MEI Pharma Reports First Quarter Fiscal Year 2017 Results

Nov 09 2016

SAN DIEGO, Nov. 9, 2016 /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, 2016. The Company also highlighted recent progress with its pipeline of drug candidates and previewed upcoming data presentations.

"The past quarter was one of unprecedented achievement for the company, highlighted by the receipt of Breakthrough Therapy Designation and a global strategic partnership for Pracinostat," said Daniel P. Gold, Ph.D., President and Chief Executive Officer of MEI Pharma. "Now we approach the end of the calendar year in a position of significant strength, armed with a fully funded Phase III program, a pipeline of drug candidates advancing in the clinic and a healthy cash position that affords us the ability to not only execute our clinical development plan, but also to enhance our pipeline with the right opportunity."

Pipeline Update

- **Strategic partnership for development and commercialization of Pracinostat.** In August 2016, the Company entered into an exclusive licensing, development and commercialization agreement with Helsinn Healthcare, SA, a Swiss pharmaceutical corporation, for Pracinostat, an investigational agent currently being evaluated in clinical studies for acute myeloid leukemia (AML) and other potential indications. Under the terms of the agreement, Helsinn is granted a worldwide exclusive license to Pracinostat and is responsible for funding its global development and commercialization. As compensation, MEI Pharma will receive near-term payments of $20 million, including a $15 million upfront payment and a $5 million payment upon the earlier of (i) dosing of the first patient in the upcoming Phase III study of Pracinostat in newly diagnosed AML patients unfit to receive induction therapy, or (ii) March 1, 2017. In addition, MEI Pharma will be eligible to receive up to $444 million in potential regulatory and sales-based milestones, along with royalty payments on the net sales of Pracinostat. In a related transaction, Helsinn made a $5 million equity investment in MEI Pharma.
- **Dose-optimization study of Pracinostat plus azacitidine in high-risk MDS**. As part of the license, development and commercialization 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 myelodysplastic syndrome (MDS). Based on its clinical experience with the combination, the Company believes that an optimized dose may improve tolerability in this population, which in turn could result in increased efficacy of the combination vs. azacitidine alone. MEI Pharma will be responsible for the conduct of the study and Helsinn will share the cost. The study is anticipated to commence in the first half of calendar year 2017.
- **Breakthrough Therapy Designation from U.S. Food and Drug Administration (FDA).** In August 2016, the Company announced that the FDA granted Breakthrough Therapy Designation for Pracinostat in combination with azacitidine for the treatment of patients with newly diagnosed AML who are ≥75 years of age or unfit for intensive chemotherapy. According to the FDA, Breakthrough Therapy Designation is intended to expedite the development and review of drugs for serious or life-threatening conditions. The criteria for Breakthrough Therapy Designation require preliminary clinical evidence that demonstrates the drug may have substantial improvement on at least one clinically significant endpoint over available therapy. In addition, the Company announced that agreement has been reached with the FDA on the proposed Phase III AML study design.
- **Phase Ib study of PI3K delta inhibitor ME-401 open for enrollment.** In September 2016, the Company's Phase 1b clinical study of ME-401 in patients with relapsed/refractory chronic lymphocytic leukemia/small lymphocytic lymphoma or follicular lymphoma was opened for enrollment. ME-401 is a potent and highly selective oral PI3K delta inhibitor with the potential for a wide therapeutic window that may lead to safer treatment options, including combination treatment options, for patients with lymphomas. This study will allow the Company to study the safety and tolerability of ME-401 over time as it seeks to identify an optimal dose for future Phase 2 studies. Interim data from the study is expected by the middle of calendar year 2017.
- **Investigator-sponsored study of mitochondrial inhibitor ME-344 open for enrollment.** In August 2016, an investigator-sponsored study of ME-344 in combination with the vascular endothelial growth factor

(VEGF) inhibitor bevacizumab (marketed as Avastin®) in patients with HER2-negative breast cancer was opened for enrollment. The study is being conducted in collaboration with the Spanish National Cancer Research Centre in Madrid. Pre-clinical data from the collaboration showed substantially enhanced anti-tumor activity of ME-344 in cancer cells when combined with VEGF inhibitors due to a disruption of both mitochondrial and glycolytic metabolism. Data from the investigator-sponsored study are expected by the end of calendar year 2017.

Upcoming Data Presentations

- **Long-term survival and response data from Phase II study of Pracinostat in AML.** Data from a multi-center Phase II clinical study of Pracinostat and azacitidine in older patients with AML who are not eligible for induction chemotherapy have been selected for oral presentation at the upcoming ASH Annual Meeting in San Diego on December 3, 2016. The presentation by principal investigator Dr. Guillermo Garcia-Manero, MD Anderson Cancer Center, is expected to highlight the durable responses and long-term survival benefit achieved in this investigational study, which appeared to compare favorably to azacitidine alone in a recent international Phase III study (AZA-AML-001). Pracinostat is an investigational agent and is not approved for use in the U.S.
- **Exposure data from clinical study of ME-401 supporting wide therapeutic window.** Additional data from a first-in-human clinical study of ME-401 in healthy volunteers will be presented at the American Association of Pharmaceutical Scientists (AAPS) Annual Meeting in Denver on November 15, 2016. The presentation will highlight formulation selection and development for ME-401, including exposure margins based on clinical data and preclinical toxicity supporting the potential for an improved therapeutic window from repeated dosing compared to the approved PI3K delta inhibitor idelalisib (marketed as Zydelig®).

Financial Highlights

- As of September 30, 2016, MEI Pharma had $58.9 million in cash, cash equivalents and short-term investments, which the Company believes will be sufficient to fund operations through at least calendar year 2017.
- Net loss was $4.3 million, or $0.12 per share, for the three months ended September 30, 2016, compared to $5.7 million, or $0.17 per share, for the previous quarter, and $4.6 million, or $0.13 per share for the same period in 2015.
- Research and development expenses were $1.6 million for the three months ended September 30, 2016, compared to $2.8 million for the same period in 2015. The decrease was primarily due to a reduction in clinical trial expenses for Pracinostat and ME-344.
- General and administrative expenses were $2.7 million for the three months ended September 30, 2016, compared to $1.8 million for the same period in 2015. The increase was primarily due to professional service costs associated with the Helsinn license agreement.

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 is being developed in combination with azacitidine for the treatment of patients with newly diagnosed AML who are ≥75 years of age or unfit for intensive chemotherapy and high-risk MDS. The Company's clinical development pipeline also includes ME-401, an oral PI3K delta inhibitor currently in a Phase Ib study in patients with recurrent chronic lymphocytic leukemia or follicular non-Hodgkin's lymphoma, and ME-344, a mitochondrial inhibitor currently in an investigator-sponsored study in combination with bevacizumab for the treatment of HER2-negative breast cancer. 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)

	September 30, 2016	June 30, 2016
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 13,789	$ 10,837
Short term investments	45,112	35,081
Total cash, cash equivalents and short-term investments	58,901	45,918
Prepaid expenses and other current assets	1,741	831
Total current assets	60,642	46,749
Intangible assets, net	357	366
Property and equipment, net	46	49
Total assets	$ 61,045	$ 47,164
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 749	$ 1,079
Accrued liabilities	2,428	4,433
Deferred revenues, current portion	14,043	-
Total current liabilities	17,220	5,512
Deferred revenues, less current portion	1,494	-
Total liabilities	18,714	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 September 30, 2016 and June 30, 2016, respectively	-	-
Additional paid-in-capital	223,602	218,653
Accumulated deficit	(181,271)	(177,001)
Total stockholders' equity	42,331	41,652
Total liabilities and stockholders' equity	$ 61,045	$ 47,164

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

	Three Months Ended September 30,	
	2016	2015
Revenues:		
Research and development revenue	$ 1,096	$ -
Total revenues	1,096	-
Operating expenses:		
Cost of research and development revenue	(1,094)	-
Research and development	(1,646)	(2,816)
General and administrative	(2,680)	(1,830)
Total operating expenses	(5,420)	(4,646)

Loss from operations	(4,324)	(4,646)
Other income (expense):		
Interest and dividend income	55	27
Income tax expense	(1)	(1)
Net loss	$ (4,270)	$ (4,620)
Net loss per share, basic and diluted	$ (0.12)	$ (0.13)
Weighted average shares outstanding - basic and diluted	35,747,367	34,334,257

Logo - http://photos.prnewswire.com/prnh/20140805/133834

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/mei-pharma-reports-first-quarter-fiscal-year-2017-results-300359512.html

SOURCE MEI Pharma, Inc.

ORIGINAL NASDAQ-SMALL:MEIP PR Newswire