MEI Pharma Reports Fiscal Year 2018 Results and Operational Highlights

Aug 30 2018

SAN DIEGO, Aug. 30, 2018 /PRNewswire/ -- MEI Pharma, Inc. (Nasdaq: MEIP), a late-stage pharmaceutical company focused on advancing new therapies for cancer, today reported results for its fiscal year ended June 30, 2018.

"We begin the 2019 fiscal year in our strongest position ever, with progress across all four clinical-stage oncology candidates, and with particular focus on the planned initiation of the ME-401 Phase 2 accelerated approval study by year-end. With ME-401 joining pracinostat as the second candidate in a global study to support marketing authorization, along with our robust cash position, we are well situated to pursue our development strategy," said Daniel
P. Gold, Ph.D., president and chief executive officer of MEI Pharma.

Dr. Gold continued, "We are also very pleased to report that in recent discussions with FDA on a ME-401 accelerated approval registration strategy, FDA expressed support of our proposed randomized Phase 2 trial in which we will evaluate continuous and intermittent dosing schedules in patients with relapsed or refractory follicular lymphoma. As we execute on our plans to start this study around year-end, we also look forward to reporting additional progress across our pipeline over the coming quarters, including clinical data from our CDK9 inhibitor, voruciclib, and clinical updates on pracinostat and ME-344."

Fiscal Year 2018 and Recent Company Highlights

Financial

- In May 2018, the Company completed a private placement of common stock, along with warrants to purchase common stock, resulting in net proceeds to MEI of approximately $70 million.
- As of June 30, 2018, MEI had $102.7 million in cash, cash equivalents and short-term investments, with no outstanding debt. The cash balance includes the proceeds of our private placement completed in May 2018.
- Research and development expenses were $17.0 million for the year ended June 30, 2018, compared to $7.2 million for 2017. The increase was primarily related to increased activities in all clinical programs including the acquisition and development costs associated with voruciclib.
- General and administrative expenses were $9.8 million for the year ended June 30, 2018, compared to $8.6 million for 2017. The increase primarily relates to professional services expenses, share-based compensation, and general corporate expenses incurred during the year ended June 30, 2018.
- The Company recognized revenues of $1.6 million for the year ended June 30, 2018. Revenues resulted from the recognition of fees allocated to research and development activities related to the Helsinn License Agreement. Revenue decreased due to lower levels of research and development activities during the year ended June 30, 2018.
- Cash expenditures for operations were $21.3 million for the year ended June 30, 2018, compared to $16.5 million for 2017. Cash expenditures were $3.8 million for the fourth quarter ended June 30, 2018, compared to $3.1 million for the same period in 2017.
- Net loss was $40.1 million, or $0.97 per share, for the fiscal year ended June 30, 2018, compared to net income of $2.7 million, or $0.07 per share for 2017. The Company's net loss includes a $9.7 million change in the fair value of the warrants issued in connection with the May 2018 financing and $2.4 million in transaction costs related to the May 2018 financing recorded as financing expense on the statement of operations. The Company is required to calculate the change in fair value of the warrants and record the non-cash charge to the statement of operations at each reporting date.

ME-401 - a next-generation selective oral inhibitor of PI3K delta

- In June 2018, the Company presented results from a Phase 1b study evaluating ME-401 in patients with relapsed/refractory follicular lymphoma, chronic lymphocytic leukemia and small lymphocytic lymphoma at the 2018 American Society of Clinical Oncology (ASCO) Annual Meeting as well as the European Hematology Association Congress. The data demonstrated a 90% overall objective response rate in patients. Based on

these data, the Company is advancing ME-401 into a Phase 2, single-agent study for the treatment of adults with relapsed or refractory follicular lymphoma. The Phase 2 study is intended to support accelerated approval and is planned to begin around the end of 2018.
- In July 2018 the Company discussed with FDA a ME-401 monotherapy accelerated approval strategy in patients with relapsed or refractory follicular lymphoma (FL). The FDA communicated support for the Company's proposed randomized Phase 2 trial evaluating continuous and intermittent dosing schedules. 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.
- MEI expects to report data updates from the Phase 1b study, including at a medical meeting late in Q4 2018. By year-end 2018, MEI also plans to initiate the Phase 2 study to support accelerated approval of ME-401 in relapsed or refractory follicular lymphoma.

Pracinostat - an oral HDAC inhibitor (partnered with Helsinn Healthcare, SA)

- In January 2018, the European Medicines Agency granted Orphan Drug Designation to pracinostat, currently in a Phase 3 study in combination with azacitidine for the treatment of acute myeloid leukemia (AML) in adult patients unfit for induction chemotherapy.
- In May 2018, the Company and Helsinn announced a successful interim analysis from the Phase 2 study evaluating the combination of pracinostat and azacitidine in high and very high-risk myelodysplastic syndrome (MDS) patients previously untreated with hypomethylating agents. Based on the successful planned interim analysis, the study expanded open-label enrollment to 60 patients. MEI is responsible for the conduct of the Phase 2 study, the cost of which will be shared by Helsinn. Helsinn is responsible for funding any further studies.
- MEI expects to provide updates to the pracinostat program at a medical meeting late in Q4 2018.

Voruciclib - an oral, selective CDK inhibitor with robust CDK9 inhibition

- In January 2018, the U.S. Food and Drug Administration cleared the Company's Investigational New Drug Application (IND) for voruciclib.
- MEI expects to report updates regarding the ongoing Phase 1 study, and the initiation of dosing of voruciclib in combination with VENCLEXTA® (venetoclax) in relapsed or refractory B-cell malignancies, at medical meetings in 2019.

ME-344 - a novel mitochondrial inhibitor

- In June 2018, the Company presented interim results from an investigator-initiated Phase 1 study in HER2 negative breast cancer in combination with bevacizumab (marketed as Avastin®) at ASCO. ME-344 in combination with Avastin demonstrated inhibition of tumor proliferation as measured by Ki-67 reductions in HER2 negative breast cancer patients. These results support continuation of the ongoing Phase 1 study.
- MEI expects to report additional data from the investigator-sponsored Phase 1 study at medical meetings in 2019.

Operational Highlights

- In February 2018, the Company announced the appointment of industry veteran Frederick W. Driscoll to the board of directors.
  Mr. Driscoll serves on the audit committee.
- In July 2018, the Company announced that David M. Urso, J.D., senior vice president of corporate development and general counsel, was promoted to chief operating officer.
  Mr. Urso is also continuing as the Company's general counsel and head of corporate development.

Conference Call and Webcast

MEI Pharma will host a conference call with simultaneous webcast today, August 30, 2018, at 5:00 p.m. Eastern time to provide a corporate update. To access the live call, please dial (866) 939-3921 (United States) or (678) 302-3550 (International), conference ID 47469059. The conference call will also be webcast live and can be accessed at www.meipharma.com. A replay of the webcast will be available approximately one hour after the conclusion of the call.

About MEI Pharma

MEI Pharma, Inc. (Nasdaq: MEIP) is a San Diego-based pharmaceutical company focused on leveraging its extensive development and oncology expertise to identify and advance new therapies for cancer. The Company's portfolio of drug candidates includes pracinostat, an oral HDAC inhibitor that is partnered with Helsinn Healthcare, SA. Pracinostat has been granted Breakthrough Therapy Designation from the U.S. Food and Drug Administration for use in combination with azacitidine for the treatment of patients with newly diagnosed acute myeloid leukemia who are unfit for intensive chemotherapy. Pracinostat is also being developed in combination with azacitidine for the treatment of patients with high and very high-risk myelodysplastic syndrome (MDS). MEI Pharma's clinical development pipeline also includes ME-401, a highly differentiated oral PI3K delta inhibitor currently in a Phase 1b study in patients with relapsed refractory follicular lymphoma or CLL, and voruciclib, an oral, selective CDK inhibitor shown to suppress MCL1, a known mechanism of resistance to BCL2 inhibitors. The Company is also developing ME-344, a novel mitochondrial inhibitor currently in an investigator-initiated study in combination with bevacizumab evaluating patients with HER2-negative breast cancer. Pracinostat, ME-401, ME-344 and voruciclib are investigational agents and are not approved for use in the U.S. For more information, please visit www.meipharma.com.

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. 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; 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; 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.

MEI PHARMA, INC.

BALANCE SHEETS

(In thousands, except per share amounts)

	June 30,	
	2018	**2017**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 13,309	$ 8,458
Short-term investments	89,434	45,107
Total cash, cash equivalents and short-term investments	102,743	53,565
Prepaid expenses and other current assets	1,586	1,758
Total current assets	104,329	55,323
Intangible assets, net	296	331
Property and equipment, net	32	50
Total assets	$ 104,657	$ 55,704
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,643	$ 585
Accrued liabilities	3,454	3,285
Deferred revenues	788	996
Total current liabilities	7,885	4,866
Warrant liability	46,313	-
Total liabilities	54,198	4,866
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock, $0.01 par value; 100 shares authorized; none outstanding	-	-

Common stock, $0.00000002 par value; 113,000 shares authorized; 70,406 and 36,772 shares issued and outstanding at June 30, 2018and 2017, respectively.	-	-
Additional paid-in-capital	264,858	225,169
Accumulated deficit	(214,399)	(174,331)
Total stockholders' equity	50,459	50,838
Total liabilities and stockholders' equity	$ 104,657	$ 55,704

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

	Years Ended June 30,		
	2018	2017	2016
Revenues:			
License revenue	$ -	$ 20,880	$ -
Research and development revenue	1,622	2,369	-
	1,622	23,249	-
Operating expenses:			
Cost of research and development revenue	3,383	5,000	-
Research and development	17,038	7,237	13,403
General and administrative	9,787	8,628	7,601
Total operating expenses	30,208	20,865	21,004
(Loss) income from operations	(28,586)	2,384	(21,004)
Other income (expense):			
Change in fair value of warrant liability	(9,705)	-	-
Financing costs associated with warrants	(2,367)	-	-
Interest and dividend income	591	287	143
Income tax expense	(1)	(1)	(1)
Net (loss) income	$ (40,068)	$ 2,670	$ (20,862)
Net (loss) income per share, basic	$ (0.97)	$ 0.07	$ (0.61)
Net (loss) income per share, diluted	$ (0.97)	$ 0.07	$ (0.61)
Shares used in computing net (loss) income per share:			
Basic	41,431	36,813	34,400
Diluted	41,431	36,938	34,400

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