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

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SAN DIEGO, Nov. 8, 2018 /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, 2018.

"Fiscal 2019 is off to a strong start both financially and strategically, with more than $90 million in cash and investments on our balance sheet at the start of the quarter, $10 million additional cash due under the recently executed Japan licensing agreement with Kyowa Hakko Kirin, a new clinical collaboration with BeiGene, and progress in preparations to start the ME-401 Phase 2 study around year-end," said Daniel P. Gold, Ph.D., president and chief executive officer of MEI Pharma. "With the planned start of the ME-401 Phase 2 study, we will have two ongoing clinical trials with the potential to support FDA marketing approval."

Dr. Gold continued: "We are also excited by our continued progress in the other programs across our pipeline, including interim data from the Phase 2 study of pracinostat in MDS, the evaluation of our CDK9 inhibitor, voruciclib, in B-cell malignancies and data from the investigator-initiated study of ME-344 in breast cancer."

Recent Program Highlights and Upcoming Milestones

Upcoming Milestones

- MEI will present data from three clinical stage drug development programs at the 2018 American Society of Hematology (ASH) Annual Meeting to be held December 1-4, 2018 in San Diego:
- Updated results from the Phase 1b study evaluating ME-401 in relapsed/refractory follicular lymphoma (FL) and other indolent B-cell malignancies.
- Data from an interim analysis of pracinostat in an ongoing Phase 2 study evaluating patients with high/very high-risk myelodysplastic syndrome (MDS).
- Results from a preclinical study demonstrating that voruciclib and venetoclax synergistically induce apoptosis in acute myeloid leukemia (AML) cells *in vitro*.

- MEI plans to initiate the Phase 2 study to support accelerated approval of ME-401 in relapsed or refractory FL around year-end of calendar 2018.
- MEI expects to report updates regarding the ongoing voruciclib Phase 1 study at medical meetings in 2019.
- MEI expects to report additional data from the investigator-sponsored Phase 1 study evaluating ME-344 at medical meetings in 2019.

Clinical Development Highlights

- In October 2018, MEI announced a clinical collaboration to evaluate the safety and efficacy of MEI's ME-401, an investigational phosphatidylinositol 3-kinase (PI3K) delta inhibitor, in combination with BeiGene's zanubrutinib, an investigational Bruton's tyrosine kinase (BTK) inhibitor, for the treatment of patients with B-cell malignancies.
- In July 2018, the Company discussed with FDA a ME-401 monotherapy accelerated approval strategy in patients with relapsed or refractory FL. Informed by the discussions with the FDA, the Company is advancing ME-401 into a Phase 2, single-agent study for the treatment of adults with relapsed or refractory FL. The Phase 2 study is intended to support accelerated approval and is planned to begin around the end of 2018. 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.

Corporate Highlights

- In November 2018, MEI announced the execution of a license development and commercialization agreement granting Kyowa Hakko Kirin exclusive rights to develop and commercialize ME-401 in Japan. Under the terms of the agreement, MEI will receive a $10.0 million upfront payment and is eligible to receive up to $87.5M in

additional development and commercialization milestones, and royalties on sales.
- 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.

Financial Highlights

- As of September 30, 2018, MEI had $90.8 million in cash, cash equivalents and short-term investments, with no outstanding debt. Additionally, a $10 million upfront payment is due under the Japan license agreement executed with Kyowa Hakko Kirin.
- Research and development expenses were $6.1 million for the quarter ended September 30, 2018, compared to $6.1 million for the same period in 2017. Research and development expenses reflect increased costs for the development of ME-401, offset by a reduction in expenses related to voruciclib, as the prior year amounts included acquisition costs for voruciclib.
- General and administrative expenses were $3.4 million for the quarter ended September 30, 2018, compared to $2.5 million for the same period in 2017. The increase primarily relates to professional services expenses, share-based compensation, and general corporate expenses.
- The Company recognized revenues of $0.5 million for the quarter ended September 30, 2018, compared to $0.3 million for the same period in 2017. The increase is related to higher levels of research and development activities performed pursuant to the Helsinn license agreement.
- Net loss for the quarter ended September 30, 2018, was $14.5 million, or $0.21 per share compared $8.8 million, or $0.24 per share for the same period in 2017. The Company had 71,115,444 shares of common stock outstanding as of September 30, 2018, compared with 36,950,177 shares as of September 30, 2017.
- 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 September 30, 2018, was $9.6 million, or $0.14 per share.
- Cash expenditures for operating activities were $12.8 million for the quarter ended September 30, 2018, compared to $6.6 million for 2017. The increase in cash used for the three months ended September 30, 2018 primarily relates to changes in working capital associated with our clinical development programs, including start-up costs related to the ME-401 Phase 2 accelerated approval study.

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 (AML) 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 chronic lymphocytic leukemia (CLL) or FL, and voruciclib, an oral, selective *cyclin-dependent kinase* (CDK) inhibitor shown to suppress myeloid leukemia cell differentiation protein (MCL1), a known mechanism of resistance to B-cell lymphoma (BCL2) inhibitors. The Company is also developing ME-344, a novel mitochondrial inhibitor currently in an investigator-initiated study in combination with bevacizumab for the treatment of 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)

	September 30, 2018	June 30, 2018
ASSETS		
Current assets:		
	$	$
Cash and cash equivalents	6,118	13,309
Short term investments	84,646	89,434
Total cash, cash equivalents and short-term investments	90,764	102,743
Prepaid expenses and other current assets	3,671	1,586
Total current assets	94,435	104,329
Intangible assets, net	287	296
Property and equipment, net	28	32
	$	$
Total assets	94,750	104,657
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
	$	$
Accounts payable	1,555	3,643
Accrued liabilities	2,489	3,454
Deferred revenue	740	788
Total current liabilities	4,784	7,885
Warrant liability	50,207	46,313
Total liabilities	54,991	54,198
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.01 par value; 100 shares authorized; none outstanding	-	-
Common stock, $0.00000002 par value; 113,000 shares authorized; 71,115 and 70,406 shares issued and outstanding at September 30, 2018 and June 30, 2018, respectively	-	-
Additional paid-in-capital	268,700	264,858
Accumulated deficit	(228,941)	(214,399)
Total stockholders' equity	39,759	50,459
	$	$
Total liabilities and stockholders' equity	94,750	104,657

MEI PHARMA, INC.

STATEMENTS OF OPERATIONS

(In thousands, except per share amounts)

	Three Months Ended September 30,	
	2018	2017
Revenues:		
Research and development revenue	$ 488	$ 283
Total revenues	488	283
Operating expenses:		
Cost of research and development revenue	989	618
Research and development	6,131	6,064
General and administrative	3,401	2,488
Total operating expenses	10,521	9,170
Loss from operations	(10,033)	(8,887)

Other income (expense):		
Change in fair value of warrant liability	(4,962)	-
Interest and dividend income	454	100
Income tax expense	(1)	(1)
Net loss	$ (14,542)	$ (8,788)
Net loss per share - basic and diluted	$ (0.21)	$ (0.24)
Shares used in computing net loss per share:		
Basic	70,885	37,245
Diluted	70,885	37,245

MEI PHARMA, INC.

Reconciliation of GAAP Net Loss to Adjusted Net Loss

(In thousands)

	Three Months Ended September 30,	
	2018	**2017**
Net loss	$ (14,542)	$ (8,788)
Add: Change in fair value of warrant liability	4,962	-
Adjusted net loss	$ (9,580)	$ (8,788)
Net loss per share - basic and diluted	$ (0.21)	$ (0.24)
Adjusted net loss per share - basic and diluted	$ (0.14)	$ (0.24)
Shares used in computing net loss per share:		
Basic and Diluted	70,885	37,245

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