MEI Pharma Reports Fiscal Year 2017 Results

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SAN DIEGO, Sept. 5, 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 fiscal year ended June 30, 2017.

"We begin our new fiscal year with strong momentum, a maturing pipeline of clinical-stage oncology drug candidates and a healthy cash balance," said
Daniel P. Gold, Ph.D., President and Chief Executive Officer of MEI Pharma. "We have made significant strides in the clinic over the past several months, underscored by the dosing of the first patients in the pivotal Phase 3 study of pracinostat in AML, as well as in the Phase 2 dose-optimization study of pracinostat in MDS. Meanwhile, we are very excited by the response and safety data that are emerging from the open-label study of our PI3K delta inhibitor ME-401. This program continues to exceed our high expectations and we look forward to the opportunity to present more data at an upcoming scientific meeting."

Financial Highlights

- As of June 30, 2017, MEI Pharma had $53.6 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 expenditures were $16.5 million for the year ended June 30, 2017, compared to $17.9 million for 2016. Cash expenditures were $3.1 million for the fourth quarter ended June 30, 2017, compared to $3.5 million for the same period in 2016.
- Research and development expenses were $7.2 million for the year ended June 30, 2017, compared to $13.4 million for 2016. The decrease was primarily due to a reduction in expenses related to pracinostat pursuant to the Helsinn License Agreement.
- General and administrative expenses were $8.6 million for the year ended June 30, 2017, compared to $7.6 million for 2016. The increase was primarily due to professional service costs.
- Revenues were $23.2 million for the year ended June 30, 2017, related to the Helsinn License Agreement. During the year ended June 30, 2017, the cost of research and development revenue was $5.0 million. Cost of research and development revenue is comprised primarily of reimbursable third-party pass-through costs.
- Net income was $2.7 million, or $0.07 per share, for the fiscal year ended June 30, 2017, compared to a net loss of $20.9 million, or $0.61 per share for 2016.

Recent Clinical Milestones

- **First patient dosed in pivotal Phase 3 study of pracinostat in AML.** In July 2017, the first patient was dosed in a pivotal Phase 3 study of the investigational drug candidate pracinostat in combination with azacitidine in adults with newly diagnosed acute myeloid leukemia (AML) who are unfit to receive intensive induction chemotherapy. The randomized, double-blind, placebo-controlled study will enroll approximately 500 eligible patients worldwide. Helsinn Healthcare, SA, a Swiss pharmaceutical company, has an exclusive license to develop, manufacture and commercialize pracinostat (Helsinn License Agreement), and is responsible for the conduct and funding of this Phase 3 study.
- **First patient dosed in Phase 2 dose-optimization study of pracinostat in MDS**. In June 2017, the first patient was dosed in a Phase 2 dose-optimization study of pracinostat in combination with azacitidine in patients with high and very high risk myelodysplastic syndrome (MDS) who are previously untreated with hypomethylating agents. The two-stage study will be conducted at approximately 25 sites and is expected to enroll up to 120 patients. Data from the first stage is expected in the first quarter of 2018. MEI Pharma is responsible for the conduct of this Phase 2 study, the cost of which will be shared by Helsinn. Helsinn will be responsible for funding any further studies.

- **Genetic mutation data from Phase 2 study of pracinostat in AML.** In June 2017, results from a mutational analysis of patients in the Phase 2 study of pracinostat and azacitidine in AML were presented at the American Society of Clinical Oncology (ASCO) and European Hematology Association (EHA) annual meetings. The findings showed: 1) a statistically significant correlation between genetic mutations in the DNA methylation pathway and clinical response; 2) the mutation profile in the Phase 2 study was representative not only of the larger population of older AML patients, but common in MDS patients as well; and 3) that median overall survival was roughly equivalent in patients with mutations typically associated with *de novo* AML (18.1 months) and secondary AML (17.7 months). In addition, longitudinal sequencing analyses showed that continued treatment with pracinostat and azacitidine increases the rate of minimal residual disease (MRD) clearance.

- **Emerging data from Phase 1b study of ME-401 in CLL and follicular lymphoma.** In May 2017, an independent safety review committee completed its review of the first cohort of six evaluable patients in an ongoing Phase 1b dose-escalation study of the Company's oral PI3K delta inhibitor ME-401 in relapsed/refractory chronic lymphocytic leukemia (CLL) and follicular lymphoma. The safety review committee found no dose-limiting toxicities, declared a minimum biologically effective dose (response rate > 50%) at the starting dose of 60 mg and recommended escalation to a 120 mg dose cohort. To date, the study has enrolled a total of 18 patients who are evaluable for safety, four of whom are still too early for a response assessment. The 18 patients have been on study for a median of approximately three months (range, 1-10 months) and no patients have discontinued due to adverse events or disease progression.

Conference Call and Webcast

MEI Pharma's management team will host a conference call with simultaneous webcast today, September 5, 2017, at 9:00 a.m. Eastern time to discuss the Company's fiscal year 2017 results. To access the live call, please dial 888-357-5399 (toll-free) or 440-996-5704 (international), conference ID 71495273. The conference call will also be webcast live and can be accessed at www.meipharma.com. A replay of the webcast will be available approximately one hour after the conclusion of the call.

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 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 MDS. MEI Pharma's clinical development pipeline also includes ME-401, a highly differentiated oral PI3K delta inhibitor currently in a dose-escalation study in patients with relapsed/refractory CLL or follicular lymphoma, and ME-344, a novel mitochondrial inhibitor currently in an investigator-sponsored study in combination with bevacizumab in HER2-negative breast cancer. Pracinostat, ME-401 and ME-344 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 ability to obtain sufficient funds to progress our clinical trials; risks relating to our collaboration agreement with Helsinn; changes in general economic conditions; costs and delays in the development and/or FDA approval, or the failure to obtain such approval, of our product candidates; our failure to satisfy foreign regulatory approval requirements; uncertainties or differences in interpretation in clinical study 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; our failure to successfully commercialize our product candidates; the effect of unfavorable pricing regulations, third-party reimbursement practices and health care regulations on our products; competitive factors; our reliance on third party clinical research organizations, suppliers and manufacturers; 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; 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; data security 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 share and per share data)

	June 30,	
	2017	**2016**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 8,458	$ 10,837
Short-term investments	45,107	35,081
Total cash, cash equivalents and short-term investments	53,565	45,918
Prepaid expenses and other current assets	1,758	831
Total current assets	55,323	46,749
Intangible assets, net	331	366
Property and equipment, net	50	49
Total assets	$ 55,704	$ 47,164
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 585	$ 1,079
Accrued liabilities	3,285	4,433
Deferred revenues	996	-
Total current liabilities	4,866	5,512
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock, $0.01 par value; 100 shares authorized; none outstanding	-	-
Common stock, $0.00000002 par value; 113,000 shares authorized; 36,772 and 34,156 shares issued and outstanding at June 30, 2017 and 2016, respectively.	-	-
Additional paid-in-capital	225,169	218,653
Accumulated deficit	(174,331)	(177,001)
Total stockholders' equity	50,838	41,652
Total liabilities and stockholders' equity	$ 55,704	$ 47,164

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

	Years Ended June 30,		
	2017	**2016**	**2015**
Revenues:			
License revenue	$ 20,880	$ -	$ -
Research and development revenue	2,369	-	-
	23,249	-	-
Operating expenses:			
Cost of research and development revenue	5,000	-	-
Research and development	7,237	13,403	23,823
General and administrative	8,628	7,601	8,948
Total operating expenses	20,865	21,004	32,771
Income (loss) from operations	2,384	(21,004)	(32,771)

Other income (expense):			
Interest and dividend income	287	143	78
Income tax expense	(1)	(1)	(1)
Net income (loss)	$ 2,670	$ (20,862)	$ (32,694)
Net income (loss) per share, basic	$ 0.07	$ (0.61)	$ (1.16)
Net income (loss) per share, diluted	$ 0.07	$ (0.61)	$ (1.16)
Shares used in computing net income (loss) per share:			
Basic	36,813	34,400	28,204
Diluted	36,938	34,400	28,204

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