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

September 26, 2023
Date of report (Date of earliest event reported)

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

Delaware	**000-50484**	**51-0407811**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

11455 El Camino Real, Suite 250 **San Diego, California**	**92130**
(Address of principal executive offices)	**(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 September 26, 2023, MEI Pharma, Inc. (the "Company") issued a press release announcing its financial results for its fiscal year ended June 30, 2023. 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 September 26, 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: September 26, 2023

By: /s/ David M. Urso
Name: David M. Urso
Title: Chief Executive Officer

MEI Pharma Reports Fiscal Year 2023 Results and Operational Highlights

— Conference Call Today at 5:00 p.m. Eastern Time —

SAN DIEGO – September 26, 2023 – MEI Pharma, Inc. (Nasdaq: MEIP), a clinical-stage pharmaceutical company focused on advancing new therapies for cancer, today reported results for its fiscal year ended June 30, 2023.

"Over just the next few quarters we look forward to data readouts from two ongoing clinical studies of voruciclib and ME-344, advancing our strategy of assessing drug candidates in combinations with standard-of-care therapies to overcome known resistance mechanisms and address clear medical needs," said David M. Urso, president and chief executive officer of MEI Pharma. "Focusing on the execution of these two clinical studies – voruciclib evaluated in combination with Venclexta® in acute myeloid leukemia and ME-344 in combination with Avastin® in colorectal cancer – we expect data readouts beginning with voruciclib early in calendar 2024 and in the first half of 2024 for ME-344. Positive data from the studies would provide important support for the further development of these therapies to address significant unmet medical needs among patients with acute myeloid leukemia and colorectal cancer."

Fiscal Year 2023 and Recent Highlights

- In August 2023, MEI announced the dosing of the first patient in a Phase 1b study evaluating ME-344 in combination with bevacizumab (AVASTIN®) in patients with previously treated metastatic colorectal cancer. ME-344 is a novel mitochondrial inhibitor targeting energy production through the OXPHOS pathway, which is important for supporting tumor cell survival and proliferation for many forms of cancer, including colorectal cancer. Bevacizumab, a vascular endothelial growth factor (VEGF) inhibitor, and other antiangiogenics, inhibit energy production through glycolysis and, thereby, increase tumor reliance on mitochondrial energy production, providing an opportunity to evaluate a combination with ME-344 to inhibit energy production in tumor cells and induce an antitumor effect. The Company anticipates announcing safety and efficacy data from the first cohort of 20 patients in the first half of 2024.
- In July 2023, at the Company's Special Meeting of Stockholders, MEI did not obtain the necessary stockholder votes to approve a merger agreement for an all-stock transaction pursuant to which Infinity Pharmaceuticals would have become a wholly-owned subsidiary of the Company. The certified results showed that 59.70% of outstanding shares were voted, of which 47.86% voted in favor of the proposed transaction, and 51.44% against. Accordingly, MEI terminated the merger agreement.

- In June 2023, in connection with the Company's succession plan, David M. Urso was appointed president and chief executive officer and also joined the Company's board of directors. Mr. Urso replaced Daniel P. Gold, Ph.D., president and chief Executive officer of MEI since 2010. Dr. Gold continues to serve on MEI's board. In June 2023, also as part of the Company's succession planning, it was announced that Jay File would be appointed chief financial officer, replacing Brian Drazba. Mr. File's appointment became effective on August 1, 2023.
- In May 2023, MEI announced an update to the ongoing Phase 1 study evaluating voruciclib, its oral cyclin-dependent kinase 9 (CDK9) inhibitor, alone and in combination with venetoclax (Venclexta®), a BCL2 inhibitor, in patients with acute myeloid leukemia (AML) or B-cell malignancies. The Company announced that early results demonstrated that voruciclib alone or in combination with venetoclax was generally well tolerated with no significant myelosuppression. The results further demonstrated encouraging clinical activity in heavily pretreated patients administered with voruciclib alone and at the initial dose level in combination with venetoclax. These early results are consistent with the hypothesis that voruciclib may address a common venetoclax resistance mechanism by inhibiting MCL-1 via CDK9 inhibition.
- In May 2023, MEI regained compliance with the Nasdaq minimum bid requirement after the Company implemented a 1-for-20 reverse stock split in April 2023. The reverse stock split was approved by MEI's stockholders on January 5, 2023.
- In March 2023, the Safety Review Committee of the Phase 1 study evaluating voruciclib plus venetoclax completed a safety assessment of the initial dose escalation cohort evaluating the combination in patients with AML and recommended opening the next cohort. The combination stage of the study started after completing the single-agent dose exploration stage of the Phase 1 study in patients with either AML or B-cell malignancies.
- In December 2022, MEI announced a realignment of its clinical development efforts following the discontinuation of zandelisib, its PI3K delta inhibitor drug candidate. As part of the realignment, the Company disclosed plans to streamline the organization towards the development of its two earlier clinical-stage assets, voruciclib and ME-344. We currently have 41 employees, which reflects a 61% reduction in full-time employees since our announcement in December 2022.
- In December 2022, after receiving new guidance in an end of Phase 2 meeting with the U.S. Food and Drug Administration (FDA), MEI and Kyowa Kirin announced the discontinuation of global development of zandelisib outside of Japan. The two companies concluded that a clinical trial consistent with the new FDA guidance, including modification of the then ongoing Phase 3 COASTAL trial, would likely not be feasible to complete within a time period that would support further investment. Kyowa Kirin, after meeting with the Pharmaceuticals and Medical Devices Agency (PMDA), subsequently discontinued zandelisib development in Japan after determining that conducting a randomized study consistent with that agency's guidance to support a marketing application would also likely not be feasible to complete within a time period that would support further investment. In July 2023, the Company and Kyowa Kirin mutually entered a termination agreement between the parties pursuant to which MEI regained full global rights to zandelisib, subject to Kyowa Kirin receiving some limited rights to use zandelisib for compassionate use.

Expected Drug Candidate Pipeline Developments

Voruciclib – Oral CDK9 inhibitor in Phase 1 Study

- Report clinical data from the ongoing Phase 1 clinical trial evaluating voruciclib plus Venclexta® (venetoclax) in patients with AML early in calendar 2024.

ME-344 – Mitochondrial inhibitor in Phase 1b Study

- Report clinical data from the Phase 1b clinical trial evaluating ME-344 plus Avastin® (bevacizumab) in patients with relapsed colorectal cancer in the first half of calendar-year 2024.

Fiscal Year 2023 Financial Results

- As of June 30, 2023, MEI had $100.7 million in cash, cash equivalents, and short-term investments with no outstanding debt.
- For the year ended June 30, 2023, cash used in operations was $52.5 million, compared to $48.7 million during the year ended June 30, 2022. The increase in cash used in operations was primarily due to changes in working capital associated with the close down of zandelisib activities with Kyowa Kirin.
- Research and development expenses were $52.5 million for the year ended June 30, 2023, compared to $85.6 million for the year ended June 30, 2022. The decrease was primarily related to a reduction in zandelisib costs as we continued the close down of development activities announced in December 2022.
- General and administrative expenses increased by $2.6 million to $33.1 million for the year ended June 30, 2023, compared to $30.5 million for the year ended June 30, 2022. The net increase was primarily related to severance costs due to our staggered reductions in the workforce announced in December 2022 and higher external professional services offset by a decrease in noncash stock-based compensation.

- MEI recognized revenue of $48.8 million for the year ended June 30, 2023, compared to $40.7 million for the year ended June 30, 2022. The increase in revenue primarily results from the discontinuation of the zandelisib program in December 2022 under our global License, Development and Commercialization Agreement with Kyowa Kirin that resulted in the recognition of $16.6 million of previously deferred revenue related to performance obligations that are being closed and $8.6 million of previously deferred revenue related to performance obligations associated with clinical trials that have not commenced and will no longer be initiated.
- Net loss was $31.8 million, or $4.78 per share, for the year ended June 30, 2023, compared to net loss of $54.5 million, or $8.75 per share for the year ended June 30, 2022. The Company had 6,662,857 shares of common stock outstanding as of June 30, 2023, compared with 6,657,602 shares as of June 30, 2022.
- The adjusted net loss (a non-GAAP measure) for the year ended June 30, 2023 and 2022, excluding noncash gains recognized for changes in the fair value of warrants, was $33.4 million and $75.2 million, respectively

The Company believes its cash balance is sufficient to fund operations for at least the next 12 months, and through the reporting of clinical data readouts from the ongoing and planned voruciclib and ME-344 Phase 1 and Phase 1b clinical programs, respectively.

Conference Call & Webcast Information

- When: September 26, 2023, 5:00 p.m. ET
- Dial-in: 1-833-974-2378 (United States) or 1-412-317-5771 (International)
- Please ask to join into the MEI Pharma earnings call

Please join the conference call at least 10 minutes early to register. You can access the live webcast here or under the investor relations section of MEI's website at: www.meipharma.com. A replay of the conference call will be archived for at least 30 days after the call.

About MEI Pharma

MEI Pharma, Inc. (Nasdaq: MEIP) is a clinical-stage pharmaceutical company committed to developing novel and differentiated cancer therapies. We build our pipeline by acquiring promising cancer agents and creating value in programs through development, strategic partnerships, out-licensing and commercialization, as appropriate. Our approach to oncology drug development is to evaluate our drug candidates in combinations with standard-of-care therapies to overcome known resistance mechanisms and address clear medical needs to provide improved patient benefit. The drug candidate pipeline includes voruciclib, an oral cyclin-dependent kinase 9 ("CDK9") inhibitor, and ME-344, an intravenous small molecule mitochondrial inhibitor targeting the oxidative phosphorylation pathway. For more information, please visit www.meipharma.com. Follow us on X (formerly Twitter) @MEI_Pharma and on LinkedIn.

Forward-Looking Statements

Certain information contained 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 our 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; 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; uncertainty regarding the impact of rising inflation and the increase in interest rates as a result; potential economic downturn; activist investors; 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. 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.

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 loss, which we believe is helpful to our investors. We use adjusted net 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 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 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 loss as net loss, adjusted to exclude noncash gains recognized for changes in the fair value of warrants. We have presented adjusted net loss because we believe excluding noncash gains recognized for 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.
CONSOLIDATED BALANCE SHEETS
(In thousands, except per share amounts)

	June 30, 2023	June 30, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 16,906	$ 15,740
Short-term investments	83,787	137,512
Unbilled receivables	85	10,044
Prepaid expenses and other current assets	6,750	3,830
Total current assets	107,528	167,126
Operating lease right-of-use asset	11,972	9,054
Property and equipment, net	1,309	1,660
Total assets	$ 120,809	$ 177,840
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 6,134	$ 7,918
Accrued liabilities	12,461	10,820
Deferred revenue	317	4,834
Operating lease liability	1,428	871
Total current liabilities	20,340	24,443
Deferred revenue, long-term	64,545	90,610
Operating lease liability, long-term	11,300	8,771
Warrant liability	—	1,603
Total liabilities	96,185	125,427
Stockholders' equity:		
Preferred stock, $0.01 par value; 100 shares authorized; none outstanding	—	—
Common stock, $0.00000002 par value; 226,000 shares authorized; 6,663 and 6,658 shares issued and outstanding at June 30, 2023 and 2022, respectively	—	—
Additional paid-in-capital	430,621	426,572
Accumulated deficit	(405,997)	(374,159)
Total stockholders' equity	24,624	52,413
Total liabilities and stockholders' equity	$ 120,809	$ 177,840

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

	Years Ended June 30,	
	2023	2022
Revenue	$ 48,816	$ 40,697
Operating expenses:		
Research and development	52,450	85,641
General and administrative	33,130	30,540
Total operating expenses	85,580	116,181
Loss from operations	(36,764)	(75,484)
Other income (expense):		
Change in fair value of warrant liability	1,603	20,752
Interest and dividend income	3,345	284
Other expense, net	(22)	(6)
Net loss	$ (31,838)	$ (54,454)
Net loss:		
Basic	$ (31,838)	$ (54,454)
Diluted	$ (31,838)	$ (62,500)
Net loss per share:		
Basic	$ (4.78)	$ (8.75)
Diluted	$ (4.78)	$ (9.99)
Shares used in computing net loss per share:		
Basic	6,663	6,224
Diluted	6,663	6,257

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

	Years Ended June 30,	
	2023	2022
Net loss:	$(31,838)	$(54,454)
Add: Change in fair value of warrant liability	(1,603)	(20,752)
Adjusted net loss:	$(33,441)	$(75,206)