual Meeting	A-99
1.3. Special Meetings	A-99
1.4. Notice of Meetings	A-99
1.5. Voting List	A-99
1.6. Quorum	A-99
1.7. Adjournments	A-100
1.8. Voting and Proxies	A-100
1.9. Action at Meeting	A-100
1.10. Conduct of Meetings	A-100
1.11. Action without Meeting	A-101
<b>ARTICLE II DIRECTORS</b>	
2.1. General Powers	A-102
2.2. Number, Election and Qualification	A-102
2.3. Chairman of the Board; Vice Chairman of the Board	A-102
2.4. Tenure	A-102
2.5. Quorum	A-102
2.6. Action at Meeting	A-102
2.7. Removal	A-102
2.8. Vacancies	A-102
2.9. Resignation	A-103
2.10. Regular Meetings	A-103
2.11. Special Meetings	A-103
2.12. Notice of Special Meetings	A-103
2.13. Meetings by Conference Communications Equipment	A-103
2.14. Action by Consent	A-103
2.15. Committees	A-103
2.16. Compensation of Directors	A-104
<b>ARTICLE III OFFICERS</b>	
3.1. Titles	A-104
3.2. Election	A-104
3.3. Qualification	A-104
3.4. Tenure	A-104
3.5. Resignation and Removal	A-104
3.6. Vacancies	A-104
3.7. President; Chief Executive Officer	A-105
3.8. Vice Presidents	A-105
3.9. Secretary and Assistant Secretaries	A-105
3.10. Treasurer and Assistant Treasurers	A-105
3.11. Salaries	A-105
3.12. Delegation of Authority	A-106

[Table of Contents](#)

	Page
<b>ARTICLE IV CAPITAL STOCK</b>	
4.1. Issuance of Stock	A-106
4.2. Stock Certificates; Uncertificated Shares	A-106
4.3. Transfers	A-106
4.4. Lost, Stolen or Destroyed Certificates	A-107
4.5. Record Date	A-107
4.6. Regulations	A-107
<b>ARTICLE V GENERAL PROVISIONS</b>	
5.1. Fiscal Year	A-107
5.2. Corporate Seal	A-107
5.3. Waiver of Notice	A-107
5.4. Voting of Securities	A-108
5.5. Evidence of Authority	A-108
5.6. Certificate of Incorporation	A-108
5.7. Severability	A-108
5.8. Pronouns	A-108
5.9. Exclusive Forum	A-108
<b>ARTICLE VI</b>	
6.1. By the Board of Directors	A-109
6.2. By the Stockholders	A-109
<b>ARTICLE VII INDEMNIFICATION OF DIRECTORS, OFFICERS AND OTHERS</b>	
7.1. Indemnification of Directors, Officers and Others	A-109
7.2. Indemnity Insurance	A-109

## ARTICLE I

### STOCKHOLDERS

1.1. Place of Meetings. All meetings of stockholders shall be held at such place as may be designated from time to time by the Board of Directors, the Chairman of the Board, the Chief Executive Officer or the President or, if not so designated, at the principal office of the corporation. The Board of Directors may, in its sole discretion, determine that a meeting shall not be held at any place, but may instead be held solely by means of remote communication in a manner consistent with the General Corporation Law of the State of Delaware.

1.2. Annual Meeting. The annual meeting of stockholders for the election of directors and for the transaction of such other business as may properly be brought before the meeting shall be held on a date and at a time designated by the Board of Directors, the Chairman of the Board, the Chief Executive Officer or the President (which date shall not be a legal holiday in the place where the meeting is to be held).

1.3. Special Meetings. Special meetings of stockholders for any purpose or purposes may be called at any time by only the Board of Directors, the Chairman of the Board, the Chief Executive Officer or the President, and may not be called by any other person or persons. The Board of Directors may postpone or reschedule any previously scheduled special meeting of stockholders. Business transacted at any special meeting of stockholders shall be limited to matters relating to the purpose or purposes stated in the notice of meeting.

1.4. Notice of Meetings. Except as otherwise provided by law, notice of each meeting of stockholders, whether annual or special, shall be given not less than 10 nor more than 60 days before the date of the meeting to each stockholder entitled to vote at such meeting. Without limiting the manner by which notice otherwise may be given to stockholders, any notice shall be effective if given by a form of electronic transmission consented to (in a manner consistent with the General Corporation Law of the State of Delaware) by the stockholder to whom the notice is given. The notices of all meetings shall state the place, if any, date and time of the meeting and the means of remote communications, if any, by which stockholders and proxyholders may be deemed to be present in person and vote at such meeting. The notice of a special meeting shall state, in addition, the purpose or purposes for which the meeting is called. If notice is given by mail, such notice shall be deemed given when deposited in the United States mail, postage prepaid, directed to the stockholder at such stockholder's address as it appears on the records of the corporation. If notice is given by electronic transmission, such notice shall be deemed given at the time specified in Section 232 of the General Corporation Law of the State of Delaware.

1.5. Voting List. The Secretary shall prepare, at least 10 days before every meeting of stockholders, a complete list of the stockholders entitled to vote at the meeting, arranged in alphabetical order, and showing the address of each stockholder and the number of shares registered in the name of each stockholder. Such list shall be open to the examination of any stockholder, for any purpose germane to the meeting, for a period of at least 10 days prior to the meeting: (a) on a reasonably accessible electronic network, provided that the information required to gain access to such list is provided with the notice of the meeting, or (b) during ordinary business hours, at the principal place of business of the corporation. If the meeting is to be held at a physical location (and not solely by means of remote communication), then the list shall be produced and kept at the time and place of the meeting during the whole time thereof, and may be inspected by any stockholder who is present. If the meeting is to be held solely by means of remote communication, then the list shall also be open to the examination of any stockholder during the whole time of the meeting on a reasonably accessible electronic network, and the information required to access such list shall be provided with the notice of the meeting. The list shall presumptively determine the identity of the stockholders entitled to vote at the meeting and the number of shares held by each of them.

1.6. Quorum. Except as otherwise provided by law, the Certificate of Incorporation or these Amended and Restated Bylaws, the holders of a majority in voting power of the shares of the capital stock of the corporation issued and outstanding and entitled to vote at the meeting, present in person, present by means of remote

## Table of Contents

communication in a manner, if any, authorized by the Board of Directors in its sole discretion, or represented by proxy, shall constitute a quorum for the transaction of business; provided, however, that where a separate vote by a class or classes or series of capital stock is required by law or the Certificate of Incorporation, the holders of a majority in voting power of the shares of such class or classes or series of the capital stock of the corporation issued and outstanding and entitled to vote on such matter, present in person, present by means of remote communication in a manner, if any, authorized by the Board of Directors in its sole discretion, or represented by proxy, shall constitute a quorum entitled to take action with respect to the vote on such matter. A quorum, once established at a meeting, shall not be broken by the withdrawal of enough votes to leave less than a quorum.

1.7. Adjournments. Any meeting of stockholders may be adjourned from time to time to any other time and to any other place at which a meeting of stockholders may be held under these Amended and Restated Bylaws by the chairman of the meeting or by the stockholders present or represented at the meeting and entitled to vote, although less than a quorum. It shall not be necessary to notify any stockholder of any adjournment of less than 30 days if the time and place, if any, of the adjourned meeting, and the means of remote communication, if any, by which stockholders and proxyholders may be deemed to be present in person and vote at such adjourned meeting, are announced at the meeting at which adjournment is taken, unless after the adjournment a new record date is fixed for the adjourned meeting. At the adjourned meeting, the corporation may transact any business which might have been transacted at the original meeting.

1.8. Voting and Proxies. Each stockholder shall have one vote for each share of stock entitled to vote held of record by such stockholder and a proportionate vote for each fractional share so held, unless otherwise provided by law or the Certificate of Incorporation. Each stockholder of record entitled to vote at a meeting of stockholders, or to express consent or dissent to corporate action without a meeting, may vote or express such consent or dissent in person (including by means of remote communications, if any, by which stockholders may be deemed to be present in person and vote at such meeting) or may authorize another person or persons to vote or act for such stockholder by a proxy executed or transmitted in a manner permitted by the General Corporation Law of the State of Delaware by the stockholder or such stockholder's authorized agent and delivered (including by electronic transmission) to the Secretary of the corporation. No such proxy shall be voted or acted upon after three years from the date of its execution, unless the proxy expressly provides for a longer period.

1.9. Action at Meeting. When a quorum is present at any meeting, any matter other than the election of directors to be voted upon by the stockholders at such meeting shall be decided by the vote of the holders of shares of stock having a majority in voting power of the votes cast by the holders of all of the shares of stock present or represented at the meeting and voting affirmatively or negatively on such matter (or if there are two or more classes or series of stock entitled to vote as separate classes, then in the case of each such class or series, the holders of a majority in voting power of the shares of stock of that class or series present or represented at the meeting and voting affirmatively or negatively on such matter), except when a different vote is required by law, the Certificate of Incorporation or these Amended and Restated Bylaws. When a quorum is present at any meeting, any election by stockholders of directors shall be determined by a plurality of the votes cast by the stockholders entitled to vote on the election.

### 1.10. Conduct of Meetings.

(a) Chairman of Meeting. Meetings of stockholders shall be presided over by the Chairman of the Board, if any, or in the Chairman's absence by the Vice Chairman of the Board, if any, or in the Vice Chairman's absence by the Chief Executive Officer, or in the Chief Executive Officer's absence, by the President, or in the President's absence by a Vice President, or in the absence of all of the foregoing persons by a chairman designated by the Board of Directors, or in the absence of such designation by a chairman chosen by vote of the stockholders at the meeting. The Secretary shall act as secretary of the meeting, but in the Secretary's absence the chairman of the meeting may appoint any person to act as secretary of the meeting.

(b) Rules, Regulations and Procedures. The Board of Directors may adopt by resolution such rules, regulations and procedures for the conduct of any meeting of stockholders of the corporation as it shall deem



## Table of Contents

appropriate including, without limitation, such guidelines and procedures as it may deem appropriate regarding the participation by means of remote communication of stockholders and proxyholders not physically present at a meeting. Except to the extent inconsistent with such rules, regulations and procedures as adopted by the Board of Directors, the chairman of any meeting of stockholders shall have the right and authority to prescribe such rules, regulations and procedures and to do all such acts as, in the judgment of such chairman, are appropriate for the proper conduct of the meeting. Such rules, regulations or procedures, whether adopted by the Board of Directors or prescribed by the chairman of the meeting, may include, without limitation, the following: (i) the establishment of an agenda or order of business for the meeting; (ii) rules and procedures for maintaining order at the meeting and the safety of those present; (iii) limitations on attendance at or participation in the meeting to stockholders of record of the corporation, their duly authorized and constituted proxies or such other persons as shall be determined; (iv) restrictions on entry to the meeting after the time fixed for the commencement thereof; and (v) limitations on the time allotted to questions or comments by participants. Unless and to the extent determined by the Board of Directors or the chairman of the meeting, meetings of stockholders shall not be required to be held in accordance with the rules of parliamentary procedure.

### 1.11. Action without Meeting.

(a) Taking of Action by Consent. Any action required or permitted to be taken at any annual or special meeting of stockholders of the corporation may be taken without a meeting, without prior notice and without a vote, if a consent in writing, setting forth the action so taken, is signed by the holders of outstanding stock having not less than the minimum number of votes that would be necessary to authorize or take such action at a meeting at which all shares entitled to vote on such action were present and voted. Except as otherwise provided by the Certificate of Incorporation, stockholders may act by written consent to elect directors; provided, however, that, if such consent is less than unanimous, such action by written consent may be in lieu of holding an annual meeting only if all of the directorships to which directors could be elected at an annual meeting held at the effective time of such action are vacant and are filled by such action.

(b) Electronic Transmission of Consents. A telegram, cablegram or other electronic transmission consenting to an action to be taken and transmitted by a stockholder or proxyholder, or by a person or persons authorized to act for a stockholder or proxyholder, shall be deemed to be written, signed and dated for the purposes of this Section 1.11(b), provided that any such telegram, cablegram or other electronic transmission sets forth or is delivered with information from which the corporation can determine (i) that the telegram, cablegram or other electronic transmission was transmitted by the stockholder or proxyholder or by a person or persons authorized to act for the stockholder or proxyholder and (ii) the date on which such stockholder or proxyholder or authorized person or persons transmitted such telegram, cablegram or electronic transmission. The date on which such telegram, cablegram or electronic transmission is transmitted shall be deemed to be the date on which such consent was signed. No consent given by telegram, cablegram or other electronic transmission shall be deemed to have been delivered until such consent is reproduced in paper form and until such paper form shall be delivered to the corporation by delivery to its registered office in the State of Delaware, its principal place of business or an officer or agent of the corporation having custody of the book in which proceedings of meetings of stockholders are recorded. Delivery made to a corporation's registered office shall be made by hand or by certified or registered mail, return receipt requested. Notwithstanding the foregoing limitations on delivery, consents given by telegram, cablegram or other electronic transmission may be otherwise delivered to the principal place of business of the corporation or to an officer or agent of the corporation having custody of the book in which proceedings of meetings of stockholders are recorded if, to the extent and in the manner provided by resolution of the Board of Directors. Any copy, facsimile or other reliable reproduction of a consent in writing may be substituted or used in lieu of the original writing for any and all purposes for which the original writing could be used, provided that such copy, facsimile or other reproduction shall be a complete reproduction of the entire original writing.

(c) Notice of Taking of Corporate Action. Prompt notice of the taking of corporate action without a meeting by less than unanimous written consent shall be given to those stockholders who have not consented in

## Table of Contents

writing and who, if the action had been taken at a meeting, would have been entitled to notice of the meeting if the record date for such meeting had been the date that written consents signed by a sufficient number of holders to take the action were delivered to the corporation.

## **ARTICLE II**

### **DIRECTORS**

2.1. General Powers. The business and affairs of the corporation shall be managed by or under the direction of a Board of Directors, who may exercise all of the powers of the corporation except as otherwise provided by law or the Certificate of Incorporation.

2.2. Number, Election and Qualification. Subject to the rights of holders of any series of Preferred Stock to elect directors, the number of directors of the corporation shall be established from time to time by the stockholders or the Board of Directors. The directors shall be elected at the annual meeting of stockholders by such stockholders as have the right to vote on such election. Election of directors need not be by written ballot. Directors need not be stockholders of the corporation.

2.3. Chairman of the Board; Vice Chairman of the Board. The Board of Directors may appoint from its members a Chairman of the Board and a Vice Chairman of the Board, neither of whom need be an employee or officer of the corporation. If the Board of Directors appoints a Chairman of the Board, such Chairman shall perform such duties and possess such powers as are assigned by the Board of Directors and, if the Chairman of the Board is also designated as the corporation's Chief Executive Officer, shall have the powers and duties of the Chief Executive Officer prescribed in Section 3.7 of these Amended and Restated Bylaws. If the Board of Directors appoints a Vice Chairman of the Board, such Vice Chairman shall perform such duties and possess such powers as are assigned by the Board of Directors. Unless otherwise provided by the Board of Directors, the Chairman of the Board or, in the Chairman's absence, the Vice Chairman of the Board, if any, shall preside at all meetings of the Board of Directors.

2.4. Tenure. Each director shall hold office until the next annual meeting of stockholders and until a successor is elected and qualified, or until such director's earlier death, resignation or removal.

2.5. Quorum. The greater of (a) a majority of the directors at any time in office and (b) one-third of the number of directors fixed pursuant to Section 2.2 of these Amended and Restated Bylaws shall constitute a quorum of the Board of Directors. If at any meeting of the Board of Directors there shall be less than such a quorum, a majority of the directors present may adjourn the meeting from time to time without further notice other than announcement at the meeting, until a quorum shall be present.

2.6. Action at Meeting. Every act or decision done or made by a majority of the directors present at a meeting of the Board of Directors duly held at which a quorum is present shall be regarded as the act of the Board of Directors, unless a greater number is required by law or by the Certificate of Incorporation.

2.7. Removal. Except as otherwise provided by the General Corporation Law of the State of Delaware, any one or more or all of the directors of the corporation may be removed, with or without cause, by the holders of a majority of the shares then entitled to vote at an election of directors, except that the directors elected by the holders of a particular class or series of stock may be removed without cause only by vote of the holders of a majority of the outstanding shares of such class or series.

2.8. Vacancies. Subject to the rights of holders of any series of Preferred Stock to elect directors, unless and until filled by the stockholders, any vacancy or newly-created directorship on the Board of Directors, however occurring, may be filled by vote of a majority of the directors then in office, although less than a

## Table of Contents

quorum, or by a sole remaining director. A director elected to fill a vacancy shall be elected for the unexpired term of such director's predecessor in office, and a director chosen to fill a position resulting from a newly-created directorship shall hold office until the next annual meeting of stockholders and until a successor is elected and qualified, or until such director's earlier death, resignation or removal.

2.9. Resignation. Any director may resign by delivering a resignation in writing or by electronic transmission to the corporation at its principal office or to the Chairman of the Board, the Chief Executive Officer, the President or the Secretary. Such resignation shall be effective upon delivery unless it is specified to be effective at some later time or upon the happening of some later event.

2.10. Regular Meetings. Regular meetings of the Board of Directors may be held without notice at such time and place as shall be determined from time to time by the Board of Directors; provided that any director who is absent when such a determination is made shall be given notice of the determination. A regular meeting of the Board of Directors may be held without notice immediately after and at the same place as the annual meeting of stockholders.

2.11. Special Meetings. Special meetings of the Board of Directors may be held at any time and place designated in a call by the Chairman of the Board, the Chief Executive Officer, the President, two or more directors, or by one director in the event that there is only a single director in office.

2.12. Notice of Special Meetings. Notice of the date, place, if any, and time of any special meeting of directors shall be given to each director by the Secretary or by the officer or one of the directors calling the meeting. Notice shall be duly given to each director (a) in person or by telephone at least 24 hours in advance of the meeting, (b) by sending written notice by reputable overnight courier, telecopy, facsimile or electronic transmission, or delivering written notice by hand, to such director's last known business, home or electronic transmission address at least 48 hours in advance of the meeting, or (c) by sending written notice by first-class mail to such director's last known business or home address at least 72 hours in advance of the meeting. A notice or waiver of notice of a meeting of the Board of Directors need not specify the purposes of the meeting.

2.13. Meetings by Conference Communications Equipment. Directors may participate in meetings of the Board of Directors or any committee thereof by means of conference telephone or other communications equipment by means of which all persons participating in the meeting can hear each other, and participation by such means shall constitute presence in person at such meeting.

2.14. Action by Consent. Any action required or permitted to be taken at any meeting of the Board of Directors or of any committee thereof may be taken without a meeting, if all members of the Board of Directors or committee, as the case may be, consent to the action in writing or by electronic transmission, and the written consents or electronic transmissions are filed with the minutes of proceedings of the Board of Directors or committee. Such filing shall be in paper form if the minutes are maintained in paper form and shall be in electronic form if the minutes are maintained in electronic form.

2.15. Committees. The Board of Directors may designate one or more committees, each committee to consist of one or more of the directors of the corporation with such lawfully delegable powers and duties as the Board of Directors thereby confers, to serve at the pleasure of the Board of Directors. The Board of Directors may designate one or more directors as alternate members of any committee, who may replace any absent or disqualified member at any meeting of the committee. In the absence or disqualification of a member of a committee, the member or members of the committee present at any meeting and not disqualified from voting, whether or not such member or members constitute a quorum, may unanimously appoint another member of the Board of Directors to act at the meeting in the place of any such absent or disqualified member. Any such committee, to the extent provided in the resolution of the Board of Directors and subject to the provisions of law, shall have and may exercise all the powers and authority of the Board of Directors in the management of the business and affairs of the corporation and may authorize the seal of the corporation to be affixed to all papers

## Table of Contents

which may require it. Each such committee shall keep minutes and make such reports as the Board of Directors may from time to time request. Except as the Board of Directors may otherwise determine, any committee may make rules for the conduct of its business, but unless otherwise provided by the directors or in such rules, its business shall be conducted as nearly as possible in the same manner as is provided in these Amended and Restated Bylaws for the Board of Directors. Except as otherwise provided in the Certificate of Incorporation, these Amended and Restated Bylaws, or the resolution of the Board of Directors designating the committee, a committee may create one or more subcommittees, each subcommittee to consist of one or more members of the committee, and delegate to a subcommittee any or all of the powers and authority of the committee.

2.16. Compensation of Directors. Directors may be paid such compensation for their services and such reimbursement for expenses of attendance at meetings as the Board of Directors may from time to time determine. No such payment shall preclude any director from serving the corporation or any of its parent or subsidiary entities in any other capacity and receiving compensation for such service.

### **ARTICLE III**

#### **OFFICERS**

3.1. Titles. The officers of the corporation shall consist of a Chief Executive Officer, a President, a Secretary, a Treasurer and such other officers with such other titles as the Board of Directors shall determine, including one or more Vice Presidents, Assistant Treasurers and Assistant Secretaries. The Board of Directors may appoint such other officers as it may deem appropriate.

3.2. Election. The Chief Executive Officer, President, Treasurer and Secretary shall be elected annually by the Board of Directors at its first meeting following the annual meeting of stockholders. Other officers may be appointed by the Board of Directors at such meeting or at any other meeting.

3.3. Qualification. No officer need be a stockholder. Any two or more offices may be held by the same person.

3.4. Tenure. Except as otherwise provided by law, by the Certificate of Incorporation or by these Amended and Restated Bylaws, each officer shall hold office until such officer's successor is elected and qualified, unless a different term is specified in the resolution electing or appointing such officer, or until such officer's earlier death, resignation or removal.

3.5. Resignation and Removal. Any officer may resign by delivering a written resignation to the corporation at its principal office or to the Chief Executive Officer, the President or the Secretary. Such resignation shall be effective upon receipt unless it is specified to be effective at some later time or upon the happening of some later event. Any officer may be removed at any time, with or without cause, by vote of a majority of the directors then in office. Except as the Board of Directors may otherwise determine, no officer who resigns or is removed shall have any right to any compensation as an officer for any period following such officer's resignation or removal, or any right to damages on account of such removal, whether such officer's compensation be by the month or by the year or otherwise, unless such compensation is expressly provided for in a duly authorized written agreement with the corporation.

3.6. Vacancies. The Board of Directors may fill any vacancy occurring in any office for any reason and may, in its discretion, leave unfilled for such period as it may determine any offices other than those of Chief Executive Officer, President, Treasurer and Secretary. Each such successor shall hold office for the unexpired term of such officer's predecessor and until a successor is elected and qualified, or until such officer's earlier death, resignation or removal.

## Table of Contents

3.7. President; Chief Executive Officer. Unless the Board of Directors has designated another person as the corporation's Chief Executive Officer, the President shall be the Chief Executive Officer of the corporation. The Chief Executive Officer shall have general charge and supervision of the business of the corporation subject to the direction of the Board of Directors, and shall perform all duties and have all powers that are commonly incident to the office of chief executive or that are delegated to such officer by the Board of Directors. The President shall perform such other duties and shall have such other powers as the Board of Directors or the Chief Executive Officer (if the President is not the Chief Executive Officer) may from time to time prescribe. In the event of the absence, inability or refusal to act of the Chief Executive Officer or the President (if the President is not the Chief Executive Officer), the Vice President (or if there shall be more than one, the Vice Presidents in the order determined by the Board of Directors) shall perform the duties of the Chief Executive Officer and when so performing such duties shall have all the powers of and be subject to all the restrictions upon the Chief Executive Officer.

3.8. Vice Presidents. Each Vice President shall perform such duties and possess such powers as the Board of Directors or the Chief Executive Officer may from time to time prescribe. The Board of Directors may assign to any Vice President the title of Executive Vice President, Senior Vice President or any other title selected by the Board of Directors.

3.9. Secretary and Assistant Secretaries. The Secretary shall perform such duties and shall have such powers as the Board of Directors or the Chief Executive Officer may from time to time prescribe. In addition, the Secretary shall perform such duties and have such powers as are incident to the office of the secretary, including without limitation the duty and power to give notices of all meetings of stockholders and special meetings of the Board of Directors, to attend all meetings of stockholders and the Board of Directors and keep a record of the proceedings, to maintain a stock ledger and prepare lists of stockholders and their addresses as required, to be custodian of corporate records and the corporate seal and to affix and attest to the same on documents.

Any Assistant Secretary shall perform such duties and possess such powers as the Board of Directors, the Chief Executive Officer or the Secretary may from time to time prescribe. In the event of the absence, inability or refusal to act of the Secretary, the Assistant Secretary (or if there shall be more than one, the Assistant Secretaries in the order determined by the Board of Directors) shall perform the duties and exercise the powers of the Secretary.

In the absence of the Secretary or any Assistant Secretary at any meeting of stockholders or directors, the chairman of the meeting shall designate a temporary secretary to keep a record of the meeting.

3.10. Treasurer and Assistant Treasurers. The Treasurer shall perform such duties and shall have such powers as may from time to time be assigned by the Board of Directors or the Chief Executive Officer. In addition, the Treasurer shall perform such duties and have such powers as are incident to the office of treasurer, including without limitation the duty and power to keep and be responsible for all funds and securities of the corporation, to deposit funds of the corporation in depositories selected in accordance with these Amended and Restated Bylaws, to disburse such funds as ordered by the Board of Directors, to make proper accounts of such funds, and to render as required by the Board of Directors statements of all such transactions and of the financial condition of the corporation.

The Assistant Treasurers shall perform such duties and possess such powers as the Board of Directors, the Chief Executive Officer or the Treasurer may from time to time prescribe. In the event of the absence, inability or refusal to act of the Treasurer, the Assistant Treasurer (or if there shall be more than one, the Assistant Treasurers in the order determined by the Board of Directors) shall perform the duties and exercise the powers of the Treasurer.

3.11. Salaries. Officers of the corporation shall be entitled to such salaries, compensation or reimbursement as shall be fixed or allowed from time to time by the Board of Directors.

3.12. Delegation of Authority. The Board of Directors may from time to time delegate the powers or duties of any officer to any other officer or agent, notwithstanding any provision hereof.

## ARTICLE IV

### CAPITAL STOCK

4.1. Issuance of Stock. Subject to the provisions of the Certificate of Incorporation, the whole or any part of any unissued balance of the authorized capital stock of the corporation or the whole or any part of any shares of the authorized capital stock of the corporation held in the corporation's treasury may be issued, sold, transferred or otherwise disposed of by vote of the Board of Directors in such manner, for such lawful consideration and on such terms as the Board of Directors may determine.

4.2. Stock Certificates; Uncertificated Shares. The shares of the corporation shall be represented by certificates, provided that the Board of Directors may provide by resolution or resolutions that some or all of any or all classes or series of the corporation's stock shall be uncertificated shares. Every holder of stock of the corporation represented by certificates shall be entitled to have a certificate, in such form as may be prescribed by law and by the Board of Directors, representing the number of shares held by such holder registered in certificate form. Each such certificate shall be signed in a manner that complies with Section 158 of the General Corporation Law of the State of Delaware.

Each certificate for shares of stock which are subject to any restriction on transfer pursuant to the Certificate of Incorporation, these Amended and Restated Bylaws, applicable securities laws or any agreement among any number of stockholders or among such holders and the corporation shall have conspicuously noted on the face or back of the certificate either the full text of the restriction or a statement of the existence of such restriction.

If the corporation shall be authorized to issue more than one class of stock or more than one series of any class, the powers, designations, preferences and relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights shall be set forth in full or summarized on the face or back of each certificate representing shares of such class or series of stock, provided that in lieu of the foregoing requirements there may be set forth on the face or back of each certificate representing shares of such class or series of stock a statement that the corporation will furnish without charge to each stockholder who so requests a copy of the full text of the powers, designations, preferences and relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights.

Within a reasonable time after the issuance or transfer of uncertificated shares, the corporation shall send to the registered owner thereof a written notice containing the information required to be set forth or stated on certificates pursuant to Sections 151, 202(a) or 218(a) of the General Corporation Law of the State of Delaware or, with respect to Section 151 of the General Corporation Law of the State of Delaware, a statement that the corporation will furnish without charge to each stockholder who so requests the powers, designations, preferences and relative participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights.

4.3. Transfers. Shares of stock of the corporation shall be transferable in the manner prescribed by law and in these Amended and Restated Bylaws. Transfers of shares of stock of the corporation shall be made only on the books of the corporation or by transfer agents designated to transfer shares of stock of the corporation. Subject to applicable law, shares of stock represented by certificates shall be transferred only on the books of the corporation by the surrender to the corporation or its transfer agent of the certificate representing such shares properly endorsed or accompanied by a written assignment or power of attorney properly executed, and with such proof of authority or the authenticity of signature as the corporation or its transfer agent may reasonably

## Table of Contents

require. Except as may be otherwise required by law, by the Certificate of Incorporation or by these Amended and Restated Bylaws, the corporation shall be entitled to treat the record holder of stock as shown on its books as the owner of such stock for all purposes, including the payment of dividends and the right to vote with respect to such stock, regardless of any transfer, pledge or other disposition of such stock until the shares have been transferred on the books of the corporation in accordance with the requirements of these Amended and Restated Bylaws.

4.4. Lost, Stolen or Destroyed Certificates. The corporation may issue a new certificate of stock in place of any previously issued certificate alleged to have been lost, stolen or destroyed, upon such terms and conditions as the Board of Directors may prescribe, including the presentation of reasonable evidence of such loss, theft or destruction and the giving of such indemnity and posting of such bond as the Board of Directors may require for the protection of the corporation or any transfer agent or registrar.

4.5. Record Date. The Board of Directors may fix in advance a date as a record date for the determination of the stockholders entitled to notice of or to vote at any meeting of stockholders or to express consent (or dissent) to corporate action without a meeting, or entitled to receive payment of any dividend or other distribution or allotment of any rights in respect of any change, conversion or exchange of stock, or for the purpose of any other lawful action. Such record date shall not precede the date on which the resolution fixing the record date is adopted, and such record date shall not be more than 60 nor less than 10 days before the date of such meeting, nor more than 10 days after the date of adoption of a record date for a consent without a meeting, nor more than 60 days prior to any other action to which such record date relates.

If no record date is fixed, the record date for determining stockholders entitled to notice of or to vote at a meeting of stockholders shall be at the close of business on the day before the day on which notice is given, or, if notice is waived, at the close of business on the day before the day on which the meeting is held. If no record date is fixed, the record date for determining stockholders entitled to express consent to corporate action without a meeting, when no prior action by the Board of Directors is necessary, shall be the day on which the first consent is properly delivered to the corporation. If no record date is fixed, the record date for determining stockholders for any other purpose shall be at the close of business on the day on which the Board of Directors adopts the resolution relating to such purpose.

A determination of stockholders of record entitled to notice of or to vote at a meeting of stockholders shall apply to any adjournment of the meeting; provided, however, that the Board of Directors may fix a new record date for the adjourned meeting.

4.6. Regulations. The issue, transfer, conversion and registration of shares of stock of the corporation shall be governed by such other regulations as the Board of Directors may establish.

## **ARTICLE V**

### **GENERAL PROVISIONS**

5.1. Fiscal Year. Except as from time to time otherwise designated by the Board of Directors, the fiscal year of the corporation shall begin on the first day of July of each year and end on the last day of June in each year.

5.2. Corporate Seal. The corporate seal shall be in such form as shall be approved by the Board of Directors.

5.3. Waiver of Notice. Whenever notice is required to be given by law, by the Certificate of Incorporation or by these Amended and Restated Bylaws, a written waiver, signed by the person entitled to notice, or a waiver

## Table of Contents

by electronic transmission by the person entitled to notice, whether before, at or after the time of the event for which notice is to be given, shall be deemed equivalent to notice required to be given to such person. Neither the business nor the purpose of any meeting need be specified in any such waiver. Attendance of a person at a meeting shall constitute a waiver of notice of such meeting, except when the person attends a meeting for the express purpose of objecting at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened.

5.4. Voting of Securities. Except as the Board of Directors may otherwise designate, the Chief Executive Officer, the President or the Treasurer may waive notice of, vote, or appoint any person or persons to vote, on behalf of the corporation at, and act as, or appoint any person or persons to act as, proxy or attorney-in-fact for this corporation (with or without power of substitution) at, any meeting of stockholders or securityholders of any other entity, the securities of which may be held by this corporation.

5.5. Evidence of Authority. A certificate by the Secretary, or an Assistant Secretary, or a temporary Secretary, as to any action taken by the stockholders, directors, a committee or any officer or representative of the corporation shall as to all persons who rely on the certificate in good faith be conclusive evidence of such action.

5.6. Certificate of Incorporation. All references in these Amended and Restated Bylaws to the Certificate of Incorporation shall be deemed to refer to the Certificate of Incorporation of the corporation, as amended and in effect from time to time.

5.7. Severability. Any determination that any provision of these Amended and Restated Bylaws is for any reason inapplicable, illegal or ineffective shall not affect or invalidate any other provision of these Amended and Restated Bylaws.

5.8. Pronouns. All pronouns used in these Amended and Restated Bylaws shall be deemed to refer to the masculine, feminine or neuter, singular or plural, as the identity of the person or persons may require.

5.9. Exclusive Forum.

(a) Delaware Courts. Unless the corporation consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery of the State of Delaware does not have jurisdiction, the federal district court for the District of Delaware) shall, to the fullest extent permitted by law, be the sole and exclusive forum for: (i) any derivative action or proceeding brought on behalf of the corporation, (ii) any action asserting a claim of breach of a fiduciary duty owed by any current or former director, officer, other employee or stockholder of the corporation to the corporation or the corporation's stockholders, (iii) any action asserting a claim arising pursuant to any provision of the General Corporation Law of the State of Delaware or as to which the General Corporation Law of the State of Delaware confers jurisdiction on the Court of Chancery of the State of Delaware, or (iv) any action asserting a claim arising pursuant to any provision of the Certificate of Incorporation or these Amended and Restated Bylaws (in each case, as they may be amended from time to time) or governed by the internal affairs doctrine. This Section 5.9 does not apply to claims arising under the Securities Act of 1933 or the Securities Exchange Act of 1934 or any other claim for which the federal courts have exclusive jurisdiction.

(b) Claims Arising Under the Securities Act of 1933. Unless the corporation consents in writing to the selection of an alternative forum, the federal district courts of the United States of America shall, to the fullest extent permitted by law, be the sole and exclusive forum for the resolution of any claims arising under the Securities Act of 1933.

(c) Notice. Any person or entity purchasing or otherwise acquiring or holding any interest in shares of capital stock of the corporation shall be deemed to have notice of and consented to the provisions of this Section 5.9.



**ARTICLE VI**

**AMENDMENTS**

6.1. By the Board of Directors. These Amended and Restated Bylaws may be altered, amended or repealed, in whole or in part, or new bylaws may be adopted by the Board of Directors.

6.2. By the Stockholders. These Amended and Restated Bylaws may be altered, amended or repealed, in whole or in part, or new bylaws may be adopted by the affirmative vote of the holders of a majority of the shares of the capital stock of the corporation issued and outstanding and entitled to vote at any annual meeting of stockholders, or at any special meeting of stockholders, provided notice of such alteration, amendment, repeal or adoption of new bylaws shall have been stated in the notice of such special meeting.

**ARTICLE VII**

**INDEMNIFICATION OF DIRECTORS, OFFICERS AND OTHERS**

7.1. Indemnification of Directors, Officers and Others.

(a) The corporation shall, to the extent legally permissible, indemnify any person serving or who has served as a Director, officer, employee or agent of the corporation in the manner prescribed by the Certificate of Incorporation, as amended and restated from time to time, of the corporation.

(b) Expenses, including attorneys' fees, incurred by a Director, officer, employee or agent in defending any civil, criminal, administrative or investigative action, suit or proceeding shall be paid by the corporation in advance of the final disposition of such action, suit or proceeding upon receipt of an undertaking by or on behalf of such Director, officer, employee or agent to repay such amount if it shall ultimately be determined that such person is not entitled to be indemnified by the corporation as authorized in this Section 7.1. Such expenses (including attorneys' fees) incurred by former Directors, officers, employees or agents may be so paid upon such terms and conditions, if any, as the Board of Directors deems appropriate.

(c) The indemnification and advancement of expenses provided by, or granted pursuant to, this Section 7.1 shall, unless otherwise provided when authorized or ratified, continue as to a person who has ceased to be a Director, officer, employee or agent and shall inure to the benefit of the heirs, executors and administrators of such a person.

7.2. Indemnity Insurance. The corporation shall, to the extent permissible, have power to purchase and maintain insurance on behalf of any person who is or was a Director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a Director, officer, employee or agent of another corporation, partnership, joint venture trust or other enterprise against any liability asserted against such person and incurred by such person in any capacity, or arising out of such person's status as such, whether or not the corporation would have the power to indemnify such person against such liability under this section.

**EXHIBIT D**

**Directors and Officers of Meadow**

**I. Officers**

<u>Name</u>	<u>Title</u>
David M. Urso	Chief Executive Officer
Robert Ilaria, Jr.	Chief Medical Officer
Stéphane Peluso	Chief Scientific Officer

**II. Board Designees – Iris**

<u>Name</u>	<u>Class</u>
Norman Selby (Chair)	Class with term expiring at <u>2025</u> annual meeting of Meadow stockholders
Adelene Perkins	Class with term expiring at <u>2024</u> annual meeting of Meadow stockholders
Dr. Richard Gaynor	Class with term expiring at <u>2023</u> annual meeting of Meadow stockholders

**III. Board Designees – Meadow**

<u>Name</u>	<u>Class</u>
Charles V. Baltic, III	Class with term expiring at <u>2024</u> annual meeting of Meadow stockholders
Dr. Thomas C. Reynolds	Class with term expiring at <u>2025</u> annual meeting of Meadow stockholders
Dr. Daniel Gold	Class with term expiring at <u>2023</u> annual meeting of Meadow stockholders
David M. Urso	Class with term expiring at <u>2025</u> annual meeting of Meadow stockholders

**IV. Board Designees – Joint**

<u>Name</u>	<u>Class</u>
Sujay Kango	Class with term expiring at 2023 annual meeting of Meadow stockholders

**V. Committee Chairs**

<u>Name</u>	<u>Committee Chair</u>
Adelene Perkins	Chair of Audit Committee
Dr. Thomas C. Reynolds	Chair of Compensation Committee
Charles V. Baltic, III	Chair of Nominating and Corporate Governance Committee

[Exhibit D to Agreement and Plan of Merger]

**SCHEDULE I**

**Protocol Synopsis Schema**

See attached.

[Schedule I to Agreement and Plan of Merger]

A-111

**SCHEDULE II**

**Net Cash**

See attached.

[Schedule II to Agreement and Plan of Merger]

A-112



Torrey Capital LLC  
555 Madison Avenue, Suite 1201  
New York, NY 10022  
(212) 257-5801  
www.torrey.com

*February 22, 2023*

The Board of Directors  
MEI Pharma, Inc.  
11455 El Camino Real, Suite 250  
San Diego, CA 92130

Dear Board of Directors:

You have asked Torrey Capital LLC (“Torrey”) to render a written opinion (the “Opinion”) to the Board of Directors of MEI Pharma, Inc. (“MEI”) as to the fairness, from a financial point of view, to the holders of MEI common stock of the Exchange Ratio (as defined herein) in the contemplated transaction described below (the “Proposed Transaction”).

### **Description of the Proposed Transaction**

It is Torrey’s understanding that MEI is considering entering into an Agreement and Plan of Merger (the “Agreement”) between MEI and Infinity Pharmaceuticals, Inc. (“Infinity”), pursuant to which, among other things, Infinity will merge with and into a wholly owned subsidiary of MEI and each outstanding share of the common stock of Infinity will be converted into the right to receive 1.0449 shares of MEI common stock (the “Exchange Ratio”), after which MEI current shareholders will beneficially own and control approximately 58% of MEI and former Infinity shareholders will beneficially own and control approximately 42% of MEI. The terms and conditions of the Merger are more fully set forth in the Agreement.

### **Scope of Analysis**

In connection with this opinion, we have, among other things:

- (a) Reviewed documents, including but not limited to the following, regarding MEI and Infinity:
  - a. Annual reports and audited financial statements of MEI on Form 10-K and 10-Q filed with the Securities and Exchange Commission (“SEC”) for the fiscal year ended June 30, 2022, and for the fiscal quarters ended December 31, 2022, September 30, 2022, and March 31, 2022
  - b. Annual reports and audited financial statements of Infinity on Form 10-K and 10-Q filed with the Securities and Exchange Commission (“SEC”) for the fiscal year ended December 31, 2021, and for the fiscal quarters ended September 30, 2022, June 30, 2022, and March 31, 2022
  - c. MEI standalone financial projections for the years ending December 31, 2023 through 2039 as prepared by MEI Management (“Management”)
  - d. Infinity standalone financial projections for the years ending December 31, 2023 through 2044 as prepared by Infinity Management
  - e. Infinity revenue and gross profit projections for the years ending December 31, 2023 through 2039, adjusted by the management of MEI, which is referred to as MEI’s Adjusted Infinity Forecast

## Table of Contents

- f. Pro forma expense projections for the years ending December 31, 2023 through 2039 by both the management of MEI and Infinity
  - g. MEI and Infinity uncommitted cash balance at year-end and transaction close as prepared by Management
  - h. Basic shares outstanding and information on dilutive securities for MEI and Infinity as prepared by Management
  - i. Historical trading price and trading volume of MEI and Infinity, per Capital IQ
  - j. Draft merger agreement dated February 19, 2023
- (b) Held discussions with the senior management team of MEI and Infinity with respect to the matters described above, as well as each respective business
  - (c) Compared the proposed financial terms of the Agreement with other financial studies and analyses and took into account such other information as we deemed appropriate in evaluating the Exchange Ratio
  - (d) Performed certain valuation and comparative analyses using generally accepted valuation and analytical techniques, as well as other analyses and factors deemed appropriate and relevant
  - (e) Reviewed public information and trading multiples of certain other companies that Torreyea deemed relevant
  - (f) Reviewed diligence findings from Management of Infinity

### **Assumptions, Qualifications and Limiting Conditions**

In connection with its review and arriving at its opinion, Torreyea did not independently verify any of the foregoing information, relied on such information, assumed that all such information was complete and accurate in all material respects, and relied on assurances of management of MEI and Infinity that they were not aware of any facts that would make such information misleading. With respect to the projections of Infinity prepared by management of Infinity, the projections prepared by management of MEI, and any other estimates or forward looking information reviewed by Torreyea, Torreyea assumed, with the consent of MEI, that such information was reasonably prepared on bases reflecting the best currently available estimates and judgments of management as to the matters covered thereby, and Torreyea relied, at the direction of MEI, on such information for purposes of its analysis and opinion. Torreyea expresses no view or opinion as to such information or the assumptions on which it was based. Torreyea also relied on information provided by the management of MEI and Infinity as to the capitalization of MEI and Infinity, respectively, and Torreyea assumed, with the consent of MEI, that such information will not vary in any material respect that would be meaningful to Torreyea's analysis.

Torreyea also assumed that (i) the Merger will be consummated upon the terms set forth in the Merger Agreement, without any adjustment to the Exchange Ratio or any waiver, modification or amendment of any material term, condition or agreement therein which would be in any way meaningful to Torreyea's analysis, (ii) the representations and warranties made by the parties to the Merger Agreement are and will be true and correct in all respects material to Torreyea's analysis, and (iii) in the course of obtaining necessary governmental, regulatory and third-party approvals and consents for the Merger, no modification, delay, limitation, restriction or conditions will be imposed which would have an adverse effect on MEI or Infinity or be in any way meaningful to Torreyea's analysis. Torreyea is not a legal, accounting, regulatory or tax expert and relied on the assessments made by MEI and its advisors with respect to such matters. Torreyea's opinion is limited to and addresses only the fairness, from a financial point of view, to the holders of MEI common stock of the Exchange Ratio as of the date of the opinion. Torreyea expresses no opinion with respect to the holders of any other class of securities, creditors, or other constituencies of MEI. Torreyea's opinion does not address the relative merits of the Merger as compared to other business strategies or transactions that might be available to MEI, nor does it address the underlying business decision of MEI to proceed with the Merger or any view on another term or aspect of the Merger, including, without limitation, the structure or form of the Merger. Torreyea did not consider, and did not express

## Table of Contents

an opinion as to, the fairness of the amount or nature of the compensation to any of the officers, directors or employees of MEI or any other party, or class of such persons. Further, Torrey Capital does not express any opinion as to what the value of MEI Common Stock or any other securities will be when issued or the price or range of prices at which MEI Common Stock or any other securities may trade or otherwise be transferable at any time, including following announcement or consummation of the Merger.

Torrey Capital was not requested to conduct, and did not conduct, nor did Torrey Capital rely upon, any independent valuation or appraisal of any of the assets or liabilities (contingent, derivative, off balance sheet or otherwise) of MEI or Infinity. Torrey Capital also did not evaluate nor express any opinion as to the solvency of any party to the Merger Agreement, or the ability of MEI or Infinity to pay its obligations when they become due, or as to the impact of the Merger on such matters, under any state, federal or other laws relating to bankruptcy, insolvency, or similar matters.

We are not expressing any opinion as to the underlying valuation, future performance, or long-term viability of MEI. We were not requested to, and we did not, participate in the negotiation or structuring of the Agreement. We express no view as to, and our Opinion does not address, any terms or other aspects or implications of the Agreement (other than the Exchange Ratio to the extent expressly specified herein) or any aspect or implication of any other agreement, arrangement or understanding entered into in connection with the Agreement or otherwise. Our Opinion is necessarily based on the information available to us and general economic, financial and stock market conditions and circumstances as they exist and can be evaluated by us on the date hereof. Although subsequent developments may affect this Opinion, we do not have any obligation to update, revise or reaffirm this Opinion.

### **Disclosure**

We have been engaged by MEI in connection with the Transaction. We will receive a fee for our services in connection with the Transaction, part of which will be received upon the delivery of this Opinion to the Board of Directors of MEI. In addition, the Company has agreed to reimburse certain of our expenses arising and indemnify us against certain liabilities that may arise out of our engagement, including liabilities under the federal securities laws. No other services have been provided to either MEI or Infinity in relation to this Transaction, nor has Torrey Capital previously provided services or received fees from either MEI or Infinity.

The issuance of this Opinion was approved by an authorized committee of Torrey Capital. As part of our investment banking business, we are regularly engaged in valuations of businesses and securities in connection with acquisitions and mergers, private placements and valuations for other purposes.

### **Conclusion**

Based upon and subject to the foregoing, we are of the opinion that, as of the date hereof, the Exchange Ratio is fair, from a financial point of view, to the holders of common stock of MEI. This Opinion is for the use of the Board of Directors of MEI (in its capacity as such) in its evaluation of the Agreement and does not constitute a recommendation to any stockholder as to how such stockholder should vote or act with respect to any matters relating to the Agreement.

Sincerely,

/s/ Torrey Capital LLC  
Torrey Capital LLC



Member FINRA/SIPC

601 California St., Suite 500  
San Francisco, CA 94108

February 22, 2023

Board of Directors  
Infinity Pharmaceuticals, Inc.  
1100 Massachusetts Ave., Floor 4  
Cambridge, Massachusetts 02138

Members of the Board of Directors:

You have asked us to advise you with respect to the fairness, from a financial point of view, to the holders of common stock, par value \$0.001 per share (the "Common Stock"), of Infinity Pharmaceuticals, Inc., a Delaware corporation ("Iris" or the "Company") (the "Company Common Stock"), of the Exchange Ratio set forth in the Agreement and Plan of Merger to be entered into by and among the Company, MEI Pharma, Inc., a Delaware corporation ("Meadow" or "MEI"), and Meadow Merger Sub, Inc., a Delaware corporation and wholly owned subsidiary of MEI (the "Merger Agreement"), which will be used to determine the number of shares of Meadow Common Stock to be issued to the holders of Company Common Stock in the transactions contemplated by the Merger Agreement (the "Transaction"). Defined terms used herein but not otherwise defined are given the meaning set forth in the Merger Agreement.

In arriving at our opinion, we have reviewed, analyzed and considered the draft Merger Agreement dated February 22, 2023; certain publicly available business and financial information relating to the Company and MEI; certain non-public business and financial information relating to the Company and MEI, including financial and business forecasts and projections prepared by management of the Company and MEI, respectively; certain publicly available market, financial and other data for certain other companies we deemed relevant for purposes of performing a comparison of those companies against the Company and MEI; the financial position, including projected cash burn rate, of each of the Company, MEI and the combined company, respectively; and such other information that we have deemed relevant. In addition, we have discussed the business, operations, financial condition and prospects of each of the Company and MEI, and the Company and MEI as a combined company.

In connection with our review, we have not assumed any responsibility for independent verification of any of the foregoing information and have, with your consent, relied on such information being complete and accurate. With respect to the financial forecasts for the Company, MEI and the combined company, the management of each of the Company and MEI, respectively, has advised us, and we have assumed with your consent, that such forecasts have been reasonably prepared on bases reflecting the best currently available estimates and judgments of the management of the Company and MEI, respectively, as to the future financial performance of the Company and MEI, respectively. We have relied upon, without independent verification, the assessment of each of the Company's management and MEI's management as to the viability of, and risks associated with, the current and future products of the combined company following the Transaction (including without limitation, the development, testing and marketing of such products, the receipt of all necessary governmental and other regulatory approvals for the development, testing and marketing thereof, and the life and enforceability of all relevant patents and other intellectual and other property rights associated with such products). We have also assumed, with your consent, that, in the course of obtaining any regulatory or third party consents, approvals or agreements in connection with the Transaction, no delay, limitation, restriction or condition will be imposed that would have an adverse effect on the Company, MEI or the combined company, or the contemplated benefits of



the Transaction, and that the Transaction will be consummated in accordance with the terms of the Merger Agreement without waiver, modification or amendment of any material term, condition or agreement thereof. In addition, we have not been requested to make, and have not made, an independent evaluation or appraisal of the assets or liabilities (contingent or otherwise) of the Company or MEI, nor did we conduct a physical inspection of any of the properties or facilities of the Company or MEI, nor have we been furnished with any such evaluations, appraisals or inspections, nor do we assume any responsibility to obtain any such evaluations, appraisals or inspections. We have also assumed that the representations and warranties contained in the Merger Agreement made by the parties thereto are true and correct in all respects material to our analysis.

Our opinion addresses only the fairness, from a financial point of view, to the holders of Company Common Stock of the Exchange Ratio and does not address any other aspect or implication of the Transaction or any other agreement, arrangement or understanding entered into in connection with the Transaction or otherwise. Our opinion is necessarily based upon information made available to us as of the date hereof and financial, economic, market and other conditions as they exist and can be evaluated on the date hereof. We do not express any opinion as to the price or range of prices at which the shares of Company Common Stock may trade subsequent to the announcement or closing of the Transaction or at any time.

We have acted as financial advisor to the Company in connection with the Transaction. We will receive a fee for our services, a portion of which is payable upon delivery of this opinion and a significant portion of which is contingent upon consummation of the Transaction. In addition, the Company has agreed to indemnify us for certain liabilities and other items arising out of our engagement.

You have not asked us to address, and this opinion does not address, the relative merits of the Transaction as compared to alternative transactions or strategies that might be available to the Company, nor the underlying business decision of the Company to proceed with the Transaction. Our opinion addresses only the fairness, from a financial point of view, to the holders of Iris Common Stock of the Exchange Ratio, and we express no opinion as to the fairness of any consideration paid in connection with the Transaction to the holders of any other class of securities, creditors or other constituencies of the Company as to the underlying decision by the Company to engage in the Transaction. We are not legal, tax or regulatory advisors and have relied upon, without independent verification, the assessment of the Company and its legal, tax and regulatory advisors with respect to such matters. We have not performed any tax analysis, nor have we been furnished with any such analysis.

The issuance of this opinion has been approved by a fairness opinion committee of Aquilo Partners, L.P. (“Aquilo Partners”). This opinion is for the use and benefit of the Board of Directors of the Company in connection with its evaluation of the Transaction. This opinion does not constitute a recommendation to any stockholder as to how such stockholder should vote with respect to the Transaction or any other matter. Except as otherwise provided in our engagement letter with the Company, this opinion shall not be reproduced, disseminated, quoted, summarized or referred to at any time, in any manner or for any purpose, nor shall any public references to Aquilo Partners or any of its affiliates be made by the Company or any of its affiliates, without the prior written consent of Aquilo Partners, provided that this opinion may be reproduced in full in any proxy or information statement provided to stockholders of the Company.

Based upon and subject to the foregoing, it is our opinion that, as of the date hereof, the Exchange Ratio is fair, from a financial point of view, to the holders of Company Common Stock.

Very truly yours,

AQUILO PARTNERS, L.P.

By: /s/ John Rumsey  
John Rumsey  
Managing Director

**PART II**  
**INFORMATION NOT REQUIRED IN PROXY**  
**STATEMENT/PROSPECTUS**

**Item 20. Indemnification of Directors and Officers**

The MEI COI, as amended, provides that MEI will indemnify its directors and officers to the full extent permitted by the Delaware General Corporation Law, or DGCL. Section 145 of the DGCL provides that the extent to which a corporation may indemnify its directors and officers depends on the nature of the action giving rise to the indemnification right. In actions not on behalf of the corporation, directors and officers may be indemnified for acts taken in good faith and in a manner reasonably believed to be in or not opposed to the best interests of the corporation. In actions on behalf of the corporation, directors and officers may be indemnified for acts taken in good faith and in a manner reasonably believed to be in or not opposed to the best interests of the corporation, except for acts as to which the director or officer is adjudged liable to the corporation, unless the relevant court determines that indemnification is appropriate despite such liability. Section 145 of the DGCL also permits a corporation to (i) reimburse present or former directors or officers for their defense expenses to the extent they are successful on the merits or otherwise and (ii) advance defense expenses upon receipt of an undertaking to repay the corporation if it is determined that payment of such expenses is unwarranted.

To supplement the general indemnification right contained in the MEI COI, the MEI Bylaws provide for the specific indemnification rights permitted by Section 145 (as described above). The MEI Bylaws also permit it to purchase Directors & Officers insurance, but no director or officer has a right to require this.

In addition to the indemnification rights described above, the MEI COI, as amended, eliminates any monetary liability of directors to it or its stockholders for breaches of fiduciary duty except for (i) breaches of the duty of loyalty, (ii) acts or omissions in bad faith, (iii) improper dividends or share redemptions and (iv) transactions from which the director derives an improper personal benefit.

Finally, MEI have entered into an indemnification agreement with each of MEI's directors and executive officers. Subject to certain exceptions, the indemnification agreements provide that an indemnitee will be indemnified for all expenses incurred or paid by the indemnitee in connection with a proceeding to which the indemnitee was or is a party, or is threatened to be made a party, by reason of the indemnitee's status with or service to MEI or to another entity at MEI's request. In connection with proceedings other than those by or in the right of the company and to which the indemnitee was or is a party, or is threatened to be made a party, by reason of the indemnitee's status with or service to MEI or to another entity at MEI's request, the indemnification agreements provide that an indemnitee will also be indemnified for all liabilities incurred or paid by the indemnitee. The indemnification agreements also provide for advancement of expenses incurred by an indemnitee in connection with an indemnifiable claim, subject to reimbursement in certain circumstances.

**Item 21. Exhibits and Financial Statement Schedules**

A list of exhibits filed with this registration statement on Form S-4 is set forth on the Exhibit Index and is incorporated herein by reference.

**Item 22. Undertakings**

(a) The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;

## Table of Contents

- (ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the SEC pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20 percent change in the maximum aggregate offering price set forth in the "Calculation in Registration Fee" table in the effective registration statement;
  - (iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;
- (2) That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
- (3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.
- (4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser:
  - (i) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and
  - (ii) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by Section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof; provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date.
- (5) That, for the purpose of determining liability of the registrant under the Securities Act to any purchaser in the initial distribution of the securities, that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:
  - (i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;
  - (ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

## Table of Contents

(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

(iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

(6) The undersigned registrant hereby undertakes as follows: that prior to any public reoffering of the securities registered hereunder through use of a prospectus which is a part of this registration statement, by any person or party who is deemed to be an underwriter within the meaning of Rule 145(c), the issuer undertakes that such reoffering prospectus will contain the information called for by the applicable registration form with respect to reofferings by persons who may be deemed underwriters, in addition to the information called for by the other items of the applicable form.

(7) The registrant undertakes that every prospectus: (i) that is filed pursuant to paragraph (6) immediately preceding, or (ii) that purports to meet the requirements of Section 10(a)(3) of the Securities Act and is used in connection with an offering of securities subject to Rule 415, will be filed as a part of an amendment to the registration statement and will not be used until such amendment is effective, and that, for purposes of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(8) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

(9) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(b) The undersigned registrant hereby undertakes to respond to requests for information that is incorporated by reference into the prospectus pursuant to Item 4, 10(b), 11, or 13 of this form, within one business day of receipt of such request, and to send the incorporated documents by first class mail or other equally prompt means. This includes information contained in documents filed subsequent to the effective date of the registration statement through the date of responding to the request.

(c) The undersigned registrant hereby undertakes to supply by means of a post-effective amendment all information concerning a transaction, and the company being acquired involved therein, that was not the subject of and included in the registration statement when it became effective.

**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Description of Exhibits</b>
2.1**	<a href="#">Agreement and Plan of Merger, by and among MEI, Merger Sub, and Infinity, dated as of February 22, 2023 (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K filed on February 23, 2023 (File No. 000-50484)).</a>
3.1**	<a href="#">Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Registrant's Quarterly Report on Form 10-Q filed on February 7, 2019 (File No. 000-50484)).</a>
3.2**	<a href="#">Certificate of Amendment to the Amended and Restated Certificate of Incorporation of MEI Pharma, Inc. (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on April 14, 2023 (File No. 000-50484)).</a>
3.3**	<a href="#">Certificate of Designation of Series A Convertible Preferred Stock of Marshall Edwards, Inc. (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on May 11, 2011 (File No. 000-50484)).</a>
3.4**	<a href="#">Certificate of Designation of Series B Preferred Stock of Marshall Edwards, Inc. (incorporated by reference to Exhibit 4 to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on March 18, 2011 (File No. 000-50484)).</a>
3.5**	<a href="#">Fifth Amended and Restated By-Laws of MEI Pharma, Inc., effective as of February 23, 2023, (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on February 23, 2023 (File No. 000-50484)).</a>
4.1**	<a href="#">Specimen Stock Certificate (incorporated by reference to Exhibit 4.1 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 filed on October 31, 2003 (File No. 333-109129)).</a>
4.2**	<a href="#">Form of Warrant (incorporated by reference to Exhibit B to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on May 16, 2018 (File No. 000-50484)).</a>
4.3**	<a href="#">Description of Capital Stock of MEI Pharma, Inc. (incorporated by reference to Exhibit 4.3 to the Registrant's Annual Report on Form 10-K filed on September 9, 2020 (File No. 000-50484)).</a>
5.1*	Opinion of Morgan Lewis & Bockius LLP as to the validity of the shares of common stock of MEI Pharma, Inc. being issued in the merger.
10.1†**	<a href="#">Employment letter dated April 23, 2010, between Marshall Edwards, Inc. and Daniel P. Gold (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on April 26, 2010 (File No. 000-50484)).</a>
10.2†**	<a href="#">Employment letter dated March 6, 2014, between MEI Pharma, Inc. and David M. Urso (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on April 8, 2014 (File No. 000-50484)).</a>
10.3†**	<a href="#">Amendment No. 1, dated July 12, 2018, to the Employment Letter dated March 6, 2014, between MEI Pharma, Inc. and David M. Urso (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on July 16, 2018 (File No. 000-50484)).</a>
10.4†**	<a href="#">Employment letter dated February 1, 2017, between MEI Pharma, Inc. and Brian G. Drazba (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on April 3, 2017 (File No. 000-50484)).</a>
10.5†**	<a href="#">Employment letter dated February 17, 2016, between MEI Pharma, Inc. and Richard G. Ghalie (incorporated by reference to Exhibit 10.5 to the Registrant's Annual Report on Form 10-K filed on September 2, 2021 (File No. 000-50484)).</a>

## Table of Contents

<b>Exhibit Number</b>	<b>Description of Exhibits</b>
10.6†**	<a href="#"><u>Amendment 2021-1 dated April 29, 2021, to the Employment letter dated February 17, 2016, between MEI Pharma, Inc. and Richard G. Ghalie (incorporated by reference to Exhibit 10.6 to the Registrant's Annual Report on Form 10-K filed on September 2, 2021 (File No. 000-50484)).</u></a>
10.7**	<a href="#"><u>Form of Indemnification Agreement (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on August 29, 2011 (File No. 000-50484)).</u></a>
10.8†**	<a href="#"><u>License Agreement, dated as of September 5, 2017, by and between MEI Pharma, Inc. and Presage Biosciences, Inc. (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed on November 8, 2017 (File No. 000-50484)).</u></a>
10.9**	<a href="#"><u>At-The-Market Equity Offering Sales Agreement, dated November 10, 2020 between MEI Pharma, Inc., Credit Suisse Securities (USA) LLC, and Stifel, Nicolaus &amp; Company, Inc. (incorporated by reference to Exhibit 1.1 to the Registrant's Current Report on Form 8-K filed on November 10, 2020 (File No. 000-50484)).</u></a>
10.10**	<a href="#"><u>Securities Purchase Agreement, dated May 11, 2018, between MEI Pharma, Inc. and the purchasers identified in Exhibit A therein (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on May 16, 2018 (File No. 000-50484)).</u></a>
10.11†**	<a href="#"><u>License, Development and Commercialization Agreement, dated as of October 31, 2018, by and between the Company and Kyowa Hakko Kirin Co., Ltd., now known as Kyowa Kirin Co., Ltd (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed on February 7, 2019 (File No. 000-50484)).</u></a>
10.12**#	<a href="#"><u>License, Development and Commercialization Agreement, dated as of April 13, 2020, by and between the Company and Kyowa Kirin Co., Ltd. (formerly known as Kyowa Hakko Kirin Co., Ltd.) (incorporated by reference to Exhibit 10.12 to the Registrant's Annual Report on Form 10-K filed on September 2, 2021 (File No. 000-50484)).</u></a>
10.13**	<a href="#"><u>Transition and Retirement Agreement between Brian G. Drazba and MEI Pharma, Inc., dated as of July 7, 2022 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on December 23, 2021 (File No. 000-50484)).</u></a>
10.14**	<a href="#"><u>Letter Agreement between Brian G. Drazba and MEI Pharma, Inc., dated as of July 7, 2022 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on July 7, 2022 (File No. 000-50484)).</u></a>
10.15†*	Amended and Restated Development and License Agreement, dated as of December 24, 2012, by and between Infinity Pharmaceuticals, Inc. and Intellikine, LLC.
10.16*	Amendment to Amended and Restated Development and License Agreement, dated as of July 29, 2014, by and between Infinity Pharmaceuticals, Inc. and Intellikine LLC.
10.17*	Amendment No. 2 to Amended and Restated Development and License Agreement, dated as of September 27, 2016, by and between Infinity Pharmaceuticals, Inc. and Intellikine LLC.
10.18*	Amendment No. 3 to Amended and Restated Development and License Agreement, dated as of July 26, 2017, by and between Infinity Pharmaceuticals, Inc. and Intellikine LLC.
10.19*	Amendment No. 4 to Amended and Restated Development and License Agreement, dated as of March 4, 2019, by and between Infinity Pharmaceuticals, Inc. and Intellikine LLC.
10.20*	Convertible Promissory Note, dated as of July 26, 2017, by and between Infinity Pharmaceuticals, Inc. and Intellikine LLC.

## Table of Contents

<u>Exhibit Number</u>	<u>Description of Exhibits</u>
10.21*	Amended and Restated License Agreement, dated as of November 1, 2016, by and between Infinity Pharmaceuticals, Inc. and Verastem, Inc.
10.22*	Termination and Revised Relationship Agreement, dated as of July 17, 2012, between Infinity Pharmaceuticals, Inc. and Mundipharma International Corporation Limited.
10.23*	Termination and Revised Relationship Agreement, dated as of July 17, 2012, between Infinity Pharmaceuticals, Inc. and Purdue Pharmaceutical Products L.P.
10.24*	Purchase and Sale Agreement, dated as of March 5, 2019, between Infinity Pharmaceuticals, Inc. and HealthCare Royalty Partners III, L.P.
10.25*	Protective Rights Agreement, dated as of March 11, 2019, between Infinity Pharmaceuticals, Inc. and HCR Collateral Managements, LLC.
10.26*	Funding Agreement, dated January 8, 2020, by and among Infinity Pharmaceuticals, Inc., BVF Partners, L.P., and Royalty Security, LLC.
10.27*	Novation and Amendment Agreement, dated January 27, 2020, by and among Infinity Pharmaceuticals, Inc., BVF Partners, L.P., Royalty Security, LLC, and Royalty Security Holdings, LLC.
10.28*	Lease Agreement, dated April 3, 2019, between Infinity Pharmaceuticals, Inc. and Sun Life Assurance Company of Canada.
10.29*	2010 Infinity Stock Incentive Plan.
10.30*	Amendment No. 1 to Infinity 2010 Stock Incentive Plan.
10.31*	Amendment No. 2 to Infinity 2010 Stock Incentive Plan.
10.32*	Amendment No. 3 to Infinity 2010 Stock Incentive Plan.
10.33*	Amendment No. 4 to Infinity 2010 Stock Incentive Plan.
10.34*	Amendment No. 5 to Infinity 2010 Stock Incentive Plan.
10.35*	Amendment No. 6 to Infinity 2010 Stock Incentive Plan.
10.36*	Form of Infinity Incentive Stock Option Agreement under 2010 Stock Incentive Plan.
10.37*	Form of Infinity Nonstatutory Stock Option Agreement under 2010 Stock Incentive Plan.
10.38*	Form of Infinity Restricted Stock Agreement under 2010 Stock Incentive Plan.
10.39*	Form of Infinity Nonstatutory Stock Option Agreement for Inducement Grant Pursuant to Nasdaq Stock Market Rule 5635(c)(4).
10.40*	Form of Infinity Nonstatutory Stock Option Award Agreement for Inducement Grant Pursuant to Nasdaq Stock Market Rule 5635(c)(4).
10.41*	Form of Infinity Restricted Stock Unit Agreement for Inducement Grant Pursuant to Nasdaq Stock Market Rule 5635(c)(4).
10.42*	Infinity 2019 Equity Incentive Plan.
10.43*	Form of Stock Option Agreement under Infinity 2019 Equity Incentive Plan.
10.44*	2019 Equity Incentive Plan of Infinity Pharmaceuticals, Inc., as amended by Amendment No. 1 and No. 2.

## Table of Contents

<u>Exhibit Number</u>	<u>Description of Exhibits</u>
10.45*	Offer Letter between Infinity Pharmaceuticals, Inc. and Stephane Peluso, Ph.D., dated July 12, 2021.
10.46*	Offer Letter between Infinity Pharmaceuticals, Inc. and Robert Ilaria, Jr., M.D., dated August 11, 2021.
10.47*	Infinity Pharmaceuticals, Inc. Executive Severance Benefits Plan effective February 6, 2013.
10.48*	Amendment No. 1, dated August 3, 2018, to Infinity Pharmaceuticals, Inc. Executive Severance Benefits Plan.
10.49*	Retention and Severance Protection Agreement between Infinity Pharmaceuticals, Inc. and Robert Ilaria dated as of February 22, 2023.
10.50*	Retention and Severance Protection Agreement between Infinity Pharmaceuticals, Inc. and Stephane Peluso dated as of February 22, 2023.
23.1	<a href="#">Consent of BDO USA, LLP, the independent registered public accounting firm for MEI Pharma, Inc.</a>
23.2	<a href="#">Consent of Ernst &amp; Young LLP, the independent registered public accounting firm for Infinity Pharmaceuticals, Inc.</a>
24.1	<a href="#">Powers of Attorney (included on signature page).</a>
99.1*	Form of MEI Pharma, Inc. Proxy Card.
99.2*	Form of Infinity Pharmaceuticals, Inc. Proxy Card.
99.3	<a href="#">Consent of Adelene Q. Perkins.</a>
99.4	<a href="#">Consent of Norman C. Selby.</a>
99.5	<a href="#">Consent of Richard Gaynor, M.D.</a>
99.6	<a href="#">Consent of Torreya Partners</a>
99.7	<a href="#">Consent of Aquilo Partners</a>
101.INS*	XBRL Instance Document.
101.SCH*	XBRL Taxonomy Extension Schema Document.
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF*	XBRL Taxonomy Extension Definitions Linkbase Document.
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document.
107	<a href="#">Filing Fee Exhibit.</a>

\* To be filed by amendment.  
\*\* Previously filed.  
‡ Denotes management contract or compensatory plan or arrangement.  
† Portions of this exhibit have been redacted pursuant to a confidential treatment request filed with the Securities and Exchange Commission.  
# Certain of the exhibits and schedules to this exhibit have been omitted in accordance with Regulation S-K Item 601(a)(5). The Registrant agrees to furnish a copy of all omitted exhibits and schedules to the SEC upon its request.



## SIGNATURES

Pursuant to the requirements of the Securities Act, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized in the San Diego, California, on April 27, 2023.

### MEI Pharma, Inc.

By: /s/ Daniel P. Gold

Name: Daniel P. Gold

Title: President and Chief Executive Officer and Director

## POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Daniel P. Gold and Brian G. Drazba, and each or any one of them, as his or her true and lawful attorney-in-fact and agent, each with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this registration statement, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Daniel P. Gold</u> Daniel P. Gold	President and Chief Executive Officer and Director (Principal Executive Officer)	April 27, 2023
<u>/s/ Brian G. Drazba</u> Brian G. Drazba	Secretary, Chief Financial Officer (Principal Financial and Accounting Officer)	April 27, 2023
<u>/s/ Charles V. Baltic III</u> Charles V. Baltic III	Chair of the Board	April 27, 2023
<u>/s/ Thomas C. Reynolds</u> Thomas C. Reynolds	Director	April 27, 2023
<u>/s/ Nicholas R. Glover</u> Nicholas R. Glover	Director	April 27, 2023
<u>/s/ Frederick W. Driscoll</u> Frederick W. Driscoll	Director	April 27, 2023
<u>/s/ Tamar D. Howson</u> Tamar D. Howson	Director	April 27, 2023
<u>/s/ Sujay Kango</u> Sujay Kango	Director	April 27, 2023

Consent of Independent Registered Public Accounting Firm

MEI Pharma, Inc.  
San Diego, California

We hereby consent to the use in the joint proxy statement/prospectus constituting a part of this Registration Statement of our report dated September 8, 2022, except for the impact of the reverse stock split described in Note 1, as to which the date is April 27, 2023, relating to the financial statements of MEI Pharma, Inc., which is contained in that joint proxy statement/prospectus.

We also consent to the reference to us under the caption “Experts” in the joint proxy statement/prospectus.

/s/ BDO USA, LLP

San Diego, California

April 27, 2023

## Consent of Independent Registered Public Accounting Firm

We consent to the reference to our firm under the caption “Experts” in the joint proxy statement/prospectus, which is part of the Registration Statement (Form S-4) of MEI Pharma, Inc., and to the inclusion in such Registration Statement of our report (which contains an explanatory paragraph describing conditions that raise substantial doubt about Infinity Pharmaceuticals, Inc.’s ability to continue as a going concern as described in Note 2 to Infinity Pharmaceuticals, Inc.’s consolidated financial statements) dated March 28, 2023 with respect to the consolidated financial statements of Infinity Pharmaceuticals, Inc., included in Infinity Pharmaceuticals, Inc.’s Annual Report (Form 10-K) for the year ended December 31, 2022, filed with the Securities and Exchange Commission.

/s/ Ernst & Young LLP

Boston, Massachusetts  
April 27, 2023

**Consent of Person Named as About to Become Director**

April 27, 2023

Pursuant to Rule 438 promulgated under the Securities Act of 1933, as amended, I hereby consent to my being named in the Registration Statement on Form S-4 MEI Pharma, Inc., and all amendments thereto (the "Registration Statement"), and any related prospectus filed pursuant to Rule 424 promulgated under the Securities Act of 1933, as amended, as a person anticipated to become a director of MEI Pharma, Inc. upon completion of the merger described therein, and to the filing of this consent as an exhibit to the Registration Statement.

Sincerely,

/s/ Adelene Q. Perkins

Name: Adelene Q. Perkins

**Consent of Person Named as About to Become Director**

April 27, 2023

Pursuant to Rule 438 promulgated under the Securities Act of 1933, as amended, I hereby consent to my being named in the Registration Statement on Form S-4 MEI Pharma, Inc., and all amendments thereto (the "Registration Statement"), and any related prospectus filed pursuant to Rule 424 promulgated under the Securities Act of 1933, as amended, as a person anticipated to become a director of MEI Pharma, Inc. upon completion of the merger described therein, and to the filing of this consent as an exhibit to the Registration Statement.

Sincerely,

/s/ Norman C. Selby

Name: Norman C. Selby

**Consent of Person Named as About to Become Director**

April 27, 2023

Pursuant to Rule 438 promulgated under the Securities Act of 1933, as amended, I hereby consent to my being named in the Registration Statement on Form S-4 MEI Pharma, Inc., and all amendments thereto (the "Registration Statement"), and any related prospectus filed pursuant to Rule 424 promulgated under the Securities Act of 1933, as amended, as a person anticipated to become a director of MEI Pharma, Inc. upon completion of the merger described therein, and to the filing of this consent as an exhibit to the Registration Statement.

Sincerely,

/s/ Richard Gaynor, M.D.

Name: Richard Gaynor, M.D.



Torrey Capital LLC  
555 Madison Avenue, Suite 1201  
New York, NY 10022  
(212) 257-5801  
www.torrey.com

#### CONSENT OF TORREYA CAPITAL

We hereby consent to the inclusion of our opinion letter, dated February 22, 2023 (the "Opinion Letter"), addressed to the Board of Directors of MEI Pharma, Inc. (the "Company" or "MEI"), included as Annex B to the joint proxy statement/prospectus contained in that certain registration statement on Form S-4 (the "Registration Statement") of MEI, relating to the proposed agreement and plan of merger involving MEI and Infinity Pharmaceuticals, Inc. ("Infinity"), and references made to our opinion under the captions "The Merger – Opinion of MEI's Financial Advisor" and "The Merger – Certain Prospective Financial Information of MEI" in the Registration Statement.

Notwithstanding the foregoing, it is understood that our consent is being delivered solely in connection with the filing of the Registration Statement and that our Opinion Letter is not to be used, circulated, quoted or otherwise referred to for any other purpose, nor is it to be filed with, included in or referred to, in whole or in part in any registration statement (including any subsequent amendments to the Registration Statement), proxy statement or any other document, except in accordance with our prior written consent.

In giving such consent, we do not admit that we come within the category of persons whose consent is required under, nor do we admit that we are "experts" for purposes of, the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

/s/ Torrey Capital LLC

---

Torrey Capital LLC  
New York, New York  
4/27/2023

## CONSENT OF AQUILO PARTNERS

We hereby consent to the inclusion of our opinion letter, dated February 22, 2023 (the “Opinion Letter”), addressed to the Board of Directors of Infinity Pharmaceuticals, Inc. (the “Company”), included as Annex C to the joint proxy statement/prospectus contained in that certain registration statement on Form S-4 (the “Registration Statement”) of MEI Pharma, Inc. (“MEI”), relating to the proposed agreement and plan of merger involving MEI and the Company, and references made to our opinion under the captions “The Merger – Opinion of Infinity Financial Advisor” and “The Merger – Summary of Certain Infinity Unaudited Prospective Financial Information” in the Registration Statement.

Notwithstanding the foregoing, it is understood that our consent is being delivered solely in connection with the filing of the Registration Statement and that our Opinion Letter is not to be used, circulated, quoted or otherwise referred to for any other purpose, nor is it to be filed with, included in or referred to, in whole or in part in any registration statement (including any subsequent amendments to the Registration Statement), proxy statement or any other document, except in accordance with our prior written consent.

In giving such consent, we do not admit that we come within the category of persons whose consent is required under, nor do we admit that we are “experts” for purposes of, the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

/s/ Aquilo Partners

Aquilo Partners

San Francisco, California

April 27, 2023



## CALCULATION OF FILING FEE TABLES

FORM S-4  
(Form Type)**MEI Pharma, Inc.**  
(Exact Name of Registrant as Specified in Its Charter)

Table 1: Newly Registered Securities

	Security Type	Security Class Title	Fee Calculation or Carry Forward Rule	Amount Registered	Proposed Maximum Offering Price Per Share	Maximum Aggregate Offering Price	Fee Rate	Amount of Registration Fee
Fees to be Paid	Equity	Common Stock, par value \$0.00000002 per share	Other	4,824,893 shares(1)	N/A	\$14,434,506.15(2)	\$0.00011020	\$1,590.68
Fees Previously Paid	—	—	—	—	—	—	—	—
	Total Offering Amounts				N/A	\$14,434,506.15	\$0.00011020	\$1,590.68
	Total Fees Previously Paid				—	—	—	—
	Total Fee Offsets				—	—	—	—
	Net Fee Due							\$1,590.68

- (1) Represents the maximum number of shares of common stock, par value \$0.00000002 per share (“MEI Common Stock”), of MEI Pharma, Inc., a Delaware corporation (the “Registrant”), that may be issued pursuant to the Agreement and Plan of Merger, dated as of February 22, 2023, by and among Registrant, Meadow Merger Sub, Inc., a Delaware corporation and a wholly-owned subsidiary of the Registrant, and Infinity Pharmaceuticals Inc. (“Infinity”), estimated solely for the purpose of calculating the registration fee. The number of shares of MEI Common Stock being registered is based on (a) (i) 92,351,287 shares of common stock, par value \$0.01 per share, of Infinity (the “Infinity Common Stock”) outstanding or underlying restricted stock units as of April 26, 2023, multiplied by (b) the exchange ratio of 0.052245 shares of MEI Common Stock for each share of Infinity Common Stock.
- (2) Estimated solely for purposes of calculating the registration fee required by Section 6(b) of the Securities Act of 1933, as amended (the “Securities Act”), and calculated pursuant to Rules 457(f)(1) and 457(c) under the Securities Act. Such amount equals the product of (i) \$0.1563, the average of the high and the low prices per share of Infinity Common Stock, as reported on The Nasdaq Global Select Market on April 26, 2023, which is within five business days prior to the filing of this registration statement, and (ii) the maximum aggregate number of shares of Infinity Common Stock expected to be cancelled in exchange for shares of the Registrant.