MEI Pharma Reports Third Quarter Fiscal Year 2019 Results and Operational Highlights

May 09 2019

SAN DIEGO, May 9, 2019 /PRNewswire/ -- MEI Pharma, Inc. (NASDAQ: MEIP), a late-stage pharmaceutical company focused on advancing new therapies for cancer, today reported results for its third quarter ended March 31, 2019.

"As progress continues across our pipeline of four clinical-stage oncology candidates, including two in clinical studies that may support future submissions for FDA marketing approval, we are particularly excited with the expanding data set from the ME-401 intermittent dosing schedule as it continues to mature and we look forward to presenting the data at upcoming medical meetings, including next month at ASCO," said Daniel P. Gold, Ph.D., president and chief executive officer of MEI Pharma. "Our immediate focus for MEI-401 is twofold: executing the ME-401 follicular lymphoma global Phase 2 study, data from which we intend to submit as an accelerated approval marketing application with the FDA, and the expansion of our investigation of ME-401 in combination with Rituxan® or zanubrutinib, a BTK inhibitor being investigated pursuant to our BeiGene collaboration, to earlier stages of follicular lymphoma as well as other B-cell malignancies."

Upcoming Program Milestones

- Advancement of ME-401 Program for B-Cell Malignancies
- Phase 1b study initiation of new arm to evaluate the combination of ME-401 with zanubrutinib under a clinical collaboration with BeiGene.
- Updates and presentations of clinical data from the ME-401 clinical development program, including at 2019 American Society of Clinical Oncology Annual Meeting (ASCO).

- Final Clinical Results: ME-344 for Breast Cancer
- Present complete results from the investigator-initiated study of ME-344 in combination with bevacizumab (marketed as Avastin®) in patients with breast cancer at ASCO 2019.

- Phase 1b Study Progress: Voruciclib for B-Cell Malignancies and AML
- Report initial clinical results from ongoing Phase 1 study, including single agent dose ranging data and results from the combination with venetoclax in patients with B-cell malignancies and relapsed and refractory acute myeloid leukemia around year end 2019.

- Phase 2 Results: Pracinostat for Myelodysplastic Syndrome
- Results from the Phase 2 clinical trial, including response and 1-year survival, expected to be available around year end 2019.

Financial Highlights

- As of March 31, 2019, MEI had $82.3 million in cash, cash equivalents and short-term investments, with no outstanding debt.
- For the three months ending March 31, 2019, cash expenditures for operating activities were $11.3 million, compared to $6.2 million for 2018. For the nine months ending March 31, 2019, cash expenditures for operating activities were $31.4 million, compared to $17.6 million for 2018. The increase in cash used for the nine months ended March 31, 2019 primarily relates to costs associated with our clinical development programs, including start-up costs related to the ME-401 Phase 2 study.
- Research and development expenses were $9.1 million for the quarter ended March 31, 2019, compared to $3.1 million for the same period in 2018. Research and development expenses primarily reflect increased costs associated with the development of ME-401.
- General and administrative expenses were $3.6 million for the quarter ended March 31, 2019, compared to $2.5 million for the same period in 2018. The increase primarily relates to increased salary and share-based compensation associated with increased headcount, and increased professional services expenses.
- The Company recognized revenue of $1.2 million for the quarter ended March 31, 2019, compared to $0.4 million for the same period in 2018. The increase is related to revenues from our agreement with KHK, and to

higher levels of research and development activities performed pursuant to the Helsinn license agreement.

- Net loss for the quarter ended March 31, 2019, was $17.4 million, or $0.24 per share compared to a net loss of $5.9 million, or $0.16 per share for the same period in 2018. The Company had 71,280,660 shares of common stock outstanding as of March 31, 2019, compared with 37,323,441 shares as of March 31, 2018.
- The adjusted net loss, excluding non-cash expenses related to changes in the fair value of the warrants issued in connection with the May 2018 financing (a non-GAAP measure) for the quarter ended March 31, 2019, was $12.2 million.

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)

	March 31, 2019	June 30, 2018
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 7,426	$ 13,309
Short term investments	74,864	89,434
Total cash, cash equivalents and short-term investments	82,290	102,743
Prepaid expenses and other current assets	3,153	1,586
Total current assets	85,443	104,329
Intangible assets, net	270	296
Property and equipment, net	213	32
Total assets	$ 85,926	$ 104,657
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,969	$ 3,643
Accrued liabilities	5,685	3,454
Deferred revenue	4,197	788
Total current liabilities	11,851	7,885
Deferred revenue, long-term	4,222	-
Warrant liability	31,971	46,313
Total liabilities	48,044	54,198

Stockholders' equity:		
Preferred stock, $0.01 par value; 100 shares authorized;		
none outstanding	-	-
Common stock, $0.00000002 par value; 226,000 shares		
authorized; 71,281 and 70,406 shares issued and outstanding		
at March 31, 2019 and June 30, 2018, respectively	-	-
Additional paid-in-capital	272,153	264,858
Accumulated deficit	(234,271)	(214,399)
Total stockholders' equity	37,882	50,459
Total liabilities and stockholders' equity	$ 85,926	$ 104,657

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

	Three Months Ended March 31,		Nine Months Ended March 31,	
	2019	2018	2019	2018
Revenues	$ 1,249	$ 433	$ 3,785	$ 1,074
Operating expenses:				
Cost of revenue	1,163	930	3,161	2,276
Research and development	9,071	3,071	24,268	12,579
General and administrative	3,631	2,486	10,853	7,332
Total operating expenses	13,865	6,487	38,282	22,187
Loss from operations	(12,616)	(6,054)	(34,497)	(21,113)
Other income (expense):				
Change in fair value of warrant liability	(5,201)	-	13,274	-
Interest and dividend income	462	106	1,352	299
Income tax expense	-	-	(1)	(1)
Net loss	$ (17,355)	$ (5,948)	$ (19,872)	$ (20,815)
Net loss:				
Basic	$ (17,355)	$ (5,948)	$ (19,872)	$ (20,815)
Diluted	$ (17,355)	$ (5,948)	$ (43,309)	$ (20,815)
Net loss per share:				
Basic	$ (0.24)	$ (0.16)	$ (0.28)	$ (0.56)
Diluted	$ (0.24)	$ (0.16)	$ (0.60)	$ (0.56)
Shares used in computing net loss per share:				
Basic	71,200	37,449	71,069	37,369
Diluted	71,200	37,449	72,011	37,369

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

	Three Months Ended March 31,		Nine Months Ended March 31,	
	2019	2018	2019	2018
Net loss	$ (17,355)	$ (5,948)	$ (19,872)	$ (20,815)
Add: Change in fair value of warrant liability	5,201	-	(13,274)	-
Adjusted net loss	$ (12,154)	$ (5,948)	$ (33,146)	$ (20,815)

View original content to download multimedia:http://www.prnewswire.com/news-releases/mei-pharma-reports-third-quarter-fiscal-year-2019-results-and-operational-highlights-300846857.html

SOURCE MEI Pharma, Inc.

ORIGINAL NASDAQ-SMALL:MEIP PR Newswire