MEI Pharma Reports Fiscal Year 2021 Results and Operational Highlights

SAN DIEGO, Sept. 2, 2021 /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, 2021.

"Fiscal year 2021 was very successful for MEI; it was highlighted by multiple data updates that continue to support the potential of the unique intermittent dosing therapy schedule we designed for zandelisib, both as a monotherapy and in combination with other therapies across a range of B-cell malignances. To that end, we are continuing to expand the clinical program with studies designed to broaden zandelisib's potential, like the Phase 3 COASTAL study in second line or later follicular lymphoma and the planned start of a Phase 2 study evaluating zandelisib plus venetoclax and rituximab in patients with relapsed chronic lymphocytic leukemia," said Daniel P. Gold, Ph.D., president and chief executive officer of MEI Pharma. "As we expect to report top-line data from the potentially registrational Phase 2 TIDAL study by the end of the calendar year, we are diligently advancing our pre-commercialization activities, including the building out of our commercial infrastructure, in preparation for the potential commercialization of zandelisib."

Dr. Gold continued: "In addition to advancing zandelisib clinical development, this past year also brought other exciting pipeline developments supporting new clinical development plans for voruciclib, our oral CDK9 inhibitor, to explore its potential to synergize with KRAS inhibitors, and plans for a Phase 2 study of ME-344 plus bevacizumab evaluating patients with colorectal cancer. We are proud of our progress over the last fiscal year and committed to maintaining our overall focus on the development and commercialization of novel, best-in-class, cancer therapies intended to improve outcomes for patients."

Expected Drug Candidate Pipeline Developments

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

Report 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 the U.S. Food and Drug Administration (FDA) to support an accelerated approval marketing application.

Initiation of a Phase 2 study evaluating zandelisib plus venetoclax and rituximab in patients with chronic lymphocytic leukemia.

Updates from the arm of a Phase 1b study evaluating zandelisib plus zanubrutinib, including in expansion cohorts enrolling patients with relapsed or refractory mantle cell and follicular lymphomas.

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

Program updates, including data from the monotherapy portion of 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 study of ME-344 in relapsed colorectal cancer in the mid calendar year 2022.

Fiscal Year 2021 and Recent Select Drug Candidate Pipeline Highlights

Zandelisib

Completed enrollment in the follicular lymphoma primary efficacy population of 91 patients, and enrollment in the complete study population of 120 patients, of the global Phase 2 TIDAL study. Topline data from the study is expected to be reported in the fourth quarter of the calendar year. If successful, the complete Phase 2 TIDAL study data are intended to be submitted to the U.S. FDA to support accelerated approval applications under 21 CFR Part 314.500, Subpart H.

Initiated 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.

The dosing of the first patient in the global Phase 3 COASTAL study evaluating zandelisib in combination with rituximab, announced in August 2021, triggered a $10,000,000 milestone payment payable to MEI from Kyowa Kirin Co. pursuant to the 2020 global license, development and commercialization agreement between the companies. Receipt of the milestone payment is expected in the quarter ending September 30, 2021.

Initiated a second arm in the Phase 2 TIDAL study evaluating zandelisib as a monotherapy for the treatment of adults with relapsed and refractory marginal zone lymphoma. Subject to results from TIDAL, data from the study are intended to support accelerated approval applications with the FDA under 21 CFR Part 314.500, Subpart H.

Presented clinical data at the European Hematology Association 2021 Virtual Congress from a Phase 1b study of zandelisib in combination with zanubrutinib (marketed as BRUKINSA®), an inhibitor of Bruton's tyrosine kinase developed by BeiGene, Ltd., in patients with relapsed or refractory B-cell malignancies. The data demonstrated that the combination was generally well tolerated in the 20 patients enrolled in the safety evaluation cohort. The combination administered on an optimized dosing regimen did not result in additive toxicity to each agent alone. Further, 100% of patients (n=16) with r/r indolent B-cell malignancies and chronic lymphocytic leukemia (CLL) achieved an objective response.

Presented clinical data at the American Society of Clinical Oncology Annual Meeting 2021 and the 16th Annual International Conference on Malignant Lymphoma from a Phase 1b study of zandelisib as a monotherapy or plus rituximab demonstrating a 95% overall response rate (ORR) with rituximab and a 78% ORR as a monotherapy in patients with relapsed or refractory follicular lymphoma. Data presented also demonstrated that a median duration of response was not reached. Zandelisib was generally well-tolerated, demonstrating an 8% discontinuation rate due to any treatment emergent adverse event.

Initiated a pivotal Phase 2 study by Kyowa Kirin of zandelisib in patients with indolent B-cell non-Hodgkin's lymphoma without small lymphocytic lymphoma, lymphoplasmacytic lymphoma and Waldenström's macroglobulinemia in Japan.

Voruciclib

Reported preclinical data demonstrating that voruciclib is potent against CDK9, has single agent activity against multiple KRAS-mutant cancer cell lines and synergistically inhibits growth of KRAS mutant cancers in combination with KRAS inhibitors at the American Association for Cancer Research Annual Meeting 2021. MEI is now expanding the clinical development of voruciclib into KRAS-mutated cancers, adding to the ongoing program evaluating voruciclib in patients with acute myeloid leukemia and B-cell malignancies.

Fiscal Year 2021 and Recent Corporate Highlights

During fiscal year 2021, MEI announced changes to its management team. In August 2021, MEI announced the planned transition and retirement of Brian Drazba as chief financial officer. The company initiated a search for a new chief financial officer. In July 2021, MEI appointed Tina C. Beamon, J.D. as chief compliance officer. In April 2021, MEI announced the retirement of Robert Mass and the promotion of Robert Ghalie as chief medical officer. In September 2020, MEI appointed Brian T. Powl as senior vice president, marketing.

Fiscal Year 2021 Financial Results

As of June 30, 2021, MEI had $153.4 million in cash, cash equivalents, and short-term investments with no outstanding debt.

For the year ended June 30, 2021, net cash used in operations was $52.4 million, compared to $45.3 million for 2020, excluding upfront cash payments from Kyowa Kirin. The increase primarily relates to increased costs associated with our clinical development programs.

Research and development expenses were $69.4 million for the year ended June 30, 2021, compared to $34.1 million for 2020. The increase was primarily related to increased development costs associated with zandelisib, including start-up costs related to the Phase 3 COASTAL study, increased drug manufacturing costs, and increased consulting fees to support clinical trial activities.

General and administrative expenses were $24.4 million for the year ended June 30, 2021, compared to $16.7 million for 2020. The increase primarily relates to increased professional services costs, increased personnel costs associated with increased headcount to support our activities, including preparation for commercial launch of zandelisib, and general corporate expenses incurred during 2021.

MEI recognized revenues of $25.5 million for the year ended June 30, 2021, compared to $28.9 million for 2020. The decrease in revenue primarily related to the license agreement with Kyowa Kirin and included the recognition of fees allocated to research and development obligations. Revenue also includes recognition of fees allocated to performance obligations in accordance with the Helsinn License Agreement.

Net loss was $50.6 million, or $0.45 per share, for the year ended June 30, 2021, compared to net loss of $46.0 million, or $0.51 per share for 2020. The Company had 112,614,643 shares of common stock outstanding as of June 30, 2021, compared with 111,513,689 shares as of June 30, 2020.

The adjusted net loss for the year ended June 30, 2021, excluding non-cash expenses related to changes in the fair value of the warrants (a non-GAAP measure), was $68.7 million, compared to an adjusted net loss of $23.1 million for 2020.

Conference Call and Webcast

MEI Pharma will host a conference call with simultaneous webcast today, September 2, 2021, at 5:00 p.m. Eastern time to provide a corporate update. To access the live call, please dial 1-833-974-2378 (United States) or 1-412-317-5771 (International). Please ask to join the MEI Pharma earnings call.

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 multiple clinical-stage assets, including zandelisib, currently in ongoing clinical trials which may support marketing approvals with the U.S. Food and Drug Administration and other regulatory authorities globally. 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. Follow us on Twitter @MEI_Pharma and on LinkedIn.

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,	
	2021	**2020**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 8,543	$ 12,331
Short term investments	144,883	170,299
Total cash, cash equivalents and short-term investments	153,426	182,630
Receivable for foreign tax withholding	-	20,420
Contract assets	7,582	2,858
Prepaid expenses and other current assets	3,809	2,736
Total current assets	164,817	208,644
Intangible assets, net	7,774	-
Property and equipment, net	1,507	1,084
Total assets	$ 174,098	$ 209,728
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 6,355	$ 2,437
Accrued liabilities	8,402	6,090
Deferred revenue	14,609	14,777
Operating lease liability	928	-
Total current liabilities	30,294	23,304

Deferred revenue, long-term	72,717	67,723
Operating lease liability, long-term	7,370	-
Warrant liability	22,355	40,483
Total liabilities	132,736	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; 112,615 and 111,514 shares issued and outstanding at June 30, 2021 and 2020, respectively	-	-
Additional paid-in-capital	369,171	355,452
Accumulated deficit	(327,809)	(277,234)
Total stockholders' equity	41,362	78,218
Total liabilities and stockholders' equity	$ 174,098	$ 209,728

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

	Years Ended June 30,		
	2021	**2020**	**2019**
Revenue	$ 25,535	$ 28,913	$ 4,915
Operating expenses:			
Cost of revenue	1,408	2,671	4,263
Research and development	69,398	34,065	32,300
General and administrative	24,414	16,717	14,597
Total operating expenses	95,220	53,453	51,160
Loss from operations	(69,685)	(24,540)	(46,245)
Other income (expense):			
Change in fair value of warrant liability	18,122	(22,870)	27,632
Interest and dividend income	510	1,395	1,795
Other income	486	-	-
Income tax expense	(8)	(1)	(1)
Net loss	$ (50,575)	$ (46,016)	$ (16,819)
Net loss:			
Basic	$ (50,575)	$ (46,016)	$ (16,819)
Diluted	$ (77,969)	$ (46,016)	$ (54,613)
Net loss per share:			
Basic	$ (0.45)	$ (0.51)	$ (0.24)
Diluted	$ (0.68)	$ (0.51)	$ (0.75)
Shares used in computing net loss per share:			
Basic	112,527	91,080	71,139
Diluted	114,481	91,080	72,385

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

	Years Ended June 30,		
	2021	**2020**	**2019**
Net loss:	$ (50,575)	$ (46,016)	$ (16,819)
Add: Change in fair value of warrant liability	(18,122)	22,870	(27,632)
Adjusted net loss:	$ (68,697)	$ (23,146)	$ (44,451)

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