

MEI Pharma Reports First Quarter Fiscal Year 2020 Results and Operational Highlights

Nov 07 2019

SAN DIEGO, Nov. 7, 2019 /PRNewswire/ -- MEI Pharma, Inc. (NASDAQ: MEIP), a late-stage pharmaceutical company focused on advancing new therapies for cancer, today reported results for its first quarter ended September 30, 2019.

"During this past quarter, our primary focus remained on advancing the clinical development of ME-401, as well as voruciclib, while continuing to explore additional clinical collaborations and partnering opportunities to effectively leverage the potential of our drug candidates for patients," said

Daniel P. Gold, Ph.D., president and chief executive officer of MEI Pharma. "As reported at the MEI Investor and Analyst event in October, the ME-401 intermittent dosing regimen continues to demonstrate high activity with a well-tolerated safety profile, supporting the Phase 2 TIDAL study in patients with relapsed or refractory follicular lymphoma. We are also focused on the expansion of the investigation of the ME-401 intermittent dosing regimen across a variety of B-cell malignancies in combination with other therapies, like Rituxan® or zanubrutinib, an investigational BTK inhibitor as per our clinical collaboration agreement with BeiGene."

Recent Highlights

- In October 2019, at MEI's Investor and Analyst Event, the company reported updated data from the ongoing Phase 1b study of ME-401, an investigational selective oral inhibitor of phosphatidylinositol 3-kinase (PI3K) delta. The data demonstrate:
 - Overall response rates of 78% in relapsed or refractory (r/r) follicular lymphoma (FL) and 89% in r/r chronic lymphocytic leukemia or small lymphocytic lymphoma (CLL/SLL).
 - Rates of Grade 3 adverse events of special interest related to ME-401 exposure were observed in <10% of patients dosed on an intermittent schedule (IS).
 - Median duration of response not yet reached in patients with FL or CLL/SLL on the IS regimen. Median follow-up for FL and CLL/SLL patients is 9.2 months (range 3.4-20.7 months) and 7.4 months (range 2.6-14.7 months), respectively.
- In July 2019, Tamar Howson, M.S., MBA, a highly experienced business development executive with over 30 years of service in the pharmaceutical and biotechnology industry, joined the Board of Directors.

First Quarter Fiscal Year 2020 Financial Results

- As of September 30, 2019, MEI had \$65.9 million in cash, cash equivalents and short-term investments, with no outstanding debt.
- For the quarter ended September 30, 2019, cash used in operations was \$14.1 million, compared to \$12.8 million for 2018.
- Research and development expenses were \$9.0 million for the quarter ended September 30, 2019, compared to \$6.1 million for 2018. The increase was primarily related to increased development costs associated with ME-401 and increased headcount and professional services to support our development activities.
- General and administrative expenses were \$4.1 million for the quarter ended September 30, 2019, compared to \$3.4 million for 2018. The increase primarily relates to increased headcount and increased professional services expenses to support our activities.
- Revenues were \$1.2 million for the quarter ended September 30, 2019, resulting from the recognition of fees allocated to research and development activities related to the Helsinn and Kyowa Kirin License Agreements. This compares with revenues of \$0.5 million for the quarter ended September 30, 2018, resulting from the recognition of fees allocated to research and development activities related to the Helsinn License Agreement.
- Net loss was \$3.0 million, or \$0.04 per share, for the quarter ended September 30, 2019, compared to net loss of \$14.5 million, or \$0.21 per share for 2018. The net loss decreased primarily as a result of a non-cash gain related to changes in the fair value of warrants issued in connection with the May 2018 financing. The company had 73,634,927 shares of common stock outstanding as of September 30, 2019, compared with

71,115,444 shares as of September 30, 2018.

- The adjusted net loss for the quarter ended September 30, 2019, excluding a non-cash gain related to changes in the fair value of the warrants (a non-GAAP measure), was \$12.3 million, compared to an adjusted net loss of \$9.6 million for 2018.

About MEI Pharma

MEI Pharma, Inc. (Nasdaq: MEIP) is a late-stage pharmaceutical company focused on developing potential new therapies for cancer. Our portfolio of drug candidates contains four clinical-stage assets, including one candidate in an ongoing global registration trial and another candidate in a Phase 2 clinical trial which may support an accelerated approval marketing application with the U.S. Food and Drug Administration. Each of our pipeline candidates leverages a different mechanism of action with the objective of developing therapeutic options that are: (1) differentiated, (2) address unmet medical needs and (3) deliver improved benefit to patients either as standalone treatments or in combination with other therapeutic options. 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.		
CONDENSED BALANCE SHEETS		
(In thousands, except per share amounts)		
	September 30,	June 30,
	2019	2019
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 5,984	\$ 9,590
Short-term investments	59,932	64,899
Total cash, cash equivalents and short-term investments	65,916	74,489
Common stock proceeds receivable	-	5,274
Prepaid expenses and other current assets	2,135	2,435
Total current assets	68,051	82,198
Intangible assets, net	253	261
Property and equipment, net	619	204
Total assets	<u>\$ 68,923</u>	<u>\$ 82,663</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		

Accounts payable	\$ 3,098	\$ 4,787
Accrued liabilities	3,295	4,559
Deferred revenue	3,675	4,955
Total current liabilities	10,068	14,301
Deferred revenue, long-term	3,231	2,819
Warrant liability	8,344	17,613
Total liabilities	21,643	34,733
Stockholders' equity:		
Preferred stock, \$0.01 par value; 100 shares authorized;		
none outstanding	-	-
Common stock, \$0.00000002 par value; 226,000 shares		
authorized; 73,635 and 73,545 shares issued and outstanding		
at September 30, 2019 and June 30, 2019, respectively	-	-
Additional paid-in-capital	281,492	279,148
Accumulated deficit	(234,212)	(231,218)
Total stockholders' equity	47,280	47,930
Total liabilities and stockholders' equity	\$ 68,923	\$ 82,663

MEI PHARMA, INC.		
CONDENSED STATEMENTS OF OPERATIONS		
(In thousands, except per share amounts)		
(Unaudited)		
	Three Months Ended	
	September 30,	
	2019	2018
Revenue	\$ 1,157	\$ 488
Operating expenses:		
Cost of revenue	688	989
Research and development	8,962	6,131
General and administrative	4,130	3,401
Total operating expenses	13,780	10,521
Loss from operations	(12,623)	(10,033)
Other income (expense):		
Change in fair value of warrant liability	9,269	(4,962)
Interest and dividend income	374	454
Other expense	(14)	(1)
Net loss	\$ (2,994)	\$ (14,542)
Net loss:		
Basic and diluted	\$ (2,994)	\$ (14,542)
Net loss per share:		
Basic and diluted	\$ (0.04)	\$ (0.21)
Shares used in computing net loss per share:		

MEI PHARMA, INC.		
Reconciliation of GAAP Net Loss to Adjusted Net Loss		
(In thousands)		
(Unaudited)		
	Three Months Ended	
	September 30,	
	2019	2018
Net loss	\$ (2,994)	\$ (14,542)
Add: Change in fair value of warrant liability	(9,269)	4,962
Adjusted net loss	\$ (12,263)	\$ (9,580)



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