

MEI Pharma Reports Fiscal Second-Quarter 2020 Results and Operational Highlights

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SAN DIEGO, Feb. 6, 2020 /PRNewswire/ -- MEI Pharma, Inc. (NASDAQ: MEIP) ("MEI"), a late-stage pharmaceutical company focused on advancing new therapies for cancer, today reported results for its second quarter ended December 31, 2019.

"We're off to a good start in calendar year 2020. Our pipeline of clinical oncology candidates continues to advance, and the successful equity offering this past December gives us added resources to execute on our clinical strategy through key value-creating inflection points," said Daniel P. Gold, Ph.D., president and chief executive officer of MEI Pharma. "We have several important milestones across our pipeline in 2020 including completing enrollment in the ME-401 TIDAL study, data updates from the Phase 1b study of ME-401 administered as a monotherapy and in combination with other agents to treat patients with B-cell malignancies, one year survival data from the Phase 2 pracinostat study in patients with MDS, and voruciclib updates in patients with AML and B-cell malignancies."

Dr. Gold added, "We remain very encouraged by the ME-401 clinical program; the maturing data on the intermittent dosing schedule in the Phase 1b study continue to demonstrate high overall response rates and durable responses, and the intermittent schedule also continues to be well tolerated. Based on the strength of the data set from these intermittent schedule patients, the TIDAL study was amended to consolidate the remaining study enrollment into the intermittent dosing arm. We expect to complete enrollment in the TIDAL study this summer and plan a submission for accelerated approval with the FDA based on the results of this study."

Recent Highlights

- In December 2019, the Company completed a public offering of common stock resulting in net proceeds to the Company of approximately \$48.5 million.
- In December 2019, the Company amended the study protocol for TIDAL (**T**rials of **PI3K DeltA** in Non-Hodgkin's **L**ymphoma), the Phase 2 trial evaluating ME-401 in patients with relapsed or refractory follicular lymphoma ("FL"). TIDAL is intended to support an accelerated approval marketing application with the FDA.
 - The amendment consolidates the remaining enrollment into the dosing arm in which patients receive ME-401 administered on the intermittent schedule ("IS").
 - The amendment was prompted by maturing data from the Phase 1b trial of ME-401 demonstrating that the IS regimen is as active as the continuous daily dosing regimen, is associated with durable responses to date, and is also associated with improved tolerability.
 - Approximately 120 patients will be enrolled in the IS arm and completion of enrollment is expected to complete in the summer of 2020.
- In October 2019, 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 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 IS.
 - Median duration of response was not reached in patients with FL or CLL/SLL on the IS regimen. Median follow-up for FL and CLL/SLL patients was 9.2 months (range 3.4-20.7 months) and 7.4 months (range 2.6-14.7 months), respectively.

Fiscal Second-Quarter Fiscal Year 2020 Financial Results

- As of December 31, 2019, MEI had \$103.9 million in cash, cash equivalents and short-term investments, with no outstanding debt.
- For the quarter ended December 31, 2019, cash used in operations was \$10.5 million, compared to \$7.2 million for 2018.

- Research and development expenses were \$8.3 million for the quarter ended December 31, 2019, compared to \$9.1 million for 2018. The decrease was primarily related to decreased drug manufacturing costs associated with ME-401.
- General and administrative expenses were \$4.2 million for the quarter ended December 31, 2019, compared to \$3.8 million for 2018. The increase primarily relates to increased headcount and increased professional services expenses to support our activities.
- Revenue was \$1.0 million for the quarter ended December 31, 2019, compared to revenue of \$2.0 million for the quarter ended December 31, 2018. Revenue resulted from the recognition of fees allocated to research and development activities related to the Helsinn and Kyowa Kirin License Agreements. During the quarter ended December 31, 2018, revenue also included \$0.9 million from transfer of the license to Kyowa Kirin.
- Net loss was \$20.2 million, or \$0.26 per share, for the quarter ended December 31, 2019, compared to net income of \$12.0 million, or \$0.17 per share for 2018. Net loss increased primarily as a result of a non-cash expense in the current quarter and a non-cash gain in the prior quarter related to changes in the fair value of the warrant liability associated with the May 2018 financing. The Company had 105,998,677 shares of common stock outstanding as of December 31, 2019, compared with 71,131,486 shares as of December 31, 2018.
- The adjusted net loss for the quarter ended December 31, 2019, excluding a non-cash expense related to changes in the fair value of the warrants (a non-GAAP measure), was \$11.8 million, compared to an adjusted net loss of \$11.4 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)		
	December 31, 2019	June 30, 2019
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 8,638	\$ 9,590

Short-term investments	95,243	64,899
Total cash, cash equivalents and short-term investments	103,881	74,489
Common stock proceeds receivable	-	5,274
Prepaid expenses and other current assets	2,564	2,435
Total current assets	106,445	82,198
Intangible assets, net	244	261
Property and equipment, net	416	204
	\$	\$
Total assets	107,105	82,663
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
	\$	\$
Accounts payable	3,038	4,787
Accrued liabilities	3,835	4,559
Deferred revenue	3,056	4,955
Total current liabilities	9,929	14,301
Deferred revenue, long-term	3,108	2,819
Warrant liability	16,783	17,613
Total liabilities	29,820	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; 105,999 and 73,545 shares issued and outstanding at December 31, 2019 and June 30, 2019, respectively	-	-
Additional paid-in-capital	331,714	279,148
Accumulated deficit	(254,429)	(231,218)
Total stockholders' equity	77,285	47,930
	\$	\$
Total liabilities and stockholders' equity	107,105	82,663

MEI PHARMA, INC.				
CONDENSED STATEMENTS OF OPERATIONS				
(In thousands, except per share amounts)				
(Unaudited)				
	Three Months Ended December 31,		Six Months Ended December 31,	
	2019	2018	2019	2018
Revenue	\$ 1,008	\$ 2,048	\$ 2,165	\$ 2,536
Operating expenses:				
Cost of revenue	641	1,009	1,329	1,998
Research and development	8,281	9,066	17,243	15,197
General and administrative	4,195	3,821	8,325	7,222
Total operating expenses	13,117	13,896	26,897	24,417
Loss from operations	(12,109)	(11,848)	(24,732)	(21,881)
Other income (expense):				
Change in fair value of warrant liability	(8,439)	23,437	830	18,475

Interest and dividend income	318	436	692	890
Other income (expense)	13	-	(1)	(1)
Net (loss) income	<u>\$ (20,217)</u>	<u>\$ 12,025</u>	<u>\$ (23,211)</u>	<u>\$ (2,517)</u>
Net (loss) income:				
Basic	<u>\$ (20,217)</u>	<u>\$ 12,025</u>	<u>\$ (23,211)</u>	<u>\$ (2,517)</u>
Diluted	<u>\$ (20,217)</u>	<u>\$ (11,412)</u>	<u>\$ (23,211)</u>	<u>\$ (25,954)</u>
Net (loss) income per share:				
Basic	<u>\$ (0.26)</u>	<u>\$ 0.17</u>	<u>\$ (0.30)</u>	<u>\$ (0.04)</u>
Diluted	<u>\$ (0.26)</u>	<u>\$ (0.15)</u>	<u>\$ (0.30)</u>	<u>\$ (0.36)</u>
Shares used in computing net (loss) income per share:				
Basic	<u>78,577</u>	<u>71,124</u>	<u>76,103</u>	<u>71,005</u>
Diluted	<u>78,577</u>	<u>73,951</u>	<u>76,103</u>	<u>72,418</u>

MEI PHARMA, INC.				
Reconciliation of GAAP Net (Loss) Income to Adjusted Net Loss				
(In thousands)				
(Unaudited)				
	Three Months Ended December 31,		Six Months Ended December 31,	
	2019	2018	2019	2018
Net (loss) income	\$ (20,217)	\$ 12,025	\$ (23,211)	\$ (2,517)
Add: Change in fair value of warrant liability	8,439	(23,437)	(830)	(18,475)
Adjusted net loss	<u>\$ (11,778)</u>	<u>\$ (11,412)</u>	<u>\$ (24,041)</u>	<u>\$ (20,992)</u>



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