

MEI Pharma Reports Third Quarter Fiscal Year 2018 Results

May 09 2018

SAN DIEGO, May 9, 2018 /PRNewswire/ -- MEI Pharma, Inc. (NASDAQ: MEIP), a pharmaceutical company focused on leveraging its extensive development and oncology expertise to identify and advance new therapies for cancer, today reported results for its third quarter ended March 31, 2018.

"Over the past quarter we continued making key advances in each of our four clinical programs, as we look forward to important data readouts before mid-year in three of the four programs," said Daniel P. Gold, Ph.D., president and chief executive officer of MEI Pharma. "In particular, we will be presenting data at ASCO 2018 from our study evaluating ME-401, an orally administered PI3K delta inhibitor demonstrating potential class leading efficacy in follicular lymphoma. Based on the data in this program, we anticipate progressing into a single-agent registration study later in 2018. In addition, we will present data at ASCO 2018 from an investigator-initiated study of ME-344 in HER2-negative breast cancer."

Dr. Gold added: "We also look forward to initiating our Phase 1 study of voruciclib, a selective and orally administered CDK inhibitor differentiated by potent inhibition of CDK9, in relapsed/refractory B lymphocyte malignancies. Finally, we are looking forward to an interim analysis this quarter from the Phase 2 pracinostat study in MDS and the potential to continue advancing the study together with our partner Helsinn."

Recent Program Highlights and Upcoming Milestones

ME-401

- An abstract with results from a Phase 1b study in relapsed/refractory CLL and FL has been accepted and will be presented at the 2018 American Society of Clinical Oncology Annual Meeting to be held June 1-5 in Chicago, IL.

Pracinostat (partnered with Helsinn Healthcare, SA)

- In January 2018, the European Medicines Agency granted Orphan Drug Designation to pracinostat, currently in a Phase 3 study in combination with azacitidine for the treatment of acute myeloid leukemia (AML) in adult patients unfit for induction chemotherapy.
- The Company anticipates results from stage 1 of a Phase 2 dose-optimization study in myelodysplastic syndrome (MDS) in the first half of 2018.

Voruciclib

- In January 2018, the U.S. Food and Drug Administration cleared the Company's Investigational New Drug Application (IND) for voruciclib.
- The Company expects to initiate a Phase 1 single-agent study in relapsed/refractory B cell malignancies in the first half of 2018.

ME-344

- In February 2018, the Company announced that a planned interim review of data supports the continuation of its multicenter, investigator-initiated, study evaluating ME-344 in patients with HER2-negative breast cancer. The interim study data show that ME-344 was generally well-tolerated and, consistent with previous preclinical data, demonstrate the potential to reverse resistance to antiangiogenic therapy.
- An abstract featuring interim results from the Phase 1 study in HER2 negative breast cancer in combination with bevacizumab (marketed as Avastin®) has been accepted and will be presented at the 2018 American Society of Clinical Oncology Annual Meeting to be held June 1-5 in Chicago, IL.

Corporate

- In February 2018, the Company announced the appointment of industry veteran Frederick W. Driscoll to its board of directors, who will also serve on the audit committee.

Financial Highlights

- As of March 31, 2018, the Company had \$36.2 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 through the first half of calendar year 2019.
- Research and development expenses, including cost of research and development revenue, were \$4.0 million for the three months ended March 31, 2018, compared to \$3.0 million for the three months ended March 31, 2017. The increase was primarily due to increased drug manufacturing expenses for ME-401, expenses related to voruciclib, and increased costs related to salaries, share-based compensation, and other internal costs.
- General and administrative expenses were \$2.5 million for the three months ended March 31, 2018, compared to \$2.2 million for the three months ended March 31, 2017. The increase was primarily due to professional services expenses and share-based compensation.
- Revenues were \$0.4 million for the three months ended March 31, 2018, compared to \$4.5 million for the three months ended March 31, 2017. The decrease was related to lower levels of research and development activities associated with the Helsinn license agreement and \$3.8 of upfront license fee revenue recognized for the three months ended March 31, 2017.
- Net loss was \$5.9 million, or \$0.16 per share, for the three months ended March 31, 2018, compared to net loss of \$0.6 million, or \$0.02 per share for the three months ended March 31, 2017.

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 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-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.

CONDENSED BALANCE SHEETS

(In thousands, except per share amounts)

March 31, June 30,	
2018	2017

	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 6,198	\$ 8,458
Short term investments	30,004	45,107
Total cash, cash equivalents and short-term investments	36,202	53,565
Prepaid expenses and other current assets	854	1,758
Total current assets	37,056	55,323
Intangible assets, net	305	331
Property and equipment, net	36	50
Total assets	\$ 37,397	\$ 55,704
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,259	\$ 585
Accrued liabilities	2,382	3,285
Deferred revenues	843	996
Total current liabilities	4,484	4,866
Commitments and contingencies (Note 5)		
Stockholders' equity:		
Preferred stock, \$0.01 par value; 100 shares authorized; none outstanding	-	-
Common stock, \$0.00000002 par value; 113,000 shares authorized; 37,323 and 36,772 shares issued and outstanding at March 31, 2018 and June 30, 2017, respectively	-	-
Additional paid-in-capital	228,059	225,169
Accumulated deficit	(195,146)	(174,331)
Total stockholders' equity	32,913	50,838
Total liabilities and stockholders' equity	\$ 37,397	\$ 55,704

MEI PHARMA, INC.				
CONDENSED STATEMENTS OF OPERATIONS				
(In thousands, except per share amounts)				
(Unaudited)				
	Three Months Ended		Nine Months Ended	
	March 31,		March 31,	
	2018	2017	2018	2017
Revenues:				
License revenue	\$ -	\$ 3,779	\$ -	\$ 20,880
Research and development revenue	433	726	1,074	1,920
Total revenues	433	4,505	1,074	22,800
Operating expenses:				
Cost of research and development revenue	930	1,147	2,276	4,012
Research and development	3,071	1,876	12,579	5,164
General and administrative	2,486	2,152	7,332	6,802
Total operating expenses	6,487	5,175	22,187	15,978
(Loss) income from operations	(6,054)	(670)	(21,113)	6,822
Other income (expense):				
Interest and dividend income	106	68	299	192
Income tax expense	-	-	(1)	(1)
Net (loss) income	\$ (5,948)	\$ (602)	\$ (20,815)	\$ 7,013
Net (loss) income per share, basic	\$ (0.16)	\$ (0.02)	\$ (0.56)	\$ 0.19
Net (loss) income per share, diluted	\$ (0.16)	\$ (0.02)	\$ (0.56)	\$ 0.19
Shares used in computing net (loss) income per share:				
Basic	37,449	37,172	37,369	36,694
Diluted	37,449	37,172	37,369	36,761



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