

MEI Pharma Reports Fiscal Year 2020 Results and Operational Highlights

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SAN DIEGO, Sept. 9, 2020 /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, 2020.

"This past year was marked by progress on multiple fronts, particularly for zandelisib, formerly called ME-401, which is our PI3K delta inhibitor in the Phase 2 TIDAL study intended to support an accelerated approval marketing application with FDA," said Daniel

P. Gold, Ph.D., president and chief executive officer of MEI Pharma. "The progress on zandelisib this past year includes entering a global license, development and commercialization agreement with Kyowa Kirin Company, maturing Phase 1b study data that continues to support best-in-class potential, as well as obtaining Fast Track designation from FDA."

Dr. Gold continued: "With about \$183 million in cash at the start of our fiscal year, we believe we have an operational runway at least through 2023 and are well positioned to advance our ongoing clinical programs. In particular, we look forward to completing TIDAL enrollment as we initiate additional clinical studies to fully explore zandelisib's potential to benefit patients with B-cell malignancies while we continue our staged build-out of a commercial infrastructure to optimally capture value from the program."

Fiscal Year 2020 Zandelisib (ME-401) and Corporate Highlights

Zandelisib (formerly called ME-401), an oral, once-daily, investigational drug-candidate selective for phosphatidylinositol 3-kinase delta (PI3K δ), for B-Cell Malignancies

- The World Health Organization approved "zandelisib" as the International Nonproprietary Name, or INN, for ME-401, the Company's investigational cancer treatment being developed as an oral, once-daily, selective PI3K δ inhibitor for the treatment of B-cell malignancies.
- In May 2020, the Company and Kyowa Kirin Co. presented updated data at the American Society of Clinical Oncology (ASCO) 2020 Virtual Scientific Program from a Phase 1b study of zandelisib (ME-401) for the treatment of B-cell malignancies. These data evaluating patients on an intermittent dosing schedule of zandelisib showed that treatment was generally well tolerated and demonstrated an 83% overall response rate in patients with relapsed or refractory follicular lymphoma (n=36). The responses were durable with no median yet reached (median follow-up of 13.2 months: range: 3.0-27.6).
- In April 2020, the Company entered into a global license, development and commercialization agreement with Kyowa Kirin Co. to further develop and commercialize MEI's zandelisib:
 - MEI and Kyowa Kirin will co-develop and co-promote zandelisib in the U.S.
 - MEI to book U.S. sales on 50-50 profit and cost sharing.
 - \$100 million upfront cash payment to MEI.
 - \$582.5 million in potential development, regulatory and commercial milestones
 - Kyowa Kirin obtains exclusive commercialization rights ex-U.S.
 - MEI to receive escalating tiered royalty payments starting in the teens on ex-U.S. sales.
- In March 2020, the Company was granted Fast Track designation by the U.S. FDA for zandelisib for the treatment of adult patients with relapsed or refractory follicular lymphoma.

Corporate Highlights

- In April 2020, Cheryl L. Cohen, former chief commercial officer of Medivation, Inc. and a product launch and commercialization veteran with over 25 years of service in the pharmaceutical and biotechnology industry, joined the Board of Directors.
- In December 2019, the Company closed an underwritten public offering of 32,343,750 shares of its common stock for total gross proceeds of approximately \$51,750,000. Additionally, during the year ended June 30, 2020, MEI sold 5,471,684 shares under the ATM Sales Agreement for net proceeds of \$20.8 million.

- 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 2020 Financial Results

- As of June 30, 2020, MEI had \$182.6 million in cash, cash equivalents, and short-term investments with no outstanding debt. Additionally, MEI has a receivable of \$20.4 million that is expected to be received from the Japanese taxing authorities in fiscal year 2021 that was withheld from the \$100 million paid by Kyowa Kirin Co. under the terms of April 2020 global license, development and commercialization agreement. The withholding was a result of the US Internal Revenue Service being closed because of the COVID pandemic, resulting in an inability to provide the necessary documentation to support an exemption from the required foreign withholding.
- For the year ended June 30, 2020, cash used in operations was \$45.3 million compared to \$39.4 million for 2019.
- Research and development expenses were \$34.1 million for the year ended June 30, 2020, compared to \$32.3 million for 2019. The increase was primarily related to increased development costs associated with zandelisib, as well as increased personnel costs to support our clinical trial activities.
- General and administrative expenses were \$16.7 million for the year ended June 30, 2020, compared to \$14.6 million for 2019. The increase primarily relates to personnel costs and general corporate expenses incurred during the year ended June 30, 2020.
- MEI recognized revenues of \$28.9 million for the year ended June 30, 2020, compared to \$4.9 million for the year ended June 30, 2019. Revenues resulted from the recognition of license revenue associated with the Kyowa Kirin license agreement as well as fees allocated to research and development activities related to the Kyowa Kirin and Helsinn license agreements.
- Net loss was \$46.0 million, or \$0.51 per share, for the fiscal year ended June 30, 2020, compared to net loss of \$16.8 million, or \$0.24 per share for 2019. The Company had 111,513,689 shares of common stock outstanding as of June 30, 2020, compared with 73,544,576 shares as of June 30, 2019.
- The adjusted net loss for the fiscal year ended June 30, 2020, 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 \$23.1 million.

Conference Call and Webcast

MEI Pharma will host a conference call with simultaneous webcast today, September 9, 2020, 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 49919899. 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. MEI Pharma's portfolio of drug candidates contains four clinical-stage assets, including zandelisib, currently in an ongoing Phase 2 clinical trial which may support an accelerated approval marketing application with the U.S. Food and Drug Administration. Each of MEI Pharma's 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.

Forward-Looking Statements

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; the impact of the COVID-19 pandemic on our industry and individual companies, including on our counterparties, the supply chain, the execution of our clinical development programs, our access to

financing and the allocation of government resources; 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,	
	2020	2019
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 12,331	\$ 9,590
Short term investments	170,299	64,899
Total cash, cash equivalents and short-term investments	182,630	74,489
Receivable for foreign tax withholding	20,420	-
Common stock proceeds receivable	-	5,274
Prepaid expenses and other current assets	5,594	2,435
Total current assets	208,644	82,198
Intangible assets, net	-	261
Property and equipment, net	1,084	204
Total assets	<u>\$ 209,728</u>	<u>\$ 82,663</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 2,437	\$ 4,787
Accrued liabilities	6,090	4,559
Deferred revenue	14,777	4,955
Total current liabilities	23,304	14,301
Deferred revenue, long-term	67,723	2,819
Warrant liability	40,483	17,613
Total liabilities	<u>131,510</u>	<u>34,733</u>
Stockholders' equity:		
Preferred stock, \$0.01 par value; 100 shares authorized;		
none outstanding	-	-
Common stock, \$0.00000002 par value; 226,000 shares		
authorized; 111,514 and 73,545 shares issued and outstanding		
at June 30, 2020 and 2019, respectively	-	-
Additional paid-in-capital	355,452	279,148
Accumulated deficit	(277,234)	(231,218)
Total stockholders' equity	<u>78,218</u>	<u>47,930</u>
Total liabilities and stockholders' equity	<u>\$ 209,728</u>	<u>\$ 82,663</u>

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

	Years Ended June 30,		
	2020	2019	2018
Revenue	\$ 28,913	\$ 4,915	\$ 1,622
Operating expenses:			
Cost of revenue	2,671	4,263	3,383
Research and development	34,065	32,300	17,038
General and administrative	16,717	14,597	9,787
Total operating expenses	53,453	51,160	30,208
Loss from operations	(24,540)	(46,245)	(28,586)
Other income (expense):			
Change in fair value of warrant liability	(22,870)	27,632	(9,705)
Financing costs associated with warrants	-	-	(2,367)
Interest and dividend income	1,395	1,795	591
Income tax expense	(1)	(1)	(1)
Net loss	\$ (46,016)	\$ (16,819)	\$ (40,068)
Net loss:			
Basic	\$ (46,016)	\$ (16,819)	\$ (40,068)
Diluted	\$ (46,016)	\$ (54,613)	\$ (40,068)
Net loss per share:			
Basic	\$ (0.51)	\$ (0.24)	\$ (0.97)
Diluted	\$ (0.51)	\$ (0.75)	\$ (0.97)
Shares used in computing net loss per share:			
Basic	91,080	71,139	41,431
Diluted	91,080	72,385	41,431

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

	Years Ended June 30,		
	2020	2019	2018
Net loss:	\$ (46,016)	\$ (16,819)	\$ (40,068)
Add: Change in fair value of warrant liability	22,870	(27,632)	9,705
Adjusted net loss:	\$ (23,146)	\$ (44,451)	\$ (30,363)

Receivable for foreign tax withholding

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