MEI Pharma Reports Third Quarter Fiscal Year 2024 Results and Operational Highlights

May 9, 2024

-- Ongoing Phase 1 Study Evaluating Voruciclib Plus Venetoclax Demonstrates Anti-leukemic Activity, Including Complete Responses, Anticipated Decreases in Mcl-1 and No Overlapping Toxicity in Heavily Pretreated R/R AML Patients --

-- Board of Directors Unanimously Aligned on Prioritization of Voruciclib Program Development--

-- MEI Begins Fourth Fiscal Quarter with $56.6 Million in Cash --

SAN DIEGO--(BUSINESS WIRE)--May 9, 2024-- MEI Pharma, Inc. (Nasdaq: MEIP), a clinical-stage pharmaceutical company evaluating novel drug candidates to address known resistance mechanisms to standard-of-care cancer therapies, today reported results for the three and nine months ended March 31, 2024, and highlighted recent corporate events.

“Over the past several months, MEI has received encouraging clinical data for voruciclib and ME-344 supporting the further development of these programs,” said David Urso, president and chief executive officer of MEI Pharma. “The clinical focus for the rest of the year will be voruciclib, our oral CDK9 inhibitor. We anticipate providing updates from the clinical trial evaluating voruciclib in combination with venetoclax in patients with relapsed/refractory AML, a study designed to provide additional evidence of the anti-leukemic activity of this combination, during the remainder of calendar 2024.”

Mr. Urso continued: “While venetoclax is an established option for patients with AML and is increasingly used as a standard treatment, the disease typically progresses and patients require therapy after venetoclax, which consistently yields limited benefit. While treatments targeting specific patient populations with mutations such as FLT3 and IDH and the menin inhibitors may be an option for some relapsed/refractory AML patients, the majority of patients do not have therapeutically actionable mutations. We believe that voruciclib in combination with venetoclax has potential, as a mutation-agnostic therapy, to benefit the largest number of patients with relapsed/refractory AML.”

Select Third Quarter Fiscal Year 2024 and Recent Highlights

- In January 2024, MEI presented a Trials in Progress poster of the Phase 1b study of ME-344, an investigational inhibitor of mitochondrial oxidative phosphorylation (“OXPHOS”), evaluating the combination with bevacizumab (Avastin®) in refractory metastatic colorectal cancer patients at the 2024 ASCO Gastrointestinal Cancers Symposium.
- In March 2024, MEI reported initiation of enrollment in an expansion cohort in the ongoing Phase 1 study evaluating voruciclib, its investigational selective oral cyclin-dependent kinase 9 (“CDK9”) inhibitor, in combination with venetoclax (Venclexta®), a B-cell lymphoma 2 (“BCL2”) inhibitor, in relapsed and refractory (“R/R”) acute myeloid leukemia (“AML”) patients. The decision to open the expansion cohort was based on initial data demonstrating anti-leukemic activity, including complete responses in heavily pretreated patients. Additionally, at doses of 100 mg or more, initial results from correlative biomarker assay analyses of available samples from patients treated with the combination demonstrated anticipated decreases of myeloid leukemia cell differentiation protein (“Mcl-1”), including progressively greater decreases in Mcl-1 in patients achieving a response compared to patients with stable disease or progressive disease. We also observed expected increases in Mcl-1 after administering venetoclax and subsequent anticipated decreases in Mcl-1 after administering voruciclib, supporting our hypothesis that voruciclib, as an inhibitor of CDK9, regulates Mcl-1 and

therefore may address the increase of Mcl-1 levels associated with venetoclax. There was no evidence of overlapping toxicity with venetoclax and no dose limiting toxicities were observed.

- In April 2024, MEI reported that 25% of evaluable patients with relapsed metastatic colorectal cancer in Cohort 1 of the Phase 1b study evaluating ME-344, an investigational inhibitor of mitochondrial oxidative phosphorylation, in combination with bevacizumab (Avastin®) had no disease progression at Week 16. This landmark analysis exceeded the 20% threshold set in the Clinical Study Protocol to add an additional 20 patients to the study via the initiation of Cohort 2. The combination was also observed to be generally well-tolerated to date. While the threshold was met to proceed to Cohort 2, following a strategic review the Company decided to continue to advance ME-344 via its ongoing development of a new formulation rather than through the addition of a new cohort of patients. The Company has already initiated research and development activity of the new formulation with the goal of increasing biological activity, improving convenience of administration and increasing the commercial opportunity.

- In April 2024, MEI reported that its Board of Directors unanimously aligned on a strategy to prioritize clinical development of voruciclib and enable development of a new ME-344 formulation for the potential of a future Phase 1 study. Additionally, the Company's Board of Directors unanimously determined not to proceed with a second return of capital under the October 31, 2023, Anson Funds and Cable Car Capital cooperation agreement in order to conserve resources and align strategic investment, and thereby extend the Company's operational cash runway.

Expected Drug Candidate Pipeline Developments

Voruciclib – Oral CDK9 inhibitor in Phase 1 Study

- MEI expects to report clinical data from additional dose escalation and expansion cohorts of the ongoing Phase 1 clinical trial evaluating voruciclib plus venetoclax in patients with R/R AML during the remainder of calendar 2024.

  The Company has completed patient enrollment of the dose expansion cohort evaluating a 300 mg dose of voruciclib administered daily for 14 consecutive days in a 28-day cycle in combination with standard dose venetoclax. Additionally, MEI is enrolling dose escalation cohorts evaluating up to four dose levels of voruciclib starting at 150 mg administered daily for 21 consecutive days in a 28-day cycle in combination with venetoclax.

ME-344 –Inhibitor of Mitochondrial OXPHOS in Phase 1b Study

- MEI has initiated research and development activity of a new ME-344 formulation with the goal of increasing biological activity, improving convenience of administration and increasing the commercial opportunity. The Company expects to provide an update on our formulation efforts in the first half of calendar 2025.

Select Third Quarter and Nine Months Financial Results for Fiscal Year 2024

- As of March 31, 2024, MEI had $56.6 million in cash, cash equivalents, and short-term investments with no outstanding debt.

- For the nine months ended March 31, 2024, cash used in operations was $32.5 million, compared to $41.2 million during the nine months ended March 31, 2023. The decrease is primarily due to the timing of payments on operating liabilities, as compared to the prior period combined with a lower clinical spend due to the wind down of the zandelisib program resulting from the discontinuation of development activities announced in December 2022.

- Research and development expenses decreased by $9.9 million to $5.2 million for the quarter ended March 31, 2024, compared to $15.1 million for the quarter ended March 31, 2023. The decrease was primarily related to a reduction in zandelisib program costs, as well as reduced personnel and related costs from our reductions in headcount. These decreases were partially offset by increases related to clinical trials, reformulation and manufacturing costs associated with ME-344 and increased clinical costs for the ongoing clinical study with voruciclib.

- General and administrative expenses decreased by $2.6 million to $4.6 million for the quarter ended March 31, 2024, compared to $7.2 million for the quarter ended March 31, 2023. The decrease was primarily related to reduced personnel and related costs from our reductions in headcount, as well as lower external legal expenses.

- MEI recognized no revenue for the quarter ended March 31, 2024, compared to $5.9 million for the quarter ended March 31, 2023. The decrease in revenue was due to all remaining noncash deferred revenue associated with the Kyowa Kirin Commercialization Agreement having been recognized in the first quarter of fiscal year 2024 due to the termination of that agreement in July 2023.

The Company believes its cash balance is sufficient to fund operations for at least the next 12 months.

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 inhibitor of mitochondrial oxidative phosphorylation. 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 Section 27A of the Securities Act of 1933, as amended, Section 21E of the Securities Exchange Act of 1934, as amended, and 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; our future financial position, including the sufficiency of our cash, cash equivalents and short-term investments to fund our operations and our ability to fund future capital returns; and the objectives of management for future 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 projections about future events. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, 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; geopolitical conflicts; 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.

MEI Pharma, Inc.
Condensed Consolidated Balance Sheets
(in thousands, except par value amounts)

	March 31, 2024	June 30, 2023
	(Unaudited)	(Audited)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 2,368	$ 16,906
Short-term investments	54,184	83,787
Unbilled receivables	—	85
Prepaid expenses and other current assets	2,814	6,750
Total current assets	59,366	107,528
Operating lease right-of-use asset	10,836	11,972
Property and equipment, net	1,058	1,309
Total assets	$ 71,260	$ 120,809
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,176	$ 6,134
Accrued liabilities	5,388	12,461
Deferred revenue	—	317
Operating lease liability	1,052	1,428
Total current liabilities	9,616	20,340
Deferred revenue, long-term	—	64,545
Operating lease liability, long-term	10,615	11,300
Total liabilities	20,231	96,185
Commitments and contingencies		
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 shares issued and outstanding at March 31, 2024 and June 30, 2023	—	—
Additional paid-in capital	420,842	430,621
Accumulated deficit	(369,813)	(405,997)
Total stockholders' equity	51,029	24,624
Total liabilities and stockholders' equity	$ 71,260	$ 120,809

MEI Pharma, Inc.
Condensed Consolidated Statements of Operations
(Unaudited)
(in thousands, except per share amounts)

	Three Months Ended March 31,		Nine Months Ended March 31,	
	2024	2023	2024	2023
Revenues	$ —	$ 5,894	$ 65,297	$ 47,359
Operating expenses:				
Research and development	5,220	15,104	12,617	49,880
General and administrative	4,609	7,181	19,158	23,163
Total operating expenses	9,829	22,285	31,775	73,043

(Loss) income from operations	(9,829)	(16,391)	33,522	(25,684)
Other income (expense):				
Change in fair value of warrant liability	—	—	—	1,603
Interest and dividend income	706	957	2,669	2,282
Other expense, net	(4)	(4)	(7)	(10)
Net (loss) income	$ (9,127)	$ (15,438)	$ 36,184	$ (21,809)
Net (loss) income per share - basic and diluted	$ (1.37)	$ (2.32)	$ 5.43	$ (3.27)
Weighted-average shares used in computing net (loss) income per share - basic and diluted:	6,663	6,663	6,663	6,663

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