MEI Pharma Reports Third Quarter Fiscal Year 2017 Results

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SAN DIEGO, May 4, 2017 /PRNewswire/ --

Company Ends Quarter with $56.8 Million in Cash

Gene Mutation and Clinical Response Data from Phase 2 Study of Pracinostat Plus Azacitidine in AML at ASCO in June

First Patient in Phase 2 Dose-Optimization Study of Pracinostat in MDS Expected in June

Initial Safety and Efficacy Data from ME-401 Phase 1b Study in June

MEI Pharma, Inc. (Nasdaq: MEIP), an oncology company focused on the clinical development of novel therapies for cancer, today reported financial results for its third quarter ended March 31, 2017. The Company also outlined a number of key upcoming milestones.

"I am proud of the progress we have made over the past quarter, with a steadfast focus on clinical study planning and execution, while maintaining a healthy cash position," said
Daniel P. Gold, Ph.D., President and Chief Executive Officer of MEI Pharma. "We have been working diligently with our partners at Helsinn on the design and implementation of a large, international Phase 3 study of Pracinostat in acute myeloid leukemia (AML) and a Phase 2 dose-optimization study in myelodysplastic syndrome (MDS), and expect to enroll the first patients next month. We also look forward to presenting new genetic analysis data from our Phase 2 study in AML at ASCO, which increases our understanding of the study's patient demographics.

"Finally,"
Dr. Gold continued, "we look forward to initial safety and efficacy data from our clinical study of ME-401 in relapsed/refractory chronic lymphocytic leukemia (CLL) and follicular lymphoma next month. ME-401 is a differentiated oral PI3K delta inhibitor that is predicted to have a wide therapeutic window which may lead to safer treatment options for patients with lymphomas. We are very encouraged by the early results from our ongoing study and look forward to presenting them in more detail. While much of our recent progress has occurred behind the scenes, the stage is now set for what should be an exciting remainder of the year."

Upcoming Milestones

- **Initiation of global Phase 3 study of Pracinostat in AML.** In August 2016, the Company entered into an exclusive license, development and commercialization agreement with Helsinn Healthcare SA, a Swiss pharmaceutical company, for the investigational drug candidate Pracinostat in AML and other potential indications (Helsinn License Agreement). Under the terms of the agreement, Helsinn is granted a worldwide exclusive license to develop, manufacture and commercialize Pracinostat, and is primarily responsible for funding its global development and commercialization. Site recruitment for the Phase 3 study of Pracinostat and azacitidine in newly diagnosed AML patients who are ≥75 years of age or unfit for intensive induction chemotherapy is ongoing.
- **First patient in Phase 2 dose-optimization study of Pracinostat in MDS**. As part of the Helsinn License Agreement, the Company will work with Helsinn to determine an optimal dosing regimen of Pracinostat in combination with azacitidine for the treatment of high and very high risk MDS. The cost of this study will be shared by Helsinn and the Company, and enrollment is anticipated to commence in June 2017.
- **Gene mutation data from Phase 2 study of Pracinostat in AML at ASCO.** Data from a post hoc analysis of a Phase 2 clinical study of Pracinostat and azacitidine in elderly patients with AML who were not eligible for induction chemotherapy were accepted for presentation at the American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago on Monday, June 5, 2017. The abstract, entitled "Correlation between Mutation Clearance and Clinical Response in Elderly Patients with Acute Myeloid Leukemia (AML) Treated with Azacitidine and Pracinostat," will be released on abstracts.asco.org at 5:00 pm EDT on May 17, 2017.

- **Interim data from Phase 1b study of ME-401 in CLL and follicular lymphoma.** Interim safety and efficacy data from the first cohort in a Phase 1b clinical study of ME-401 in patients with relapsed/refractory CLL or follicular lymphoma are expected in June. ME-401 is a highly differentiated oral PI3K delta inhibitor that has a distinct chemical structure from other drugs in its class, including idelalisib (marketed as Zydelig®). Results from a first-in-human study of ME-401 showed levels of drug exposure that support the potential for an improved therapeutic window compared to idelalisib, with a half-life that supports once-daily dosing.

Financial Highlights

- In March 2017, the Company received a $5 million payment from Helsinn in accordance with the Helsinn License Agreement. The Company is also eligible to receive up to $444 million in potential regulatory and sales-based milestones, along with royalty payments on the net sales of Pracinostat.
- As of March 31, 2017, the Company had $56.8 million in cash, cash equivalents and short-term investments, compared to $55.2 million as of December 31, 2016, with no outstanding debt. The Company believes its cash position will be sufficient to fund operations through at least the end of calendar year 2018.
- Research and development expenses were $1.9 million for the three months ended March 31, 2017, and $5.2 million for the nine months ended March 31, 2017. This compares with research and development expenses of $3.4 million for the three months ended March 31, 2016, and $9.4 million for the nine months ended March 31, 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 $2.2 million for the three months ended March 31, 2017, and $6.8 million for the nine months ended March 31, 2017, compared to $2.0 million and $5.8 million, respectively, for the same periods in 2016. The increase was primarily due to professional service costs.
- Revenues were $4.5 million during the three months ended March 31, 2017, and $22.8 million during the nine months ended March 31, 2017, related to the Helsinn License Agreement. During the three and nine months ended March 31, 2017, the cost of research and development revenue was $1.1 million and $4.0 million, respectively. Cost of research and development revenue is comprised primarily of reimbursable third-party pass-through costs.
- Net loss was $0.6 million, or $0.02 per share, for the three months ended March 31, 2017, compared to $5.4 million, or $0.16 per share, for the quarter ended March 31, 2016. Net income was $7.0 million, or $0.19 per share, for the nine months ended March 31, 2017, compared to a net loss of $15.1 million, or $0.44 per share for the same period in 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 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. MEI Pharma's clinical development pipeline also includes ME-401, a potent and highly selective oral PI3K delta inhibitor currently in a Phase Ib study in patients with relapsed/refractory CLL or follicular lymphoma. 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 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 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 share and per share data)

	March 31, 2017	June 30, 2016
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 11,644	$ 10,837
Short term investments	45,116	35,081
Total cash, cash equivalents and short-term investments	56,760	45,918
Prepaid expenses and other current assets	2,756	831
Total current assets	59,516	46,749
Intangible assets, net	340	366
Property and equipment, net	35	49
Total assets	$ 59,891	$ 47,164
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 242	$ 1,079
Accrued liabilities	3,711	4,433
Deferred revenues	1,036	-
Total current liabilities	4,989	5,512
Commitments and contingencies (Note 4)		
Stockholders' equity:		
Preferred stock, $0.01 par value; 100,000 shares authorized; none outstanding	-	-
Common stock, $0.00000002 par value; 113,000,000 shares authorized; 36,772,428 and 34,155,997 shares issued and outstanding at March 31, 2017 and June 30, 2016, respectively	-	-
Additional paid-in-capital	224,890	218,653
Accumulated deficit	(169,988)	(177,001)
Total stockholders' equity	54,902	41,652
Total liabilities and stockholders' equity	$ 59,891	$ 47,164

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

	Three Months Ended March 31,		Nine Months Ended March 31,	
	2017	2016	2017	2016
Revenues:				
License revenue	$ 3,779	$ -	$ 20,880	$ -
Research and development revenue	726	-	1,920	-
Total revenues	4,505	-	22,800	-
Operating expenses:				
Cost of research and development revenue	(1,147)	-	(4,012)	-
Research and development	(1,876)	(3,420)	(5,164)	(9,418)
General and administrative	(2,152)	(1,990)	(6,802)	(5,765)
Total operating expenses	(5,175)	(5,410)	(15,978)	(15,183)
Income (loss) from operations	(670)	(5,410)	6,822	(15,183)
Other income (expense):				
Interest and dividend income	68	39	192	92
Income tax expense	-	-	(1)	(1)
Net income (loss)	$ (602)	$ (5,371)	$ 7,013	$ (15,092)
Earnings (loss) per share, basic	$ (0.02)	$ (0.16)	$ 0.19	$ (0.44)

Earnings (loss) per share, diluted	$ (0.02)	$ (0.16)	$ 0.19	$ (0.44)
Shares used in computing earnings (loss) per share:				
Basic	37,172,428	34,422,663	36,693,940	34,393,087
Diluted	37,172,428	34,422,663	36,760,754	34,393,087

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