

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

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(D)
of the Securities Exchange Act of 1934**

**February 9, 2023
Date of report (Date of earliest event reported)**

MEI Pharma, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

000-50484
(Commission
File Number)

51-0407811
(IRS Employer
Identification No.)

**11455 El Camino Real, Suite 250
San Diego, California**
(Address of principal executive offices)

92130
(Zip Code)

Registrant's telephone number, including area code (858) 369-7100
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of Each Class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, \$0.00000002 par value	MEIP	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter)

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02. Results of Operations and Financial Condition.

On February 9, 2023, MEI Pharma, Inc. (the “Company”) issued a press release announcing its financial results for its second quarter ended December 31, 2022. The text of the press release is included as an exhibit to this Current Report on Form 8-K. The information in this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, regardless of any general incorporation language in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release issued by MEI Pharma, Inc., dated February 9, 2023.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Company has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

MEI PHARMA, INC.

Dated: February 9, 2023

By: /s/ Daniel P. Gold
Name: Daniel P. Gold
Title: Chief Executive Officer



MEI Pharma Reports Second Quarter Fiscal Year 2023 Results and Operational Highlights

— MEI Begins Third Fiscal Quarter with \$124 Million in Cash —

SAN DIEGO – February 9, 2023 – MEI Pharma, Inc. (Nasdaq: MEIP), a clinical-stage pharmaceutical company focused on advancing new therapies for cancer, today reported results for the quarter ended December 31, 2022, and highlighted recent corporate events.

“MEI anticipates reporting key clinical data readouts on two clinical-stage oncology candidates, voruciclib and ME-344, around the end of the calendar year for each program,” said Daniel P. Gold, Ph.D., president and chief executive officer of MEI Pharma. “These clinical data will inform future plans in two promising areas of oncology drug development: CDK9 inhibition and mitochondrial inhibition, respectively. With approximately \$124 million at the end of the quarter, we remain well capitalized to pursue these objectives and estimate that we will be able to fund operations for two years based upon our current development plans.”

Second Quarter Fiscal Year 2023 Recent Developments

- In December 2022, MEI Pharma and Kyowa Kirin announced that after receiving the most recent guidance in a late November meeting with the U.S. Food and Drug Administration, the companies jointly decided to discontinue global development of zandelisib, an orally administered investigational phosphatidylinositol 3-kinase delta (“PI3Kd”) inhibitor, outside of Japan for B-cell malignancies. Kyowa Kirin is continuing the Phase 2 MIRAGE study evaluating Japanese patients with relapsed or refractory indolent B-cell non-Hodgkin lymphomas, and will explore the potential for a marketing authorization submission to Japanese health authorities based on data from the MIRAGE and TIDAL clinical trials.
- In December 2022, MEI announced that it is realigning its clinical development efforts following the discontinuation of global development outside Japan of zandelisib. As part of the announced program realignment and workforce reduction, the company is resizing its organization to support continued development of voruciclib and ME-344, while concurrently supporting the winding down of the zandelisib program outside of Japan. The company additionally announced that it had engaged Torrey Partners as financial advisor to help explore additional strategic opportunities.
- In December 2022, MEI received notice from the U.S. Food and Drug Administration that it may proceed to initiate the Phase 1 study evaluating ME-344 plus Avastin®(bevacizumab) in relapsed colorectal cancer patients. The study is expected to dose the first patient in the first half of calendar year 2023.
- In November 2022, MEI dosed the first patient in the Phase 1b study evaluating voruciclib in combination with Venclexta® (venetoclax), a BCL2 inhibitor. Initially the study is evaluating patients with acute myeloid leukemia (AML) after failure of prior standard therapies to assess safety and possible synergies for the combination treatment. Pending results from this ongoing study, the company may also evaluate the combination in patients across multiple indications with relapsed and refractory B-cell malignancies.

- In November 2022, MEI and Kyowa Kirin announced topline data from the Phase 2 MIRAGE study evaluating zandelisib in Japanese patients with indolent B-cell Non-Hodgkin's Lymphoma without small lymphocytic lymphoma, lymphoplasmacytic lymphoma, and Waldenström's macroglobulinemia in Japan. The data demonstrated a 75.4% objective response rate and 24.6% of patients achieved a complete response as determined by Independent Review Committee assessment. Additionally, 14.8% of patients discontinued therapy due to any treatment emergent adverse event.

Expected Drug Candidate Pipeline Developments

Voruciclib – Oral CDK9 inhibitor for the treatment of B-cell malignancies and acute myeloid leukemia

- Report key clinical data from the ongoing Phase 1b trial evaluating voruciclib plus Venclexta® (venetoclax) in patients with acute myeloid leukemia around calendar year-end 2023.

ME-344 – Tumor selective mitochondrial inhibitor

- Initiate a Phase 1b clinical trial evaluating ME-344 plus Avastin® in relapsed colorectal cancer patients in the first half of calendar year 2023.
- Report key clinical data from the Phase 1b clinical trial evaluating ME-344 plus Avastin in patients with relapsed colorectal cancer around calendar year-end 2023.

Zandelisib – Oral PI3K delta inhibitor for the treatment of indolent B-cell Non-Hodgkin's Lymphoma without small lymphocytic lymphoma, lymphoplasmacytic lymphoma, and Waldenström's macroglobulinemia in Japan

- Provide an update on Kyowa Kirin's plans for continued zandelisib development in Japan for patients with relapsed or refractory indolent B-cell non-Hodgkin lymphomas.

Second Quarter Fiscal Year 2023 Financial Results

- As of December 31, 2022, MEI had \$124.2 million in cash, cash equivalents, and short-term investments with no outstanding debt.
- For the quarter ended December 31, 2022, cash used in operations was \$14.3 million, compared to \$18.6 million used in operations (after adjusting for the receipt of a \$10.0 million milestone payment from Kyowa Kirin during the quarter ended December 31, 2021). The decrease in cash used in operations is due to a reduction in zandelisib costs as we discontinued the program and initiated the close down of development activities and changes in working capital.
- Research and development expenses were \$15.3 million for the quarter ended December 31, 2022, compared to \$21.5 million for the quarter ended December 31, 2021. The decrease was primarily related to a reduction in zandelisib costs as we discontinued the program and initiated the closing down of development activities during the quarter ended December 31, 2022.

- General and administrative expenses were \$8.5 million for the quarter ended December 31, 2022, compared to \$7.9 million for the quarter ended December 31, 2021. The increase primarily relates to personnel costs, including costs related to severance from a workforce reduction, professional services and general corporate expenses.
- MEI recognized revenue of \$32.7 million for the quarter ended December 31, 2022, compared to \$11.8 million for the quarter ended December 31, 2021. As a result of the discontinuation of the zandelisib program, we updated our estimated costs to complete each development performance obligation under the license agreement with Kyowa Kirin. This resulted in a higher progress towards completion and revenue for performance obligations that will not commence.
- Net income was \$10.3 million, or \$0.08 per share, for the quarter ended December 31, 2022, compared to net loss of \$12.2 million, or \$0.10 per share for the quarter ended December 31, 2021. The Company had 133,260,865 shares of common stock outstanding as of December 31, 2022, compared with 132,904,545 shares as of December 31, 2021.
- The adjusted net income (a non-GAAP measure) for the quarter ended December 31, 2022, excluding non-cash expenses related to changes in the fair value of the warrants, was \$9.8 million, compared to an adjusted net loss of \$17.6 million for the quarter ended December 31, 2021.

About MEI Pharma

MEI Pharma, Inc. (Nasdaq: MEIP) is a clinical-stage pharmaceutical company focused on developing potential new therapies for cancer. MEI Pharma's portfolio of drug candidates includes clinical stage candidates with differentiated or novel mechanisms of action intended to address unmet medical needs and deliver improved benefit to patients, either as standalone treatments or in combination with other therapeutic options. For more information, please visit www.meipharma.com. Follow us on Twitter [@MEI_Pharma](https://twitter.com/MEI_Pharma) and on [LinkedIn](https://www.linkedin.com/company/meipharma).

Forward-Looking Statements

Under U.S. law, a new drug cannot be marketed until it has been investigated in clinical studies and approved by the FDA as being safe and effective for the intended use. Statements included in this press release that are not historical in nature are "forward-looking statements" within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995 including, without limitation, statements regarding: the potential, safety, efficacy, and regulatory and clinical progress of zandelisib and our other product candidates, including the anticipated timing for initiation of clinical trials and release of clinical trial data and our expectations surrounding potential regulatory submissions, approvals and timing thereof; our business strategy and plans; and the sufficiency of our cash, cash equivalents and short-term investments to fund our operations. You should be aware that our actual results could differ materially from those contained in the forward-looking statements, which are based on management's current expectations and are subject to a number of risks and uncertainties, including, but not limited to our failure to successfully commercialize our product candidates; the availability or appropriateness of utilizing the FDA's accelerated approval pathway for

our product candidates; final data from our pre-clinical studies and completed clinical trials may differ materially from reported interim data from ongoing studies and trials; costs and delays in the development and/ or FDA approval, or the failure to obtain such approval, of our product candidates; uncertainties or differences in interpretation in clinical trial results; adverse effects on the Company's business as a result of the restatement of our previously issued financial statements; uncertainty regarding the impact of rising inflation and the increase in interest rates as a result; the impact of the COVID-19 pandemic on our industry and individual companies, including on our counterparties, the supply chain, the execution of our clinical development programs, our access to financing and the allocation of government resources; our inability to maintain or enter into, and the risks resulting from our dependence upon, collaboration or contractual arrangements necessary for the development, manufacture, commercialization, marketing, sales and distribution of any products; 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; general economic conditions; the failure of any products to gain market acceptance; our inability to obtain any additional required financing; technological changes; government regulation; changes in industry practice; and one-time events. We do not intend to update any of these factors or to publicly announce the results of any revisions to these forward-looking statements.

Non-GAAP Financial Measures

To supplement our financial statements, which are prepared and presented in accordance with generally accepted accounting principles in the United States ("GAAP"), we provide investors with a non-GAAP financial measure, adjusted net income (loss), which we believe is helpful to our investors. We use adjusted net income (loss) for financial and operational decision-making purposes and as a means to evaluate period-to-period comparisons. We believe this non-GAAP financial measure provides useful information about our operating results, enhances the overall understanding of past financial performance and future prospects and allows for greater transparency with respect to metrics used by our management in its financial and operational decision-making.

The presentation of adjusted net income (loss) is not meant to be considered in isolation or as a substitute for net loss, the directly comparable financial measure prepared in accordance with GAAP. While we believe adjusted net income (loss) is an important tool for financial and operational decision-making and for evaluating our own operating results over different periods of time, we urge investors to review the reconciliation of this financial measures to the comparable GAAP financial measures included below, and not to rely on any single financial measure to evaluate our business.

We define adjusted net income (loss) as net income (loss), adjusted to exclude non-cash expenses related to changes in the fair value of the warrants. We have presented adjusted net income (loss) because we believe excluding the non-cash expenses related to changes in the fair value of warrants can produce a useful measure for period-to-period comparisons of our business.

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

	December 31, 2022 (Unaudited)	June 30, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 10,917	\$ 15,740
Short-term investments	113,256	137,512
Total cash, cash equivalents and short-term investments	124,173	153,252
Unbilled receivables	5,704	10,044
Prepaid expenses and other current assets	3,568	3,830
Total current assets	133,445	167,126
Operating lease right-of-use asset	12,698	9,054
Property and equipment, net	1,456	1,660
Total assets	<u>\$ 147,599</u>	<u>\$ 177,840</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 4,067	\$ 7,918
Accrued liabilities	14,346	10,820
Deferred revenue	2,897	4,834
Operating lease liability	1,343	871
Total current liabilities	22,653	24,443
Deferred revenue, long-term	64,545	90,610
Operating lease liability, long-term	12,027	8,771
Warrant liability	—	1,603
Total liabilities	99,225	125,427
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.01 par value; 100 shares authorized; none outstanding	—	—
Common stock, \$0.0000002 par value; 226,000 shares authorized; 133,261 and 133,152 shares issued and outstanding at December 31, 2022 and June 30, 2022, respectively	—	—
Additional paid-in capital	428,904	426,572
Accumulated deficit	(380,530)	(374,159)
Total stockholders' equity	48,374	52,413
Total liabilities and stockholders' equity	<u>\$ 147,599</u>	<u>\$ 177,840</u>



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

	Three Months Ended December 31,		Six Months Ended December 31,	
	2022	2021	2022	2021
Revenue	\$ 32,735	\$ 11,832	\$ 41,465	\$ 19,589
Operating expenses:				
Research and development	15,313	21,531	34,776	41,484
General and administrative	8,496	7,926	15,982	15,835
Total operating expenses	23,809	29,457	50,758	57,319
Income (loss) from operations	8,926	(17,625)	(9,293)	(37,730)
Other income (expense):				
Change in fair value of warrant liability	486	5,458	1,603	8,046
Interest and dividend income	845	11	1,325	18
Other expense, net	(4)	—	(6)	—
Net income (loss)	\$ 10,253	\$ (12,156)	\$ (6,371)	\$ (29,666)
Net income (loss):				
Basic	\$ 10,253	\$ (12,156)	\$ (6,371)	\$ (29,666)
Diluted	\$ 10,253	\$ (17,614)	\$ (6,371)	\$ (37,712)
Net income (loss) per share:				
Basic	\$ 0.08	\$ (0.10)	\$ (0.05)	\$ (0.26)
Diluted	\$ 0.08	\$ (0.14)	\$ (0.05)	\$ (0.32)
Shares used in computing net income (loss) per share:				
Basic	133,261	126,725	133,258	115,982
Diluted	133,261	128,160	133,258	118,657



MEI PHARMA, INC,
Reconciliation of GAAP Net Loss to Adjusted Net Loss
(In thousands)
(Unaudited)

	Three Months Ended		Six Months Ended	
	December 31,		December 31,	
	2022	2021	2022	2021
Net income (loss)	\$10,253	\$(12,156)	\$(6,371)	\$(29,666)
Add: Change in fair value of warrant liability	(486)	(5,458)	(1,603)	(8,046)
Adjusted net income (loss)	<u>\$ 9,767</u>	<u>\$(17,614)</u>	<u>\$(7,974)</u>	<u>\$(37,712)</u>