MEI Pharma Reports Fiscal Year 2019 Results and Operational Highlights

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SAN DIEGO, Aug. 28, 2019 /PRNewswire/ -- MEI Pharma, Inc. (NASDAQ: MEIP), a late-stage pharmaceutical company focused on advancing new therapies for cancer, today reported results for its fiscal year ended June 30, 2019.

"It was a very productive year, with each of the four clinical-stage programs within our oncology portfolio advancing in development, led by ME-401 and the initiation of our global Phase 2 study which may support an accelerated approval of a marketing application with FDA, the BeiGene clinical collaboration to combine ME-401 with zanubrutinib, BeiGene's BTK inhibitor, and a regional licensing deal with Kyowa Kirin for the development and commercialization of ME-401 in Japan," said Daniel P. Gold, Ph.D., president and chief executive officer of MEI Pharma. "We were also pleased to report the progress made from all our programs as featured at key medical meetings including ICML 2019, ASCO 2019 and ASH 2018."

Dr. Gold continued: "Looking to the year ahead, we are in a great position to continue strengthening our foundation and creating value through data generation across our development pipeline, evaluating drug combination opportunities, unlocking innovations like the intermittent schedule for ME-401, and exploring additional collaboration and licensing opportunities to most effectively leverage the potential of our drug candidates."

Fiscal Year 2019 and Recent Highlights

ME-401 for B-Cell Malignancies

- In October 2018, MEI (the Company) entered into a clinical collaboration to evaluate in patients with B-cell malignancies the safety and efficacy of ME-401 in combination with BeiGene's zanubrutinib, an investigational Bruton's tyrosine kinase ("BTK") inhibitor
- In October 2018, MEI entered into a license, development and commercialization agreement granting Kyowa Kirin Company exclusive rights to develop and commercialize ME-401 in Japan. MEI received a $10.0 million upfront payment and is eligible to receive up to $87.5 million in additional development and commercialization milestones, and royalties on sales.
- In December 2018, the Company initiated the ongoing Phase 2 clinical trial evaluating ME-401 in patients with relapsed or refractory follicular lymphoma which may support an accelerated approval of a marketing application with FDA.
- In December 2018, at the American Society of Hematology (ASH) Annual Meeting, the Company presented interim results from the ongoing Phase 1b study demonstrating that ME-401 continues to be associated with overall high objective response rates as a single agent and in combination with rituximab. Lower rates of Grade 3 adverse events of special interest were observed in patients on the intermittent dosing schedule.
- In June 2019, at the American Society of Clinical Oncology (ASCO) Annual Meeting and the International Conference on Malignant Lymphoma (ICML), the Company presented updated data from the ongoing ME-401 Phase 1b study demonstrating an 80% overall response rate in patients with relapsed or refractory follicular lymphoma and an 83% overall response rate in patients with relapsed or refractory follicular lymphoma, chronic lymphocytic leukemia or small lymphocytic lymphoma. The intermittent dosing schedule demonstrated comparable overall response rates with a lower rate of delayed Grade 3 adverse events of special interest (≤10%) compared to the continuous dosing schedule.

Voruciclib for B-Cell Malignancies and Acute Myeloid Leukemia ("AML")

- In December 2018 at ASH, the Company presented preclinical data demonstrating that voruciclib synergistically induced apoptosis at clinically relevant concentrations when combined with venetoclax (marketed as Venclexta®) in human derived AML cells lines and patient samples.

ME-344 for Solid Tumors

- In June 2019 at ASCO, the Company presented the data from an investigator-initiated study of ME-344 in combination with bevacizumab (marketed as Avastin®) in patients with early HER2-negative breast cancer. The data demonstrated proof of biologic anti-tumor activity as measured by a statistically significant reduction in Ki67, a measure of cell proliferation that is highly correlated with tumor response, in patients treated with ME-344 compared to an increase in the group receiving saline.

Pracinostat for Myelodysplastic Syndrome ("MDS")

- In December 2018 at ASH, the Company and Helsinn Healthcare presented interim results from the ongoing Phase 2 study evaluating pracinostat in combination with azacitidine for the treatment of patients with IPSS-R high/very high-risk of MDS. The data demonstrate a 9% discontinuation rate due to adverse events, a substantially lower rate than observed in an earlier Phase 2 study, as well as an encouraging 36% complete response rate among patients receiving at least 6 cycles of treatment.
- In February 2019, the Company and Helsinn Healthcare published data in the medical journal, Blood Advances, from a Phase 2 study evaluating the safety and efficacy of pracinostat in combination with azacitidine for the treatment of patients suffering from AML who cannot undergo treatment with intensive chemotherapy. The full article can be found here.

Corporate Highlights

- In July 2018, the Company announced that David M. Urso, J.D., senior vice president of corporate development and general counsel, was promoted to chief operating officer.
  Mr. Urso continues as the Company's general counsel and head of corporate development.
- In July 2019,
  Tamar Howson, M.S., MBA a highly experienced business development executive with over 30 years of service in the pharmaceutical and biotechnology industry joined the Board of Directors.

Fiscal Year 2019 Financial Results

- As of June 30, 2019, MEI had $79.8 million in cash, cash equivalents, short-term investments, and common stock proceeds receivable, with no outstanding debt.
- For the year ended June 30, 2019, cash used in operations was $39.4 million, compared to $21.0 million for 2018
- Research and development expenses were $32.3 million for the year ended June 30, 2019, compared to $17.0 million for 2018. The increase was primarily related to increased activities in all clinical programs including development costs associated with ME-401 and voruciclib.
- General and administrative expenses were $14.6 million for the year ended June 30, 2019, compared to $9.8 million for 2018. The increase primarily relates to professional services expenses, share-based compensation, and general corporate expenses incurred during the year ended June 30, 2019.
- MEI recognized revenues of $4.9 million for the year ended June 30, 2019, compared to $1.6 million for the year ended June 30, 2018. Revenues resulted from the recognition of fees allocated to research and development activities related to the Helsinn and Kyowa Kirin license agreements. Revenue increased due to higher levels of research and development activities during the year ended June 30, 2019.
- Net loss was $16.8 million, or $0.24 per share, for the fiscal year ended June 30, 2019, compared to net loss of $40.1 million, or $0.97 per share for 2018. The Company had 73,544,576 shares of common stock outstanding as of June 30, 2019, compared with 70,406,283 shares as of June 30, 2018.
- The adjusted net loss for the fiscal year ended June 30, 2019, excluding non-cash expenses related to changes in the fair value of the warrants issued in connection with the May 2018 financing (a non-GAAP measure), was $44.5 million.

Conference Call and Webcast

MEI Pharma will host a conference call with simultaneous webcast today, August 28, 2019, at 5:00 p.m. Eastern time to provide a corporate update. To access the live call, please dial (866) 939-3921 (United States) or (678) 302-3550 (International), conference ID 48926540. 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 late-stage pharmaceutical company focused on developing potential new

therapies for cancer. Our portfolio of drug candidates contains four clinical-stage assets, including one candidate in an ongoing global registration trial and another candidate in a Phase 2 clinical trial which may support an accelerated approval marketing application with the U.S. Food and Drug Administration. Each of our pipeline candidates leverages a different mechanism of action with the objective of developing therapeutic options that are: (1) differentiated, (2) address unmet medical needs and (3) deliver improved benefit to patients either as standalone treatments or in combination with other therapeutic options. 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 per share amounts)

	June 30,	
	2019	**2018**
ASSETS		
Current assets:		
	$	$
Cash and cash equivalents	9,590	13,309
Short term investments	64,899	89,434
Total cash, cash equivalents and short-term investments	74,489	102,743
Common stock proceeds receivable	5,274	-
Prepaid expenses and other current assets	2,435	1,586
Total current assets	82,198	104,329
Intangible assets, net	261	296
Property and equipment, net	204	32
	$	$
Total assets	82,663	104,657
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
	$	$
Accounts payable	4,787	3,643
Accrued liabilities	4,559	3,454
Deferred revenue	4,955	788
Total current liabilities	14,301	7,885
Deferred revenue, long-term	2,819	-
Warrant liability	17,613	46,313
Total liabilities	34,733	54,198
Stockholders' equity:		
Preferred stock, $0.01 par value; 100 shares authorized; none outstanding	-	-
Common stock, $0.00000002 par value; 226,000 shares authorized; 73,545 and 70,406 shares issued and outstanding at June 30, 2019 and 2018, respectively	-	-
Additional paid-in-capital	279,148	264,858
Accumulated deficit	(231,218)	(214,399)

Total stockholders' equity	47,930	50,459
	$	$
Total liabilities and stockholders' equity	82,663	104,657

MEI PHARMA, INC.
STATEMENTS OF OPERATIONS
(In thousands, except per share amounts)

	Years Ended June 30,		
	2019	**2018**	**2017**
Revenue	$ 4,915	$ 1,622	$ 23,249
Operating expenses:			
Cost of revenue	4,263	3,383	5,000
Research and development	32,300	17,038	7,237
General and administrative	14,597	9,787	8,628
Total operating expenses	51,160	30,208	20,865
(Loss) income from operations	(46,245)	(28,586)	2,384
Other income (expense):			
Change in fair value of warrant liability	27,632	(9,705)	-
Financing costs associated with warrants	-	(2,367)	-
Interest and dividend income	1,795	591	287
Income tax expense	(1)	(1)	(1)
Net (loss) income	$ (16,819)	$ (40,068)	$ 2,670
Net (loss) income:			
Basic	$ (16,819)	$ (40,068)	$ 2,670
Diluted	$ (54,613)	$ (40,068)	$ 2,670
Net (loss) income per share:			
Basic	$ (0.24)	$ (0.97)	$ 0.07
Diluted	$ (0.75)	$ (0.97)	$ 0.07
Shares used in computing net (loss) income per share:			
Basic	71,139	41,431	36,813
Diluted	72,385	41,431	36,938

MEI PHARMA, INC.
Reconciliation of GAAP Net Loss to Adjusted Net Loss
(In thousands)

	Years Ended June 30,		
	2019	**2018**	**2017**
Net (loss) income	$ (16,819)	$ (40,068)	$ 2,670
Add: Change in fair value of warrant liability	(27,632)	9,705	-
Adjusted net (loss) income	$ (44,451)	$ (30,363)	$ 2,670

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