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

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended March 31, 2019

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number: 000-50484

MEI Pharma, Inc.

(Exact name of registrant as specified in its charter)

DELAWARE
(State or other jurisdiction of
incorporation or organization)

51-0407811
(I.R.S. Employer
Identification No.)

3611 Valley Centre Drive, Suite 500, San Diego, CA 92130
(Address of principal executive offices) (Zip Code)

(858) 369-7100

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

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"/>	Non-accelerated filer	<input type="checkbox"/>
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 checkmark 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 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of May 6, 2019, the number of shares outstanding of the issuer's common stock, \$0.00000002 par value, was 71,290,460.

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, \$0.00000002 par value	MEIP	The NASDAQ Stock Market LLC

MEI PHARMA, INC.

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PART I FINANCIAL INFORMATION**Item 1: Condensed Financial Statements – Unaudited**

MEI PHARMA, INC.
CONDENSED BALANCE SHEETS
(In thousands, except per share amounts)

	March 31, 2019	June 30, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 7,426	\$ 13,309
Short term investments	74,864	89,434
Total cash, cash equivalents and short-term investments	82,290	102,743
Prepaid expenses and other current assets	3,153	1,586
Total current assets	85,443	104,329
Intangible assets, net	270	296
Property and equipment, net	213	32
Total assets	<u>\$ 85,926</u>	<u>\$ 104,657</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,969	\$ 3,643
Accrued liabilities	5,685	3,454
Deferred revenue	4,197	788
Total current liabilities	11,851	7,885
Deferred revenue, long-term	4,222	—
Warrant liability	31,971	46,313
Total liabilities	48,044	54,198
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock, \$0.01 par value; 100 shares authorized; none outstanding	—	—
Common stock, \$0.00000002 par value; 226,000 shares authorized; 71,281 and 70,406 shares issued and outstanding at March 31, 2019 and June 30, 2018, respectively	—	—
Additional paid-in-capital	272,153	264,858
Accumulated deficit	(234,271)	(214,399)
Total stockholders' equity	37,882	50,459
Total liabilities and stockholders' equity	<u>\$ 85,926</u>	<u>\$ 104,657</u>

See accompanying notes to financial statements.

MEI PHARMA, INC.
CONDENSED STATEMENTS OF OPERATIONS
(In thousands, except per share amounts)
(Unaudited)

	Three Months Ended		Nine Months Ended	
	March 31,		March 31,	
	2019	2018	2019	2018
Revenue	\$ 1,249	\$ 433	\$ 3,785	\$ 1,074
Operating expenses:				
Cost of revenue	1,163	930	3,161	2,276
Research and development	9,071	3,071	24,268	12,579
General and administrative	3,631	2,486	10,853	7,332
Total operating expenses	<u>13,865</u>	<u>6,487</u>	<u>38,282</u>	<u>22,187</u>
Loss from operations	(12,616)	(6,054)	(34,497)	(21,113)
Other income (expense):				
Change in fair value of warrant liability	(5,201)	—	13,274	—
Interest and dividend income	462	106	1,352	299
Income tax expense	—	—	(1)	(1)
Net loss	<u>\$(17,355)</u>	<u>\$ (5,948)</u>	<u>\$(19,872)</u>	<u>\$(20,815)</u>
Net loss:				
Basic	<u>\$(17,355)</u>	<u>\$ (5,948)</u>	<u>\$(19,872)</u>	<u>\$(20,815)</u>
Diluted	<u>\$(17,355)</u>	<u>\$ (5,948)</u>	<u>\$(43,309)</u>	<u>\$(20,815)</u>
Net loss per share:				
Basic	<u>\$ (0.24)</u>	<u>\$ (0.16)</u>	<u>\$ (0.28)</u>	<u>\$ (0.56)</u>
Diluted	<u>\$ (0.24)</u>	<u>\$ (0.16)</u>	<u>\$ (0.60)</u>	<u>\$ (0.56)</u>
Shares used in computing net loss per share:				
Basic	<u>71,200</u>	<u>37,449</u>	<u>71,069</u>	<u>37,369</u>
Diluted	<u>71,200</u>	<u>37,449</u>	<u>72,011</u>	<u>37,369</u>

See accompanying notes to financial statements.

MEI PHARMA, INC.
CONDENSED STATEMENTS OF STOCKHOLDERS' EQUITY
(In thousands)
(Unaudited)

	Common Shares	Additional paid in capital	Accumulated Deficit	Total Stockholders' Equity
Balance at June 30, 2018	70,406	\$264,858	\$ (214,399)	\$ 50,459
Net loss	—	—	(14,542)	(14,542)
Issuance of common stock for vested restricted stock units	246	(324)	—	(324)
Exercise of warrants	440	2,186	—	2,186
Exercise of stock options	23	43	—	43
Share-based compensation expense	—	1,937	—	1,937
Balance at September 30, 2018	71,115	268,700	(228,941)	39,759
Net income	—	—	12,025	12,025
Exercise of stock options	16	24	—	24
Share-based compensation expense	—	1,663	—	1,663
Balance at December 31, 2018	71,131	270,387	(216,916)	53,471
Net loss	—	—	(17,355)	(17,355)
Exercise of stock options	150	252	—	252
Share-based compensation expense	—	1,514	—	1,514
Balance at March 31, 2019	<u>71,281</u>	<u>\$272,153</u>	<u>\$ (234,271)</u>	<u>\$ 37,882</u>
	Common Shares	Additional paid in capital	Accumulated Deficit	Total Stockholders' Equity
Balance at June 30, 2017	36,772	\$225,169	\$ (174,331)	\$ 50,838
Net loss	—	—	(8,788)	(8,788)
Issuance of common stock for milestone payment	167	500	—	500
Exercise of stock options	11	20	—	20
Share-based compensation expense	—	996	—	996
Balance at September 30, 2017	36,950	226,685	(183,119)	43,566
Net loss	—	—	(6,079)	(6,079)
Exercise of stock options	102	169	—	169
Share-based compensation expense	—	702	—	702
Balance at December 31, 2017	37,052	227,556	(189,198)	38,358
Net loss	—	—	(5,948)	(5,948)
Issuance of common stock for vested restricted stock units	271	(267)	—	(267)
Share-based compensation expense	—	770	—	770
Balance at March 31, 2018	<u>37,323</u>	<u>\$228,059</u>	<u>\$ (195,146)</u>	<u>\$ 32,913</u>

See accompanying notes to financial statements.

MEI PHARMA, INC.
CONDENSED STATEMENTS OF CASH FLOWS
(In thousands)
(Unaudited)

	Nine Months Ended	
	March 31,	
	2019	2018
Cash flows from operating activities:		
Net loss	\$(19,872)	\$(20,815)
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in fair value of warrant liability	(13,274)	—
Share-based compensation	5,114	2,468
Depreciation and amortization	52	40
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(1,567)	904
Accounts payable	(1,674)	674
Accrued liabilities	2,231	(670)
Deferred revenue	7,631	(153)
Net cash used in operating activities	<u>(21,359)</u>	<u>(17,552)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(207)	—
Purchases of short-term investments	(39,756)	(29,937)
Proceeds from maturity of short-term investments	54,326	45,040
Net cash provided by investing activities	<u>14,363</u>	<u>15,103</u>
Cash flows from financing activities:		
Proceeds from exercise of stock options	319	189
Proceeds from exercise of warrants	1,118	—
Payment of RSU tax withholdings in exchange for common shares surrendered by RSU holders	(324)	—
Net cash provided by financing activities	<u>1,113</u>	<u>189</u>
Net decrease in cash and cash equivalents	(5,883)	(2,260)
Cash and cash equivalents at beginning of the period	13,309	8,458
Cash and cash equivalents at end of the period	<u>\$ 7,426</u>	<u>\$ 6,198</u>

See accompanying notes to financial statements.

MEI PHARMA, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS
(Unaudited)

Note 1. The Company and Summary of Significant Accounting Policies

We are a late-stage pharmaceutical company focused on leveraging our extensive development and oncology expertise to identify and advance new therapies intended to meaningfully improve the treatment of cancer. Our portfolio of drug candidates contains four clinical-stage candidates, including one candidate in an ongoing Phase 3 global registration trial and another candidate in an on-going Phase 2 clinical trial that we intend to submit to the U.S. Food and Drug Administration (“FDA”) to support accelerated approval of a marketing application. Our common stock is listed on the NASDAQ Capital Market under the symbol “MEIP”.

Clinical Development Programs

Our approach to building our pipeline is to license promising cancer agents and build value in programs through development and commercialization, or strategic partnerships, as appropriate. Our drug candidate pipeline includes:

- ME-401, an oral phosphatidylinositol 3-kinase (“PI3K”) delta inhibitor;
- Voruciclib, an oral cyclin-dependent kinase (“CDK”) inhibitor;
- ME-344, a mitochondrial inhibitor targeting the oxidative phosphorylation (“OXPHOS”) complex; and
- Pracinostat, an oral histone deacetylase (“HDAC”) inhibitor.

Basis of Presentation

The accompanying unaudited financial statements have been prepared in accordance with accounting principles generally accepted in the United States (“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. Certain amounts have been reclassified to conform to current period presentation. We have evaluated subsequent events through the date the financial statements were issued.

The accompanying unaudited financial statements should be read in conjunction with the audited financial statements and notes thereto as of and for the fiscal year ended June 30, 2018, included in our Annual Report on Form 10-K (“2018 Annual Report”) filed with the Securities and Exchange Commission (“SEC”) on August 30, 2018. Interim results are not necessarily indicative of results for a full year.

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.

Revenue Recognition

Beginning July 1, 2018, 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. Any adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment. To date, we have not recognized any material cumulative catch-up adjustments from changes in our estimate of the transaction price.

We develop estimates of the stand-alone selling price for each distinct performance obligation and allocate the overall transaction price to each accounting unit based on a relative stand-alone selling price approach. We develop assumptions that require

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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 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 obligations, we use judgment to assess the nature of the combined performance obligation to determine whether the combined 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. To date, we have not recognized any material cumulative catch-up adjustments from changes in our estimate of the measure of progress.

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 royalty revenue from license agreements.

We recognized revenue associated with the following license agreements (in thousands):

	Three Months Ended March 31,		Nine Months Ended March 31,	
	2019	2018	2019	2018
KHK License Agreement	\$ 631	\$ —	\$ 1,992	\$ —
Helsinn License Agreement	618	433	1,793	1,074
	<u>\$ 1,249</u>	<u>\$ 433</u>	<u>\$ 3,785</u>	<u>\$ 1,074</u>

Revenue for the three and nine months ended March 31, 2019 included revenue related to the KHK License Agreement (Note 3). Based on the characteristics of the KHK License Agreement, delivery of the license is a distinct performance obligation, and we recognized related revenue of \$0.8 million during the nine months ended March 31, 2019 when the license was transferred to the licensee and the licensee could use and benefit from the license. The license agreement included other distinct performance obligations that will be satisfied over time, and accordingly we recognized \$1.1 million related to our progress toward satisfying those obligations during the nine months ended March 31, 2019.

Revenue for the three and nine months ended March 31, 2019 and 2018 included revenue related to the Helsinn License Agreement (Note 3). Based on the characteristics of the Helsinn License Agreement, control of the remaining deliverables occurs over time and therefore we recognize revenue based on the extent of progress towards completion of the performance obligations.

As of March 31, 2019, we had \$8.4 million of deferred revenue associated with our remaining performance obligations under the KHK and Helsinn license agreements. We expect to recognize approximately \$4.2 million of deferred revenue in the next 12 months, and an additional \$4.2 million thereafter.

Contract Balances

The following table presents changes in contract assets and contract liabilities during the nine months ended March 31, 2019 (in thousands):

	As of July 1, 2018	Net Change	As of March 31, 2019
Receivables	\$ 82	\$ 51	\$ 133
Contract Assets	\$ 312	\$ 85	\$ 397
Contract Liabilities	\$ 788	\$ 7,631	\$ 8,419

The timing of revenue recognition, invoicing and cash collections results in billed accounts receivable and unbilled receivables (contract assets), which are classified as “prepaid expenses and other current assets” on our Condensed Balance Sheet, and deferred revenue (contract liabilities). We invoice our customers in accordance with agreed-upon contractual terms, typically at

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periodic intervals or upon achievement of contractual milestones. Invoicing may occur subsequent to revenue recognition, resulting in contract assets. We may receive advance payments from our customers before revenue is recognized, resulting in contract liabilities. The contract assets and liabilities reported on the Condensed Balance Sheet relate to the KHK License Agreement and Helsinn License Agreement.

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.

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.

Share-Based Compensation

Share-based compensation expense for employees and directors is recognized in the Condensed Statement of Operations based on estimated amounts, including the grant date fair value and the expected service period. For stock options, we estimate 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. We estimate 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 restricted stock unit ("RSU") equity awards, we estimate the grant date fair value using our closing stock price on the date of grant. We recognize the effect of forfeitures in compensation expense when the forfeitures occur. The estimated forfeiture rates may differ from actual forfeiture rates which would affect the amount of expense recognized during the period. We recognize the value of the awards over the awards' requisite service or performance periods. 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 March 31, 2019 and June 30, 2018, we have established a valuation allowance to fully reserve our net deferred tax assets. Changes in our ownership may limit the amount of net operating loss carry-forwards that can be utilized in the future to offset taxable income.

The Financial Accounting Standards Board ("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 March 31, 2019 or June 30, 2018.

There have been no material changes in our unrecognized tax benefits since June 30, 2018, and, as such, the disclosures included in our 2018 Annual Report continue to be relevant for the nine month period ended March 31, 2019.

Recent Accounting Pronouncements

Adopted Accounting Standards

In May 2014, the FASB issued Accounting Standards Update No. 2014-09 (Topic 606) "Revenue from Contracts with Customers." The FASB subsequently issued a number of narrow-scope technical improvements to Topic 606 before it became effective. The guidance in Topic 606 provides companies with a single model for accounting for revenue arising from contracts with customers and supersedes prior revenue recognition guidance under ASC Topic 605, "Revenue Recognition" (Topic 605). On July 1, 2018, we adopted Topic 606 using the modified retrospective method applied to those contracts which were not completed as of the adoption date. We did not record any adjustment to opening retained earnings as of July 1, 2018 as the adoption of Topic 606 did not have an impact on our financial statements. Refer to *Revenue Recognition* for further details of accounting for revenue with customers.

Accounting Standards Not Yet Adopted

In February 2016, the FASB issued ASU 2016-02 Leases, which introduces the recognition of lease assets and lease liabilities by lessees for those leases classified as operating leases under previous guidance. The new standard establishes a right-of-use (“ROU”) model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as finance or operating, with classification affecting the pattern and classification of expense recognition in the income statement.

A modified retrospective transition approach is required, applying the new standard to all leases existing at the date of initial application. An entity may choose to use either (1) its effective date or (2) the beginning of the earliest comparative period presented in the financial statements as its date of initial application. We will adopt the new lease standard effective July 1, 2019 and use the effective date as our date of initial application. Consequently, financial information will not be updated and the disclosures required under the new standard will not be provided for dates and periods before July 1, 2019.

The new standard provides a number of optional practical expedients in transition. We expect to elect the package of practical expedients, which permits us not to reassess under the new standard our prior conclusions about lease identification, lease classification and initial direct costs.

We expect that this standard will not have a material effect on our financial statements. While we continue to assess all of the effects of adoption, we currently believe the most significant effects relate to (1) the recognition of new ROU assets and lease liabilities on our balance sheet for our real property operating lease; and (2) providing new disclosures about our leasing activities.

On adoption, we currently expect to recognize an additional operating lease liability with a corresponding ROU asset based on the present value of the remaining minimum rental payments under current leasing standards for existing operating leases.

The new standard also provides practical expedients for an entity’s ongoing accounting. We currently expect to elect the short-term lease recognition exemption for our office equipment leases. This means, for those leases that qualify, that we will not recognize ROU assets or lease liabilities, including not recognizing ROU assets or lease liabilities for existing short-term leases of those assets during the transition.

Note 2. 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.

We measure the following financial instruments at fair value on a recurring basis. The fair values of these financial instruments were as follows (in thousands):

	March 31, 2019			June 30, 2018		
	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
Warrant liability	\$ —	\$ —	\$(31,971)	\$ —	\$ —	\$(46,313)
Total	\$ —	\$ —	\$(31,971)	\$ —	\$ —	\$(46,313)

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, where applicable, 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 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

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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 Statement of Operations for the three and nine months ended March 31, 2019.

To calculate the fair value of the warrant liability, the following assumptions were used:

	March 31, 2019	June 30, 2018
Risk-free interest rate	2.2%	2.7%
Expected life (years)	4.1	4.8
Expected volatility	81.6%	77.3%
Dividend yield	0.0%	0.0%
Fair value of common stock	\$ 3.07	\$ 3.94

The following table sets forth a summary of changes in the estimated fair value of our Level 3 warrant liability for the nine months ended March 31, 2019 (in thousands):

	Fair Value of Warrants Using Significant Unobservable Inputs (Level 3)
Balance at July 1, 2018	\$ 46,313
Reclassification of derivative liability to equity upon exercise of warrants	(1,068)
Change in estimated fair value of liability classified warrants	(13,274)
Balance at March 31, 2019	\$ 31,971

Note 3. License Agreements

KHK License Agreement

In October 2018, we entered into a license agreement with Kyowa Hakko Kirin Co., Ltd., a Japanese life sciences company (“KHK”) for ME-401 (“the KHK License Agreement”). Under the terms of the KHK License Agreement, KHK was granted the exclusive right to develop and commercialize ME-401 in Japan. We also granted KHK the right to purchase supply of ME-401 for commercial requirements at cost plus a pre-negotiated percentage, as well as manufacturing rights in Japan. In return, we received an upfront payment of \$10.0 million and are also eligible to receive up to \$87.5 million in additional development and commercialization milestones, as well as royalties on net sales of ME-401 in Japan extending into the mid-teens. The KHK License Agreement expires at the end of the royalty term, that is, upon the last to occur of (a) expiration of our patents in Japan, (b) expiration of regulatory exclusivity for ME-401 in Japan or (c) 10 years from the first commercial sale of ME-401 in Japan.

We assessed the KHK License Agreement in accordance with ASC 606 and determined that our performance obligations comprise the license, research and development obligations, and our obligation to provide clinical trial materials to KHK.

We determined that the transaction price amounts to the upfront payment of \$10.0 million. Future milestone payments are fully contingent as the risk of significant revenue reversal will only be resolved depending on future research and development and/or regulatory approval outcomes. We will re-evaluate the likelihood of achieving future milestones at the end of each reporting period.

We determined that control of the license was transferred to KHK during the nine months ended March 31, 2019. Revenue allocated to the research and development obligations is recognized based on the proportional performance of these research and development activities, which we expect to recognize through fiscal year 2022. Revenue allocated to providing clinical trial materials is recognized upon delivery.

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 (“Helsinn”) for pracinostat in acute myeloid leukemia (“AML”), myelodysplastic syndrome (“MDS”) and other potential indications (the “Helsinn License Agreement”). Under the terms

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of the agreement, Helsinn was granted a worldwide exclusive license to develop, manufacture and commercialize pracinostat, and is primarily responsible for funding its global development and commercialization. As compensation for such grant of rights, we received payments of \$20.0 million. In addition, we are eligible to receive up to \$444 million in potential regulatory and sales-based milestones, along with royalty payments on the net sales of pracinostat, which, in the U.S., are tiered and begin in the mid-teens.

We determined that the agreement contains multiple performance obligations for purposes of revenue recognition. Revenue related to the research and development elements of the arrangement is recognized based on the extent of progress toward completion of each performance obligation. Revenue is recognized on a gross basis as we are the primary obligor and have discretion in supplier selection. During the nine months ended March 31, 2019, our only remaining performance obligation under the agreement is the conduct of a Phase 2 dose-optimization study of pracinostat in combination with azacitidine in patients with high and very high risk MDS who are previously untreated with hypomethylating agents (the “POC study”), for which Helsinn has agreed to share third-party expenses.

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.

CyDex License Agreement

We are party to a license agreement with CyDex Pharmaceuticals, Inc. (“CyDex”). Under the license agreement, CyDex granted to us an exclusive, nontransferable license to intellectual property rights relating to Captisol® for use with our isoflavone-based drug compounds (currently ME-344). We agreed to pay to CyDex a non-refundable license issuance fee, future milestone payments, and royalties at a low, single-digit percentage rate on future sales of our approved drugs utilizing Captisol. Contemporaneously with the license agreement, CyDex entered into a commercial supply agreement with us, pursuant to which we agreed to purchase 100% of our requirements for Captisol from CyDex. We may terminate both the license agreement and the supply agreement at any time upon 90 days’ prior written notice.

Note 4. BeiGene Collaboration

In October 2018, we entered into a clinical collaboration with BeiGene, Ltd. (“BeiGene”) to evaluate the safety and efficacy of ME-401 in combination with BeiGene’s zanubrutinib, 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, we amended our ongoing Phase 1b trial to include evaluation of ME-401 in combination with zanubrutinib in patients with B-cell malignancies. Study costs are being shared equally by the parties, and we agreed to supply ME-401 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 ME-401 and BeiGene retained full commercial rights for zanubrutinib.

Note 5. 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 three and nine months ended March 31, 2019 and 2018. Diluted net 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 loss used to calculate basic and diluted loss per share (in thousands):

	Three Months Ended March 31,		Nine Months Ended March 31,	
	2019	2018	2019	2018
Net loss – basic	<u>\$(17,354)</u>	<u>\$(5,948)</u>	<u>\$(19,872)</u>	<u>\$(20,815)</u>
Change in fair value of warrant liability	<u>—</u>	<u>—</u>	<u>(23,437)</u>	<u>—</u>
Net loss – diluted	<u>\$(17,354)</u>	<u>\$(5,948)</u>	<u>\$(43,309)</u>	<u>\$(20,815)</u>

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The following table presents the calculation of weighted average shares used to calculate basic and diluted loss per share (in thousands):

	Three Months Ended March 31,		Nine Months Ended March 31,	
	2019	2018	2019	2018
Weighted average shares outstanding	71,200	37,052	71,069	36,970
Effect of vested restricted stock units	—	397	—	399
Weighted average shares used in calculating basic net loss per share	71,200	37,449	71,069	37,369
Effect of potentially dilutive common shares from equity awards and liability-classified warrants	—	—	942	—
Weighted average shares used in calculating diluted net loss per share	71,200	37,449	72,011	37,369
Potentially dilutive shares excluded from calculation due to anti-dilutive effect	24,207	5,913	18,819	7,912

Note 6. 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.

We have leased approximately 13,700 square feet of office space, located at 3611 Valley Centre Drive, San Diego, California 92130. The monthly rental rate is approximately \$46,000 over the remaining lease term, plus a pro rata share of certain building expenses. In September 2018, we entered into a lease agreement for approximately 7,000 additional square feet of office space at the same location, at a rental rate of approximately \$21,000 per month, plus a pro rata share of certain building expenses. Each lease term expires in May 2020. The location houses our executive and administrative offices. The remaining contractual obligations for the two leases are \$0.6 million and \$0.3 million, respectively.

Presage License Agreement

As discussed in Note 3, 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 March 31, 2019, we have not accrued any amounts for potential future payments.

*S*Bio Purchase Agreement*

We are party to a definitive asset purchase agreement with S*Bio, pursuant to which we acquired certain assets comprised of intellectual property and technology including rights to pracinostat. We agreed to make certain milestone payments to S*Bio based on the achievement of certain clinical, regulatory and net sales-based milestones, as well as to make certain contingent earnout payments to S*Bio. Milestone payments will be made to S*Bio up to an aggregate amount of \$74.5 million if certain U.S., E.U. and Japanese regulatory approvals are obtained and if certain net sales thresholds are met in North America, the E.U. and Japan. As of March 31, 2019, we have not accrued any amounts for potential future payments.

CyDex License Agreement

As discussed in Note 3, we are party to a license agreement with CyDex under which we may be required to make future payments upon the achievement of certain milestones, as well as potential future royalties based upon net sales. Contemporaneously with the license agreement, CyDex entered into a commercial supply agreement with us, pursuant to which we agreed to purchase 100% of our requirements for Captisol from CyDex. As of March 31, 2019, we have not accrued any amounts for potential future payments.

Note 7. Short-Term Investments

As of March 31, 2019 and June 30, 2018, our short-term investments consisted of \$74.9 million and \$89.4 million, respectively, in U.S. government securities. The short-term investments held as of March 31, 2019 and June 30, 2018 had maturity dates of less than one year, are considered to be "held to maturity" and are carried at amortized cost. As of March 31, 2019 and June 30, 2018, the gross holding gains and losses were immaterial.

Note 8. Stockholders' Equity

Equity Transactions

May 2018 Private Placement

In May 2018, we raised \$70.2 million, net of transaction costs, in a private placement of common shares and warrants. We issued and sold 33,003,296 shares of common stock, as well as warrants to purchase 16,501,645 shares. The price was approximately \$2.27 to purchase one share with an accompanying warrant; each warrant is for the purchase of one-half of a share. The warrants are exercisable at a price of \$2.54 per share and expire in May 2023. The warrants were fully vested upon issuance in May 2018. In the event of a sale of the Company, the terms of the warrants require us to use our best efforts to ensure the holders of such warrants will have a continuing right to purchase shares of the acquirer and, if our efforts are unsuccessful, to make a payment to such warrant holders based on a Black-Scholes valuation (using variables as specified in the warrants). Therefore, we are required to account for the warrants as liabilities and record them at fair value. We recorded the fair value of the warrants of \$36.6 million upon issuance using the Black-Scholes valuation model. The warrants were revalued as of June 30, 2018 at \$46.3 million and as of March 31, 2019 at \$32.0 million; the changes in fair value were recorded in our Condensed Statement of Operations. During the nine months ended March 31, 2019, warrants were exercised for 440,043 shares of common stock, and we received proceeds of \$1.1 million. As of March 31, 2019, there were outstanding warrants to purchase 16,061,602 shares of our common stock.

Shelf Registration Statement

We have a shelf registration statement that permits us to sell, from time to time, up to \$150.0 million of common stock, preferred stock and warrants. In November 2017, we entered into an At-The-Market Equity Offering Sales Agreement (the "ATM Sales Agreement"), pursuant to which we may sell an aggregate of up to \$30.0 million of our common stock pursuant to the shelf registration statement. As of March 31, 2019, we have not sold any shares under the ATM Sales Agreement, and there is \$150.0 million aggregate value of securities available under the shelf registration statement.

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.

Our 2008 Stock Omnibus Equity Compensation Plan (the "2008 Equity Plan") provides for the grant of options and/or other share-based or share-denominated awards to our non-employee directors, officers, employees and advisors. The 2008 Equity Plan was initially adopted in 2008 and was amended and restated in 2011, 2013, 2014, 2015, 2016 and 2018. There are 19,089,794 shares of common stock authorized for issuance under the 2008 Equity Plan. As of March 31, 2019, there were 9,856,077 shares available for future grant under the 2008 Equity Plan.

Total share-based compensation expense for all stock awards consists of the following, (in thousands):

	Three Months Ended March 31,		Nine Months Ended March 31,	
	2019	2018	2019	2018
Research and development	\$ 515	\$ 310	\$ 1,699	\$ 851
General and administrative	999	460	3,415	1,617
Total share-based compensation	<u>\$ 1,514</u>	<u>\$ 770</u>	<u>\$ 5,114</u>	<u>\$ 2,468</u>

Stock Options

Stock option activity for the nine months ended March 31, 2019 was as follows:

	Number of Options	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at June 30, 2018	6,281,615	\$ 3.08		
Granted	2,489,250	4.07		
Exercised	(188,552)	1.69		
Forfeited / Cancelled	(311,473)	3.16		
Expired	(233,854)	7.43		
Outstanding at March 31, 2019	<u>8,036,986</u>	3.29	7.6	\$4,632,560
Vested and exercisable at March 31, 2019	<u>3,718,739</u>	\$ 3.02	6.1	\$3,428,724

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The fair value of each stock option granted during the nine months ended March 31, 2019 is estimated on the grant date under the fair value method using a Black-Scholes valuation model. Stock options granted to employees during the nine months ended March 31, 2019 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 during the nine months ended March 31, 2019 vest ratably each month for a period of 12 months from the date of grant and expire ten years from the date of grant. The estimated fair values of the stock options, including the effect of estimated forfeitures, are expensed over the service period.

The following weighted-average assumptions were used to determine the fair value of options granted during the period:

	Nine Months Ended March 31,	
	2019	2018
Risk-free interest rate	2.8%	2.1%
Expected life (years)	6.0	6.0
Expected volatility	84.9%	95.7%
Dividend yield	0.0%	0.0%
Weighted-average grant date fair value	\$ 2.95	\$ 2.10

As of March 31, 2019, there was \$6.0 million of unrecognized compensation expense related to the unvested portion of stock options. Such compensation expense is expected to be recognized over a weighted-average period of 1.7 years.

Restricted Stock Units

In June 2016, we granted 364,726 RSUs to employees. Each RSU represented the contingent right to receive one share of our common stock. The RSUs were subject to performance criteria that were met in August 2016. The fair value of the RSUs was measured at \$1.61 per unit on the date the performance criteria were met. The RSUs vested in August 2018, and we released 332,193 RSU shares. We issued 245,782 shares of common stock to RSU holders; 86,411 shares were surrendered to us by RSU holders as payment for the employee portion of the required withholding of associated payroll taxes.

Item 2: Management’s Discussion and Analysis of Financial Condition and Results of Operations

This Quarterly Report on Form 10-Q includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”) and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). All statements other than statements of historical facts contained in this Quarterly Report, including statements regarding the future financial position, business strategy and plans and objectives of management for future operations, are forward-looking statements. The words “believe,” “may,” “will,” “estimate,” “continue,” “anticipate,” “intend,” “should,” “plan,” “expect,” and similar expressions, as they relate to us, are intended to identify forward-looking statements. We have based these forward-looking statements largely on current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including, without limitation, those described in “Risk Factors” in our 2018 Annual Report, and elsewhere in this report, including, among other things:

- our inability to obtain required additional financing or financing available to us on acceptable terms, or at all, which may cause us to delay, scale-back or eliminate plans related to development of our drug candidates;
- parties with which we have entered into collaboration, license, development and/or commercialization agreements may not satisfy their obligations under the agreements which could impact future revenues;
- our payment obligations under the Presage License Agreement and the S*Bio Purchase Agreement, which may reduce our cash available for other development efforts, and other obligations and risks related to the Presage License Agreement and the S*Bio Purchase Agreement;
- clinical studies by their nature typically have a high level of risk and may not produce successful results;
- 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;
- our inability to maintain or enter into, and the risks resulting from our dependence upon, contractual arrangements necessary for the clinical development, manufacture, commercialization, marketing, sales and distribution of our product candidates;
- costs and delays in our clinical development programs and/or receipt of FDA or other required foreign and domestic governmental or regulatory approvals, or the failure to obtain such approvals, for our product candidates;
- the FDA’s interpretation and our interpretation of data from preclinical and clinical studies may differ significantly;
- our failure to successfully commercialize our product candidates;
- pricing regulations, third-party reimbursement practices and healthcare reform initiatives;
- the failure of any products to gain market acceptance;
- our reliance on third parties to conduct our clinical trials and manufacture our products;
- our inability to control the costs of manufacturing our products;
- our reliance on acquisitions or licenses from third parties to expand our pipeline of drug candidates;
- competition and competitive factors;
- our inability to protect our patents or proprietary rights and obtain necessary rights to third party patents and intellectual property to operate our business;
- our inability to operate our business without infringing the patents and proprietary rights of others;
- costs stemming from our defense against third party intellectual property infringement claims;
- general economic conditions;
- our ability to attract and retain key employees;
- technological changes;
- cybersecurity;
- government regulation generally;
- changes in industry practice; and
- one-time events.

These risks are not exhaustive. Other sections of this report and our other filings with the SEC include additional factors which could adversely impact our business and financial performance. Moreover, we operate in a very competitive and rapidly changing environment. New risk factors emerge from time to time and it is not possible for us to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. We cannot assure you that the events and circumstances reflected in the forward-looking statements will be achieved or occur. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Past performance may not be an indicator of future results. The following discussion is qualified in its entirety by, and should be read in conjunction with, the more detailed information set forth in the financial statements and the notes thereto appearing elsewhere in this Quarterly Report on Form 10-Q and the audited financial statements and notes thereto included in our 2018 Annual Report, as filed with the SEC. Operating results are not necessarily indicative of results that may occur in future periods.

Overview and Recent Developments

We are a late-stage pharmaceutical company focused on leveraging our extensive development and oncology expertise to identify and advance new therapies intended to meaningfully improve the treatment of cancer. Our portfolio of drug candidates contains four clinical-stage candidates, including one candidate in an ongoing Phase 3 global registration trial and another candidate in an ongoing Phase 2 clinical trial that we intend to submit to the FDA to support accelerated approval of a marketing application. Our common stock is listed on the NASDAQ Capital Market under the symbol “MEIP”.

Clinical Development Programs

Cancer is often a highly adaptable disease capable of evading the body’s defenses and resisting treatment, allowing it to grow and spread. Despite new treatments that strive to leverage actionable insights into cancer biology, even the most cutting-edge therapies can struggle to balance potency with safety. As a result, the oncology community strives to improve on existing therapies and search for new and better options to optimize benefits for patients. This approach includes medicines that not only act alone, but also work well in combination with other therapies to deliver the best possible outcomes.

We currently have four clinical-stage development programs, each of which is in active development, with diverse approaches to inhibiting cancer, including epigenetics, cell signaling and cancer metabolism:

- ME-401, an oral phosphatidylinositol 3-kinase (“PI3K”) delta inhibitor;
- Voruciclib, an oral cyclin-dependent kinase (“CDK”) inhibitor;
- ME-344, a mitochondrial inhibitor targeting the oxidative phosphorylation (“OXPHOS”) complex; and
- Pracinostat, an oral histone deacetylase (“HDAC”) inhibitor.

DRUG CANDIDATE	INDICATION / COMBINATION	PRE-CLINICAL	CLINICAL PROOF-OF-CONCEPT	MARKETING APPROVAL STUDY
ME-401 PI3Kδ Inhibitor KYOWA KIRIN (Japan)	Follicular Lymphoma Relapsed/refractory Single agent		Phase 2 Accelerated Approval Trial*	
	B-Cell Malignancies Relapsed/refractory • Single-agent • Rituxan® (rituximab) • Zanubrutinib**			
Voruciclib CDK Inhibitor	B-Cell Malignancies Relapsed/refractory Single agent			
ME-344 Mitochondrial Inhibitor	HER2- Breast Cancer*** Treatment-naïve, early stage Avastin® (bevacizumab)			
FULLY PARTNERED PROGRAMS				
Pracinostat HDAC Inhibitor HELSINN	Acute Myeloid Leukemia Unfit for intensive chemotherapy Vidaza® (azacitidine)		Phase 3 Pivotal Trial	
	Myelodysplastic Syndrome High & very high risk Vidaza® (azacitidine)			

* Phase 2 study intended to support an accelerated approval marketing application with the FDA
 ** Study arm to be initiated under clinical collaboration with BeiGene, Ltd.
 *** Investigator-initiated study

ME-401: PI3K Delta Inhibitor in Phase 2 Study to Support Accelerated Approval in Relapsed or Refractory Follicular Lymphoma

We own exclusive worldwide rights to ME-401, a selective oral inhibitor of PI3K delta. In the fourth quarter of calendar year 2018, we started patient recruitment in a Phase 2 clinical trial evaluating ME-401 as a single-agent for the treatment of adults with relapsed or refractory follicular lymphoma (“FL”). We intend to submit the results of this trial to the FDA for accelerated approval of the marketing application under 21 CFR Part 314, Subpart H.

We believe ME-401 holds best-in-class potential as a PI3K delta inhibitor based on clinical data observed to date. Clinical data from an ongoing Phase 1b, open-label, dose-escalation study has demonstrated an 82% objective response rate in patients with relapsed/refractory indolent B-cell malignances (FL, chronic lymphocytic leukemia (“CLL”), small lymphocytic lymphoma (“SLL”) and marginal zone lymphoma (“MZL”). ME-401 was generally well-tolerated in the Phase 1b trial and no dose-limiting toxicities were identified at any dose level.

The clinical data generated to date, along with important differentiating pharmaceutical properties of ME-401, support its potential as a single-agent therapy and the potential to be used in combination with existing or emerging therapies to treat multiple difficult-to-treat oncology indications.

ME-401 Scientific Overview: Cell Cycle Signaling

The PI3K/AKT/mTOR pathway is an important signaling pathway for many cellular functions such as cell survival, cell cycle progression and cellular growth. PI3Ks are a family of enzymes within this pathway that have been shown to play a critical role in the proliferation and survival of certain cancer cells. There are several isoforms of PI3K that are expressed in different types of cells. The PI3K delta isoform is believed to be important for survival of certain B-cell leukemias and lymphomas.

PI3K delta Inhibitors and B-Cell Malignancies

As a class of therapies, PI3K delta inhibitors may have application across a range of B-cell malignancies and compare favorably to other therapeutic approaches.

PI3K delta inhibitors as a group demonstrate promise in the treatment of B-cell malignancies. However, the FDA and the European Medicines Agency (“EMA”) approved oral PI3K delta inhibitor idealisib (marketed as Zydelig[®]), the FDA approved intravenous PI3K alpha/delta inhibitor copanlisib (marketed as Aliqopa[®]), the FDA approved oral PI3K delta inhibitor duvelisib (marketed as COPIKTRA[®]) as well as other candidates in development, are challenged by treatment associated toxicities which may reduce their overall clinical utility. We believe this provides an opportunity for the development of a next generation candidate with superior pharmaceutical properties that can better maximize the biological potential of PI3K delta inhibition without being limited by toxicities that reduce clinical utility.

Through our extensive pre-clinical and ongoing clinical work, we have demonstrated that ME-401 has important pharmaceutical properties, including prolonged target binding, preferential cellular accumulation, significant distribution throughout the body tissues, and a 28-hour half-life suitable for once daily oral administration. We believe these positive attributes support the promising clinical results observed to date and the continued clinical advancement of ME-401 as an attractive drug candidate with single-agent activity and the potential to be used in combination with existing or emerging therapies to treat multiple difficult-to-treat oncology indications.

Clinical Program

ME-401 is in two ongoing studies: a Phase 2 study evaluating patients with relapsed/refractory FL that we intend to submit to the FDA to support accelerated approval of a marketing application under 21 CFR Part 314, Subpart H, and a multi-arm Phase 1b study evaluating patients with FL and other B-cell malignancies.

Phase 1b Multi-arm Study

Patients in the Phase 1b study receive ME-401 as a single agent dosed on a continuous daily schedule (CS) or intermittent schedule (IS) and in combination with rituximab (dosed on the IS only) to explore treatment options for patients with B-cell malignancies. The CS dosing regimen consists of 60 mg administered once daily and the IS dosing regimen consists of 60 mg given continuously, once-daily, for the first 2 cycles followed by 60 mg given on days 1-7 of each subsequent cycle. A cycle is 28 days.

In December 2018, at the American Society of Hematology (“ASH”) Annual Meeting, we reported updated Phase 1b data indicating that ME-401 administered both as a single-agent and in combination with rituximab continues to be associated with high response rates: ME-401 demonstrated an 82% objective response rate among 50 evaluable patients with FL, CLL, SLL and MZL, as well as a response rate of 76% in the group of 38 patients with FL. Response rates were maintained by the large majority of patients on IS (72%). For those patients that did show evidence of disease progression on IS, disease control could be reestablished in the majority of patients when returned to CS dosing (70%). A median duration of response has not yet been reached; the lead patient has a duration of response of approximately 20 months and the median follow-up is 9.3 months.

ME-401 has been generally well-tolerated. In addition, a lower incidence of Grade 3 immune-related adverse events (irAEs) has been observed in patients administered ME-401 with IS dosing (11%) versus patients administered CS dosing (34%). No opportunistic infections or non-infectious pneumonitis were reported. There have been no Grade 4-5 adverse events. Laboratory abnormalities in the Phase 1b trial were infrequent.

The Phase 1b study is evaluating ME-401 (60 mg) in combination with rituximab (marketed as Rituxan[®]) in patients with various B-cell malignancies. Additionally, in October 2018, we entered into a clinical collaboration with BeiGene, Ltd. under which we will evaluate the safety and efficacy of ME-401 in combination with BeiGene’s zanubrutinib, an investigational inhibitor of BTK, for the treatment of patients with B-cell malignancies. The cost of the combination study will be equally shared. Each company will supply its own compound. We retain all commercial rights to ME-401 and BeiGene retains all commercial rights to zanubrutinib.

Phase 2 Accelerated Approval Study

In July 2018, the Company discussed with the FDA a ME-401 monotherapy accelerated approval strategy in patients with relapsed or refractory follicular lymphoma. The FDA communicated support for the Company’s proposed randomized Phase 2 trial. Accelerated approval of ME-401 will be subject to FDA review of the improvement provided by ME-401 over other therapies available at the time of the regulatory action.

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Informed by our communications with the FDA, we are recruiting patients in a global randomized Phase 2 study evaluating the efficacy, safety, and tolerability of ME-401 in patients with FL after failure of at least two prior systemic therapies including chemotherapy and an anti-CD20 antibody. The study will evaluate both the CS and IS dosing regimens; in one arm, ME-401 will be administered once daily continuously and in the other arm, ME-401 will be administered once daily for two cycles (i.e., eight weeks) followed by an intermittent schedule whereby ME-401 will be administered once daily for the first seven days of a 28-day cycle followed by 21 days of placebo. Approximately 150 patients will be randomized in the study and the primary efficacy endpoint will be the rate of objective response to therapy.

Voruciclib: CDK Inhibitor with CDK9 Inhibition in Phase 1 Studies

Voruciclib is an orally administered CDK inhibitor differentiated by its potent in vitro inhibition of CDK9 in addition to CDK6, 4 and 1. Voruciclib is currently being evaluated in a Phase 1b dose ranging study in patients with B-cell malignancies.

Voruciclib Scientific Overview: Cell Cycle Signaling

The CDK family of proteins are important cell cycle regulators. 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 Venclaxa™).

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 efficacy in an aggressive subset of DLBCL pre-clinical models. (Scientific Reports. (2017) 7:18007. DOI:10.1038/s41598-017-18368-w).

CDK9 is also a transcriptional regulator of MYC, a transcription factor regulating cell proliferation and growth which contributes to many human cancers and is frequently associated with poor prognosis and unfavorable patient survival. Targeting MYC directly has historically been difficult, but CDK9 is a transcriptional regulator of MYC and is a promising approach to target this oncogene.

Clinical Program

In January 2018, we announced the FDA cleared the voruciclib Investigational New Drug Application (“IND”) for hematologic malignancies. In August 2018 we dosed our first patient in a dose ranging Phase 1b clinical trial of voruciclib. The study is intended to evaluate voruciclib as a single agent in patients with relapsed and/or refractory B-cell malignancies or acute myeloid leukemia (“AML”) after failure of prior standard therapies to determine the safety, preliminary efficacy and maximum tolerated dose. We also plan to evaluate voruciclib in combination with venetoclax to assess synergies and the opportunity for combination treatments across multiple indications.

Voruciclib was previously evaluated in more than 70 patients in multiple Phase 1 studies with a tolerability profile consistent with other drugs in its class. In pre-clinical studies, voruciclib shows dose-dependent suppression of MCL1 at concentrations achievable with doses that appear to be generally well tolerated in earlier Phase 1 studies. Pre-clinical studies additionally show inhibition of MYC protein expression.

ME-344: Mitochondrial Inhibitor with Combinatorial Potential

ME-344 is our novel and tumor selective, isoflavone-derived mitochondrial inhibitor drug candidate. It directly targets the OXPHOS complex 1, a pathway involved in ATP production in the mitochondria. ME-344 is under evaluation in an investigator-initiated, multi-center, randomized study in combination with the vascular endothelial growth factor (“VEGF”) inhibitor bevacizumab (marketed as Avastin®) in a total of 40 patients with 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 adenosine triphosphate (“ATP”). The two major sources of ATP are the specialized cellular organelles termed mitochondria and through the metabolism of carbohydrates, proteins and lipids.

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. We believe that some of these synthetic compounds, including our 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 study, 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. While anti-angiogenics reduce the rate of glycolysis in tumors as a mechanism to block growth, tumor metabolism often shifts to mitochondrial metabolism to continue 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.

We are investigating this approach in a multicenter, investigator-initiated, randomized, open-label, clinical trial, which is evaluating ME-344 in a total of up to 40 patients with HER2-negative breast cancer in combination with the VEGF inhibitor bevacizumab (marketed as Avastin®). Patients are randomized one-to-one to either ME-344 in combination with bevacizumab or saline in combination with bevacizumab. The interim data review was predefined to take place after 20 patients were randomized. The primary efficacy endpoint is inhibition of cell proliferation as measured by Ki-67 reductions.

Interim data presented from the study at the American Society of Clinical Oncology Annual Meeting in June 2018 demonstrate evidence of inhibition of tumor proliferation. Mean absolute (relative) Ki-67 decreases were 5.13 (29%) and 1.2 (9%) in the active versus control arms (P=0.06). Patients with standardized uptake values via PET scan ³ 10% experienced an absolute average Ki-67 decrease of 16.6 vs. 2.3 in the active versus control arms (P=0.19). Treatment was generally well tolerated; two Grade 3 adverse events (high blood pressure) were reported, one in each arm, and deemed related to bevacizumab. These interim data are consistent with pre-clinical results indicating ME-344's potential to reverse resistance to anti-angiogenic therapy, thereby warranting the continuation of the ongoing study.

Results from our 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 issue 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 study. 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 three peripheral neuropathy.

In June 2016, pre-clinical data from a collaboration with the Spanish National Cancer Research Centre in Madrid showing 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, were published in *Cell Reports*. These data demonstrate that the anti-cancer effects when combining ME-344 with a VEGF inhibitor are due to an inhibition of both mitochondrial and glycolytic metabolism and provided a basis for commencement of the ongoing investigator-initiated study of ME-344 in combination with the VEGF inhibitor bevacizumab (marketed as Avastin®) in HER2 negative breast cancer patients.

Pracinostat: HDAC Inhibitor Candidate in a Phase 3 Global Registration Clinical Trial

Pracinostat is an oral HDAC inhibitor being evaluated in a pivotal Phase 3 global registration clinical trial for the treatment of adults with newly diagnosed AML who are unfit to receive intensive chemotherapy. Pracinostat is also being evaluated in a Phase 2 study in patients with high or very high-risk myelodysplastic syndrome ("MDS"). In August 2016, we entered into an exclusive worldwide license, development, manufacturing and commercialization agreement with Helsinn Healthcare SA, a Swiss pharmaceutical corporation ("Helsinn") for pracinostat in AML, MDS and other potential indications (the "Helsinn License Agreement"). Under the agreement, Helsinn is primarily responsible for funding global development and commercialization costs for pracinostat. We are responsible for conducting the Phase 2 MDS study, the cost of which is being shared equally with Helsinn.

Breakthrough Therapy Designation for pracinostat was granted by the FDA in 2016, and in January 2018 the EMA granted Orphan Drug Designation to pracinostat for the treatment of AML. The designations in the US and European Union are supported by data from a Phase 2 study of pracinostat plus azacitidine in elderly patients with newly diagnosed AML who are not candidates for induction chemotherapy. The study showed a median overall survival of 19.1 months and a complete remission ("CR") rate of 42% (21 of 50 patients). These data compare favorably to an international Phase 3 study of azacitidine (AZA-001; Dombret et al. *Blood*. 2015 May 18), which showed a median overall survival of 10.4 months with azacitidine alone and a CR rate of 19.5% in a similar patient population. The combination of pracinostat and azacitidine was generally well tolerated, with no unexpected toxicities. The most common grade 3/4 treatment-emergent adverse events included febrile neutropenia, thrombocytopenia, anemia and fatigue.

Pracinostat Scientific Overview; Epigenetics

HDACs play a key role in epigenetic regulation of gene expression by regulating chromatin structure. Acetylation of positively charged lysine residues present in histone proteins by the histone acetyltransferase ("HATs") reduces the affinity between histones and negatively charged DNA, resulting in the opening of the chromatin structure. This makes it easier for the transcriptional machinery to access the DNA, enhancing RNA transcription. Conversely, deacetylation by the HDACs closes the chromatin structure leading to a repression of gene transcription. In normal cells, HDACs and HATs together control histone acetylation levels to maintain a balance. In diseases such as cancer, this regulation can be disturbed. HDAC inhibitors cause accumulation of acetylated histones, enhance transcription and result in changes to a variety of cellular responses including differentiation, proliferation, migration, survival and response to metabolic and hypoxic stress. In general, tumor cells are more susceptible than normal cells to the anti-proliferative and pro-apoptotic effects of HDAC inhibitors.

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There are currently three HDAC inhibitors, one oral and two injectable, approved by the FDA for the treatment of T-cell lymphoma and a fourth orally administered HDAC inhibitor approved for multiple myeloma. Other HDAC inhibitors are being evaluated in clinical trials as single agents and in combination for the treatment of various hematologic diseases and solid tumors.

Pracinostat is an orally available, potent HDAC inhibitor with potentially improved physicochemical, pharmaceutical and pharmacokinetic properties when compared to other compounds of this class, including increased bioavailability and increased half-life.

Clinical Program

The ongoing pivotal Phase 3 registration study, which is being run by Helsinn and was initiated in June 2017, is a randomized, double-blind, placebo-controlled study that will enroll worldwide approximately 500 adults with newly diagnosed AML who are unfit to receive intensive chemotherapy. Patients are randomized 1:1 to receive pracinostat or placebo with azacitidine as background therapy. The primary endpoint of the study is overall survival. Secondary endpoints include morphologic CR rate, event-free survival and duration of CR.

Additionally, pracinostat is being investigated in a Phase 2 dose optimization study evaluating patients with high and very high-risk MDS who are previously untreated with hypomethylating agents. This patient group represents the highest unmet need in MDS, with median survival estimates, as stated by the American Cancer Society, of 1.6 years and 0.8 years, respectively. The ongoing Phase 2 open-label study is evaluating a 45 mg dose of pracinostat in combination with the standard dose of azacitidine. The study is designed to improve tolerability and retain patients in the study longer than in an earlier Phase 2 study evaluating a 60 mg dose. A prolonged treatment may result in a systemic exposure to pracinostat sufficient to achieve the desired treatment effect; data from the earlier Phase 2 study suggested that insufficient exposure to treatment may have limited overall efficacy of the combination.

A pre-planned interim analysis of the Phase 2 MDS study demonstrated a 10% discontinuation rate among the first 20 evaluable patients treated, meeting the predefined threshold in the first 3 treatment cycles. The 10% rate is consistent with the discontinuation rate for azacitidine given as a monotherapy in earlier studies with pracinostat. Having met this threshold, the study expanded open-label enrollment to 60 patients. A subsequent interim analysis presented at the 2018 ASH meeting has demonstrated a discontinuation rate due to adverse events in the first 3 months of 4%, substantially lower than the rate of 26% reported in the Company's prior Phase 2 study. The Phase 2 study has completed enrollment and patients will be followed for one year to evaluate safety and efficacy. The primary endpoints of the study are 1) safety and tolerability and 2) overall response rate, defined as CR, partial remission ("PR") and marrow CR. Secondary endpoints include CR rate, overall hematologic improvement ("HI") response rate, clinical benefit rate (defined as rate of CR + PR + HI + Marrow CR), rate of cytogenetic complete response/remission, duration of response, rate of leukemic transformation, event-free survival, progression-free survival and overall survival. If the Phase 2 open-label study is successful, Helsinn intends to initiate a global registration study. All future development and commercialization costs after the completion of the Phase 2 study are the responsibility of Helsinn.

Pracinostat has been previously investigated in more than 300 patients in multiple Phase 1 and Phase 2 clinical trials and found to be generally well tolerated with manageable side effects often associated with drugs of this class, including fatigue, myelosuppression and gastrointestinal toxicity.

Results of Operations

Three Months Ended March 31, 2019 and 2018

We had a loss from operations of \$12.6 million for the three months ended March 31, 2019 compared to a loss from operations of \$6.1 million for the three months ended March 31, 2018.

Revenue: We recognized revenue of \$1.2 million for the three months ended March 31, 2019 compared to \$0.4 million for the three months ended March 31, 2018. Revenue increased primarily due to our license agreement with KHK and resulted from the transfer of the license, the partial satisfaction of our research and development obligations and providing clinical trial materials. Revenue related to the license agreement with KHK was \$0.6 million for the three months ended March 31, 2019. There was no revenue related to the license agreement with KHK for the three months ended March 31, 2018. Revenue also includes recognition of amounts allocated to performance obligations in accordance with the Helsinn License Agreement. Revenue related to the Helsinn License agreement was \$0.6 million for the three months ended March 31, 2019 compared to \$0.4 million for the three months ended March 31, 2018.

Cost of Revenue: We recognized cost of revenue of \$1.2 million for the three months ended March 31, 2019 compared to \$0.9 million for the three months ended March 31, 2018. The cost of revenue 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 associated with pracinostat. Costs of revenue relate to expenses for pracinostat incurred in connection with our development activities in accordance with the Helsinn License Agreement, including both Helsinn's share and our share of costs related to the POC study, which we are responsible for conducting.

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Research and Development: The following is a summary of our research and development expenses to supplement the more detailed discussion below. The dollar values in the following table are in thousands.

Research and development expenses	Three Months Ended March 31,	
	2019	2018
ME-401	\$ 5,475	\$ 951
Voruciclib	570	314
ME-344	132	97
Pracinostat	—	—
Other	2,894	1,709
Total research and development expenses	<u>\$ 9,071</u>	<u>\$ 3,071</u>

Research and development expenses consist primarily of clinical trial costs (including payments to clinical research organizations), pre-clinical study costs, and costs to manufacture our 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. Research and development expenses were \$9.1 million for the three months ended March 31, 2019 compared to \$3.1 million for the three months ended March 31, 2018. Costs related to ME-401 were higher for the three months ended March 31, 2019 due to \$2.5 million of increased clinical trial costs as a result of starting the Phase 2 study and \$1.7 million of associated drug manufacturing costs. Costs related to voruciclib were higher for the three months ended March 31, 2019 due to increased clinical trial costs. Other research and development costs increased for the three months ended March 31, 2019 due to higher levels of salaries and share-based compensation associated with increased headcount to support our clinical activities.

General and Administrative: General and administrative expenses increased by \$1.1 million to \$3.6 million for the three months ended March 31, 2019 compared to \$2.5 million for the three months ended March 31, 2018. The increase is primarily due to \$0.8 million in increased salaries and share-based compensation associated with increased headcount to support our activities and \$0.2 million in increased professional services expenses during the three months ended March 31, 2019.

Other income or expense: We recorded a non-cash loss of \$5.2 million during the three months ended March 31, 2019 due to a change in the fair value of our warrant liability for warrants issued in May 2018 as part of our private placement. The change in the warrant liability is primarily due to changes in our stock price. Additionally, we received interest and dividend income of \$0.5 million for the three months ended March 31, 2019 compared to \$0.1 million for the three months ended March 31, 2018. The increase was due to higher investment balances and higher yields during the three months ended March 31, 2019 compared to the three months ended March 31, 2018.

Nine Months Ended March 31, 2019 and 2018

We had a loss from operations of \$34.5 million for the nine months ended March 31, 2019 compared to a loss from operations of \$21.1 million for the nine months ended March 31, 2018.

Revenue: We recognized revenue of \$3.8 million for the nine months ended March 31, 2019 compared to \$1.1 million for the nine months ended March 31, 2018. Revenue increased primarily due to our license agreement with KHK and resulted from the transfer of the license, the partial satisfaction of our research and development obligations and providing clinical trial materials. Revenue related to the license agreement with KHK was \$2.0 million for the nine months ended March 31, 2019. There was no revenue for the nine months ended March 31, 2018. Revenue also includes recognition of fees allocated to performance obligations in accordance with the Helsinn License Agreement. Revenue related the Helsinn License agreement was \$1.8 million for the nine months ended March 31, 2019 compared to \$1.1 million for the nine months ended March 31, 2018.

Cost of Revenue: We recognized cost of revenue of \$3.2 million for the nine months ended March 31, 2019 compared to \$2.3 million for the nine months ended March 31, 2018. The cost of revenue 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 associated with pracinostat. Costs of revenue relate to expenses for pracinostat incurred in connection with our development activities in accordance with the Helsinn License Agreement, including both Helsinn's share and our share of costs related to the POC study, which we are responsible for conducting.

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Research and Development: The following is a summary of our research and development expenses to supplement the more detailed discussion below. The dollar values in the following table are in thousands.

Research and development expenses	Nine Months Ended March 31,	
	2019	2018
ME-401	\$13,304	\$ 4,095
Voruciclib	2,649	3,469
ME-344	436	394
Pracinostat	—	22
Other	7,879	4,599
Total research and development expenses	<u>\$24,268</u>	<u>\$12,579</u>

Research and development expenses consist primarily of clinical trial costs (including payments to clinical research organizations), pre-clinical study costs, and costs to manufacture our 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. Research and development expenses were \$24.3 million for the nine months ended March 31, 2019 compared to \$12.6 million for the nine months ended March 31, 2018. Costs related to ME-401 were higher for the nine months ended March 31, 2019 due to \$4.7 million of increased clinical trial costs as a result of starting the Phase 2 study and \$4.1 million of associated drug manufacturing costs. Costs related to voruciclib decreased for the nine months ended March 31, 2019 compared with the nine months ended March 31, 2018, related to a license fee payment of \$2.9 million made in the prior period, partially offset by increased clinical trial costs. Other research and development costs increased for the nine months ended March 31, 2019 due to higher levels of salaries and share-based compensation associated with increased headcount to support our clinical activities.

General and Administrative: General and administrative expenses increased by \$3.6 million to \$10.9 million for the nine months ended March 31, 2019 compared to \$7.3 million for the nine months ended March 31, 2018. The increase is primarily due to \$2.5 million in increased salaries and share-based compensation associated with increased headcount to support our activities and \$0.7 million in increased professional services expenses during the nine months ended March 31, 2019.

Other income or expense: We recorded a non-cash gain of \$13.3 million during the nine months ended March 31, 2019 due to a change in the fair value of our warrant liability for warrants issued in May 2018 as part of our private placement. The change in the warrant liability is primarily due to changes in our stock price. Additionally, we received interest and dividend income of \$1.4 million for the nine months ended March 31, 2019 compared to \$0.3 million for the nine months ended March 31, 2018. The increase was due to higher investment balances and higher yields during the nine months ended March 31, 2019 compared to the nine months ended March 31, 2018.

Liquidity and Capital Resources

We have accumulated losses of \$234.3 million since inception and expect to incur operating losses and generate negative cash flows from operations for the foreseeable future. As of March 31, 2019, we had \$82.3 million in cash, cash equivalents and short-term investments, which we believe will be sufficient to fund our operations through at least fiscal year 2020. 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. To date, we have obtained cash and funded our operations primarily through equity financings and license payments. 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, license agreements or entry into strategic partnerships.

Sources and Uses of Our Cash

Net cash used in operating activities for the nine months ended March 31, 2019 was \$21.4 million, reflecting \$31.4 million used in operating activities, offset by the \$10.0 million upfront payment from KHK. This compares to \$17.6 million used in operating activities for the nine months ended March 31, 2018. The increase in cash used in operating activities reflects increased costs in our clinical development programs, including start-up costs related to the ME-401 Phase 2 study.

Net cash provided by investing activities for the nine months ended March 31, 2019 was \$14.4 million compared to net cash provided by investing activities of \$15.1 million in the nine months ended March 31, 2018. Cash provided by investing activities represents maturities of investments in short-term U.S. government securities in excess of purchases. Cash used in investing activities represents purchases of investments in short-term U.S. government securities in excess of maturities.

Net cash provided by financing activities for the nine months ended March 31, 2019 was \$1.1 million compared to \$0.2 million for the nine months ended March 31, 2018. Cash provided during the nine months ended March 31, 2019 primarily represents proceeds received from the exercise of warrants and stock options.

Contractual Obligations

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. Additionally, we 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.

We have leased approximately 13,700 square feet of office space, located at 3611 Valley Centre Drive, San Diego, California 92130. The monthly rental rate is approximately \$46,000 over the remaining lease term, plus a pro rata share of certain building expenses. In September 2018, we entered into a lease agreement for approximately 7,000 additional square feet of office space at the same location, at a rental rate of approximately \$21,000 per month, plus a pro rata share of certain building expenses. The location houses our executive and administrative office. Each lease term expires in May 2020. The remaining contractual obligations for the two leases are \$0.6 million and \$0.3 million, respectively.

Presage License Agreement

In September 2017, we entered into the Presage License Agreement. Under the terms of 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 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. 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. As of March 31, 2019, we have not accrued any amounts for potential future payments.

*S*Bio Purchase Agreement*

We are party to a definitive asset purchase agreement with S*Bio, pursuant to which we acquired certain assets comprised of intellectual property and technology including rights to pracinostat. We agreed to make certain milestone payments to S*Bio based on the achievement of certain clinical, regulatory and net sales-based milestones, as well as to make certain contingent earnout payments to S*Bio. Milestone payments will be made to S*Bio up to an aggregate amount of \$74.5 million if certain U.S., E.U. and Japanese regulatory approvals are obtained and if certain net sales thresholds are met in North America, the E.U. and Japan. The first milestone payment of \$200,000 plus 166,527 shares of our common stock having a value of \$500,000 was paid in August 2017 upon the first dosing of a patient in a Phase 3 clinical trial. Subsequent milestone payments will be due upon certain regulatory approvals and sales-based events. As of March 31, 2019, we have not accrued any amounts for potential future payments.

CyDex License Agreement

We are party to a license agreement with CyDex. Under the license agreement, CyDex granted to us an exclusive, nontransferable license to intellectual property rights relating to Captisol® for use with our two isoflavone-based drug compounds (currently ME-344). We agreed to pay to CyDex a non-refundable license issuance fee, future milestone payments, and royalties at a low, single-digit percentage rate on future sales of our approved drugs utilizing Captisol. Contemporaneously with the license agreement, CyDex entered into a commercial supply agreement with us, pursuant to which we agreed to purchase 100% of our requirements for Captisol from CyDex. We may terminate both the license agreement and the supply agreement for convenience at any time upon 90 days' prior written notice. As of March 31, 2019, we have not accrued any amounts for potential future payments.

Critical Accounting Policies and Management Estimates

We describe our significant accounting policies in Note 1, The Company and Summary of Significant Accounting Policies, of the notes to financial statements included in our 2018 Annual Report. We discuss our critical accounting estimates in Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations, in our 2018 Annual Report. Except for the adoption of ASC 606, there have been no changes in our significant accounting policies or critical accounting estimates since June 30, 2018.

Recent Accounting Pronouncements

See Note 1 to the Financial Statements included in Item 1 of this Quarterly Report.

Item 3: Quantitative and Qualitative Disclosures about Market Risk

Our exposure to market interest rates relates primarily to the investment of cash balances and short-term investments. We have cash reserves held in U.S. dollars and we place funds on deposit with financial institutions, which are readily available. Our short-term investments consist solely of U.S. government securities with a maturity of three to twelve months.

We place our cash deposits with high credit quality financial institutions and by policy limit the amount of credit exposure to any one corporation or bank. These deposits are in excess of the FDIC insurance limits. We are adverse to principal loss and we ensure the safety and preservation of our invested funds by limiting default risk, market risk and reinvestment risk. We seek to mitigate default risk by depositing funds with high credit quality financial institutions, by limiting the amount of credit exposure to any one corporation or bank, by purchasing short-term investments consisting of U.S. government securities, and by positioning our portfolio to respond appropriately to a significant reduction in a credit rating of any such financial institution.

We do not consider the effects of interest rate movements to be a material risk to our financial condition.

Item 4: Controls and Procedures

At the end of the period covered by this Quarterly Report on Form 10-Q, our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Exchange Act is accumulated and communicated to the issuer's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective to ensure that the information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

There were no changes in our internal control over financial reporting during the period covered by this Quarterly Report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II OTHER INFORMATION

Item 1: Legal Proceedings

None.

Item 1A: Risk Factors

There have been no material changes in our risk factors from those included in our 2018 Annual Report.

Item 2: Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3: Defaults upon Senior Securities

None.

Item 4: Mine Safety Disclosures

Not applicable.

Item 5: Other Information

None.

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Item 6: Exhibits

Exhibit Index

<u>Exhibits</u>	
31.1	Rule 13a-14(a) or Rule 15d-14(a) Certification of Principal Executive Officer
31.2	Rule 13a-14(a) or Rule 15d-14(a) Certification of Principal Financial Officer
32.1	Certification of Principal Executive Officer and Principal Financial Officer required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C 1350).
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 Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this Quarterly Report to be signed on its behalf by the undersigned, thereunto duly authorized.

MEI Pharma, Inc.

/s/ Daniel P. Gold

Daniel P. Gold

President and Chief Executive Officer

Date: May 9, 2019

CERTIFICATION

I, Daniel P. Gold, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of MEI Pharma, Inc.;
2. Based on my knowledge, this Quarterly Report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this Quarterly Report;
3. Based on my knowledge, the financial statements, and other financial information included in this Quarterly Report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this Quarterly Report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this Quarterly Report is being prepared;
 - (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in the Quarterly Report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this Quarterly Report based on such evaluation; and
 - (d) disclosed in this Quarterly Report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 9, 2019

/s/ Daniel P. Gold

Daniel P. Gold
Chief Executive Officer
(Principal Executive Officer)

CERTIFICATION

I, Brian G. Drazba, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of MEI Pharma, Inc.;
2. Based on my knowledge, this Quarterly Report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this Quarterly Report;
3. Based on my knowledge, the financial statements, and other financial information included in this Quarterly Report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this Quarterly Report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this Quarterly Report is being prepared;
 - (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in the Quarterly Report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this Quarterly Report based on such evaluation; and
 - (d) disclosed in this Quarterly Report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.
5. Our other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 9, 2019

/s/ Brian G. Drazba

Brian G. Drazba
Chief Financial Officer
(Principal Financial Officer)

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934, as amended, and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. § 1350), Daniel P. Gold, the Chief Executive Officer of MEI Pharma, Inc. (the “Registrant”), and Brian G. Drazba, the Chief Financial Officer of the Registrant, each hereby certifies that, to his knowledge:

1. The Registrant’s Quarterly Report on Form 10-Q for the period ended March 31, 2019, (the “Form 10-Q”) to which this Certification is attached as Exhibit 32.1, fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Form 10-Q fairly presents, in all material respects, the financial condition of the Registrant at the end of the period covered by the Form 10-Q and results of operations of the registrant for the period covered by the Form 10-Q.

These certifications accompanying the Form 10-Q to which they relate, are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of the registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.

Dated: May 9, 2019

/s/ Daniel P. Gold

Daniel P. Gold
Chief Executive Officer
(Principal Executive Officer)

/s/ Brian G. Drazba

Brian G. Drazba
Chief Financial Officer
(Principal Financial Officer)