MEI Pharma Reports First Quarter Fiscal Year 2018 Results

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SAN DIEGO, Nov. 8, 2017 /PRNewswire/ -- MEI Pharma, Inc. (Nasdaq: MEIP), an oncology company focused on the clinical development of novel therapies for cancer, today reported results for its first quarter ended September 30, 2017.

"In this first quarter of the new fiscal year we announced an important milestone with the dosing of the first patient in the pivotal Phase 3 study of pracinostat in combination with azacitidine in adults with newly diagnosed acute myeloid leukemia (AML) who are unfit to receive intensive induction chemotherapy. In addition, we announced that we had further strengthened our oncology clinical pipeline with the addition of the clinical-stage cyclin-dependent kinase (CDK) inhibitor voruciclib," said
Daniel P. Gold, Ph.D., president and chief executive officer of MEI Pharma. "We are well positioned for a momentous year ahead, with a healthy cash balance and a series of key milestones in each of our clinical programs."

Upcoming Milestones

Pracinostat

- Expecting results from Stage 1 of a Phase 2 dose-optimization study in myelodysplastic syndrome (MDS) in the first half of 2018.

ME-401

- Expecting to initiate combination study with Rituxan® in indolent lymphoma & diffuse large B-cell lymphoma (DLBCL) in the fourth quarter of 2017.
- Expecting results from proof-of-concept study in relapsed/refractory chronic lymphocytic leukemia (CLL) and follicular lymphoma to be presented at a scientific meeting in the first half of 2018.

Voruciclib

- Expecting to initiate Phase1/2 single-agent study in relapsed/refractory B lymphocyte malignancies and subsequently in a combination study with venetoclax (marketed as Venclexta™) in the second quarter of 2018.

ME-344

- Expecting interim results from the proof-of-concept study in human epidermal growth factor receptor 2 (HER2) negative breast cancer in combination with bevacizumab (marketed as Avastin®) in the first half of 2018.

Financial Highlights

- As of September 30, 2017, MEI Pharma had $47.0 million in cash, cash equivalents and short-term investments, with no outstanding debt. The Company believes its cash position will be sufficient to fund operations into calendar year 2019.
- Cash used in operating activities was $6.6 million for the three months ended September 30, 2017, compared to cash provided by operating activities of $8.8 million for 2016. Included in cash expenditures for the three months ended September 30, 2017 was $1.9 million cash paid for the voruciclib acquisition. Included in the cash provided by operating activities in 2016 is the $15 million upfront payment from Helsinn for pracinostat.
- Research and development expenses, including cost of research and development revenue, were $6.7 million for the three months ended September 30, 2017, compared to $2.7 million for 2016. The increase was primarily due to the acquisition of voruciclib and increased costs for ME-401, offset by a reduction in expenses related to pracinostat.
- General and administrative expenses were $2.5 million for the three months ended September 30, 2017,

compared to $2.7 million for 2016. The decrease was primarily due to professional service costs incurred in 2016 related to the Helsinn license agreement.
- Revenues were $0.3 million for the three months ended September 30, 2017, compared to $1.1 million in 2016. The decrease is related to activities performed pursuant to the Helsinn license agreement.
- Net loss was $8.8 million, or $0.24 per share, for the three months ended September 30, 2017, compared to a net loss of $4.3 million, or $0.12 per share for the three months ended September 30, 2016.

About MEI Pharma

MEI Pharma, Inc. (Nasdaq: MEIP) is a San Diego-based oncology company focused on the clinical development of novel 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 Ib study in patients with relapsed/refractory CLL or follicular lymphoma, 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-sponsored 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.

CONDENSED BALANCE SHEETS

(In thousands, except per share amounts)

	September 30, 2017	June 30, 2017
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 6,958	$ 8,458
Short term investments	40,065	45,107
Total cash, cash equivalents and short-term investments	47,023	53,565
Prepaid expenses and other current assets	641	1,758
Total current assets	47,664	55,323
Intangible assets, net	322	331
Property and equipment, net	45	50
Total assets	$ 48,031	$ 55,704
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		

	$	
Accounts payable	751	$ 585
Accrued liabilities	2,767	3,285
Deferred revenues	947	996
Total current liabilities	4,465	4,866
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; 36,950 and 36,772 shares issued and outstanding at September 30, 2017 and June 30, 2017, respectively	-	-
Additional paid-in-capital	226,685	225,169
Accumulated deficit	(183,119)	(174,331)
Total stockholders' equity	43,566	50,838
	$	
Total liabilities and stockholders' equity	48,031	$ 55,704

MEI PHARMA, INC.

CONDENSED STATEMENTS OF OPERATIONS

(In thousands, except per share amounts)

(Unaudited)

	Three Months Ended September 30,	
	2017	**2016**
Revenues:		
Research and development revenue	$ 283	$ 1,096
Total revenues	283	1,096
Operating expenses:		
Cost of research and development revenue	618	1,094
Research and development	6,064	1,646
General and administrative	2,488	2,680
Total operating expenses	9,170	5,420
Loss from operations	(8,887)	(4,324)
Other income (expense):		
Interest and dividend income	100	55
Income tax expense	(1)	(1)
Net loss	$ (8,788)	$ (4,270)
Net loss per share, basic	$ (0.24)	$ (0.12)
Net loss per share, diluted	$ (0.24)	$ (0.12)
Shares used in computing net loss per share:		
Basic	37,245	35,747
Diluted	37,245	35,747

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