MEI Pharma Reports Third Quarter Fiscal 2021 Results and Operational Highlights

May 6, 2021

SAN DIEGO, May 6, 2021 /PRNewswire/ -- MEI Pharma, Inc. (NASDAQ: MEIP), a late-stage pharmaceutical company focused on advancing new therapies for cancer, today reported results for the quarter ended March 31, 2021 and highlighted recent corporate progress.

"The first several months of 2021 have been very eventful for MEI, highlighted by the completion of enrollment in the follicular lymphoma efficacy population arm of the zandelisib TIDAL study. In addition, we recently reported preclinical data at AACR 2021, demonstrating the ability of voruciclib to downregulate MYC and synergize with KRAS inhibitors in KRAS mutant cancers," said Daniel P. Gold, Ph.D., president and chief executive officer of MEI Pharma. "While we continue to work diligently to advance the clinical development of voruciclib and ME-344, we anticipate additional important milestones from the zandelisib program this calendar year, including top-line TIDAL data by the end of 2021, the initiation of our Phase 3 COASTAL study evaluating zandelisib in combination with rituximab in patients with second line follicular or marginal zone lymphomas expected to start around mid-year, and clinical data updates from the ongoing Phase 1b study at the ASCO, EHA and ICML annual meetings."

Anticipated Calendar Year 2021 Drug Candidate Pipeline Developments

Zandelisib – Oral PI3K delta inhibitor for the treatment of various B-cell malignancies

- Reporting of topline data from the Phase 2 TIDAL study in the fourth quarter from the follicular lymphoma primary efficacy population. The complete data from the follicular lymphoma arm of the Phase 2 TIDAL study data are intended to be submitted to FDA to support an accelerated approval application.
- Initiation around mid-2021 of enrollment in COASTAL, a Phase 3 study evaluating zandelisib in combination with rituximab in follicular and marginal zone lymphoma patients who received one or more prior lines of treatment. This study is intended to support FDA approval for additional indications and act as the required confirmatory study for the potential accelerated approval of zandelisib in patients with relapsed or refractory follicular lymphoma or marginal zone lymphoma.
- Clinical data updates from the Phase 1b study of zandelisib at the 2021 American Society of Clinical Oncology and European Hematology Association annual meetings, including the combination with zanubrutinib.

Voruciclib – CDK9 inhibitor for the treatment of B-cell malignancies and acute myeloid leukemia

- Program updates, including data from the Phase 1 program evaluating voruciclib in patients with acute myeloid leukemia and B-cell malignancies.

ME-344 – Tumor selective mitochondrial inhibitor

- Initiation of a Phase 2 pilot study of ME-344 in solid tumors in the first half of calendar 2022.

Recent and Third Quarter Fiscal Year 2021 Corporate Highlights

- In April 2021, MEI completed enrollment in the follicular lymphoma primary efficacy population of the global Phase 2 TIDAL study evaluating zandelisib. Topline data from the study is on track to be reported in the fourth quarter. The complete Phase 2 TIDAL study data are intended to be submitted to FDA to support accelerated approval applications.

- In April 2021, MEI reported preclinical data demonstrating that voruciclib, an orally administered cyclin-dependent kinase (CDK) inhibitor that is potent against CDK9, downregulates MYC by inhibiting MYC transcription and stabilization, and synergizes with KRAS inhibitors in KRAS mutant cancers. The research was featured as an E-Poster Session presentation titled, "Voruciclib, a CDK9 inhibitor, downregulates MYC and inhibits proliferation of KRAS mutant cancers in preclinical models" at the American Association for Cancer Research Annual Meeting 2021.

- In January 2021, MEI announced that the Phase 1b trial arm exploring zandelisib in combination with zanubrutinib in collaboration with BeiGene, Ltd. completed the dose optimization stage in patients with B-cell malignancies and is expanding into disease specific B-cell malignancy cohorts. The *Safety Review Committee* recommended moving forward with a dosing regimen found to be generally well tolerated and active following a planned safety analysis.

Third Quarter Fiscal Year 2021 Financial Results

- As of March 31, 2021, MEI had $164.6 million in cash, cash equivalents, and short-term investments with no outstanding debt.

- For the quarter ended March 31, 2021, cash used in operations was $15.6 million, compared to $10.3 million for the same period in 2020. The increase in cash used in operations primarily relates to costs associated with our clinical development programs. For the nine months ended March 31, 2021, cash used in operations was $20.7 million, compared to $34.9 million for the same period in 2020. The year-to-date decrease in cash used in operations reflects $20.9 million of cash received from the Japanese taxing authorities as a refund of withholding tax associated with the Kyowa Kirin commercialization agreement signed in April 2019, offset by increased costs associated with our clinical development programs.

- Research and development expenses were $17.9 million for the quarter ended March 31, 2021, compared to $9.0 million for the quarter ended March 31, 2020. The increase was primarily related to increased development costs associated with zandelisib, including increased activity in the TIDAL study and start-up costs related to the Phase 3 study, as well as increased personnel costs to support clinical trial activities.

- General and administrative expenses were $6.2 million for the quarter ended March 31, 2021, compared to $3.9 million for the quarter ended March 31, 2020. The increase primarily relates to personnel costs and general corporate expenses incurred during the quarter ended March 31, 2021.

- MEI recognized revenues of $2.4 million for the quarter ended March 31, 2021, compared to $1.2 million for the quarter ended March 31, 2020. The increase in revenue primarily related to the license agreement with Kyowa Kirin and included the recognition of fees allocated to research and development obligations.

- Net loss was $31.3 million, or $0.28 per share, for the quarter ended March 31, 2021, compared to net loss of $4.3 million, or $0.04 per share for the quarter ended March 31, 2020. The Company had 112,591,778 shares of common stock outstanding as of March 31, 2021, compared with 105,998,677 shares as of March 31, 2020.

- The adjusted net loss for the quarter ended March 31, 2021, excluding non-cash expenses related to changes in the fair value of the warrants (a non-GAAP measure), was $22.0 million, compared to an adjusted net loss of $12.1 million for the quarter ended March 31, 2020.

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 accelerated approval marketing applications 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.
CONDENSED BALANCE SHEETS
(In thousands, except per share amounts)

	March 31, 2021 (unaudited)	**June 30, 2020**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 9,745	$ 12,331
Short-term investments	154,879	170,299
Total cash, cash equivalents and short-term investments	164,624	182,630
Receivable for foreign tax withholding	-	20,420
Prepaid expenses and other current assets	11,937	5,594
Total current assets	176,561	208,644
Operating lease right-of-use asset	7,992	-
Property and equipment, net	1,569	1,084
Total assets	$ 186,122	$ 209,728
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 5,571	$ 2,437
Accrued liabilities	7,762	6,090
Deferred revenue	19,143	14,777
Operating lease liability	900	-
Total current liabilities	33,376	23,304
Deferred revenue, long-term	70,734	67,723
Operating lease liability, long-term	7,608	-
Warrant liability	29,442	40,483
Total liabilities	141,160	131,510
Stockholders' equity:		
Preferred stock, $0.01 par value; 100 shares authorized;		

none outstanding	-	-
Common stock, $0.00000002 par value; 226,000 shares authorized; 112,592 and 111,514 shares issued and outstanding at March 31, 2021 and June 30, 2020, respectively	-	-
Additional paid-in-capital	367,055	355,452
Accumulated deficit	(322,093)	(277,234)
Total stockholders' equity	44,962	78,218
Total liabilities and stockholders' equity	$ 186,122	$ 209,728

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

	Three Months Ended March 31,		Nine Months Ended March 31,	
	2021	**2020**	**2021**	**2020**
Revenue	$ 2,418	$ 1,244	$ 15,419	$ 3,409
Operating expenses:				
Cost of revenue	405	860	1,408	2,189
Research and development	17,884	8,963	53,104	26,206
General and administrative	6,215	3,864	17,780	12,189
Total operating expenses	24,504	13,687	72,292	40,584
Loss from operations	(22,086)	(12,443)	(56,873)	(37,175)
Other income (expense):				
Change in fair value of warrant liability	(9,272)	7,732	11,035	8,562
Interest and dividend income	58	382	497	1,074
Other income (expense)	(13)	-	482	(1)
Net loss	$ (31,313)	$ (4,329)	$ (44,859)	$ (27,540)
Net loss:				
Basic	$ (31,313)	$ (4,329)	$ (44,859)	$ (27,540)
Diluted	$ (31,313)	$ (4,329)	$ (65,166)	$ (27,540)
Net loss per share:				
Basic	$ (0.28)	$ (0.04)	$ (0.40)	$ (0.32)
Diluted	$ (0.28)	$ (0.04)	$ (0.57)	$ (0.32)
Shares used in computing net loss per share:				
Basic	112,557	105,999	112,505	85,995
Diluted	112,557	105,999	113,991	85,995

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

	Three Months Ended March 31,		Nine Months Ended March 31,	
	2021	2020	2021	2020
Net loss	$ (31,313)	$ (4,329)	$ (44,859)	$ (27,540)
Add: Change in fair value of warrant liability	9,272	(7,732)	(11,035)	(8,562)
Adjusted net loss	$ (22,041)	$ (12,061)	$ (55,894)	$ (36,102)

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