

MEI Pharma Reports Third Quarter Fiscal Year 2022 Results and Operational Highlights

--MEI Begins Fourth Fiscal Quarter with \$169.0 Million in Cash--

SAN DIEGO--(BUSINESS WIRE)--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, 2022, and highlighted recent corporate events.

“The third fiscal quarter of 2022 was underscored by a meeting with the FDA in which we were informed that data from randomized studies are now needed to adequately assess the benefit-risk of PI3K inhibitor drug candidates, including zandelisib, and where it was emphasized that we should continue efforts with the ongoing randomized COASTAL study. Accordingly, we no longer plan to submit an FDA marketing application under the accelerated approval pathway using the single arm TIDAL study. However, we continue to have confidence in zandelisib's differentiated therapeutic profile as observed in our data generated to date, and remain committed to advancing the program to a marketing authorization submission with our partner, Kyowa Kirin,” said Daniel P. Gold, Ph.D., president and chief executive officer of MEI Pharma.

Dr. Gold continued: “While progression free survival is the primary endpoint for COASTAL, we are actively working with our partner, Kyowa Kirin, to determine if a more expeditious approach exists to bring zandelisib to the market sooner which we will then discuss with the FDA and we will plan to provide an update as appropriate. We remain well capitalized with \$169 million to advance our pipeline and continue operations for over two years.”

Third Quarter Fiscal Year 2022 Recent Developments and Financial Highlights

On May 12, 2022, we announced that two abstracts highlighting data and information for zandelisib, an orally administered investigational phosphatidylinositol 3-kinase delta (“PI3K δ ”) inhibitor in clinical development for the treatment of B-cell malignancies, will be presented at the upcoming European Hematology Association (EHA) 2022 Hybrid Congress to be held June 9 – 17, 2022.

On April 8, 2022, we announced that two posters reporting preclinical data for zandelisib, an orally administered investigational PI3K δ inhibitor, and ME-344, a tumor selective mitochondrial inhibitor, were presented at the American Association for Cancer Research (AACR) Annual Meeting 2022.

On March 24, 2022, we reported that the FDA had recently informed us of its position that randomized data is now needed to adequately assess drug efficacy and safety of PI3K inhibitor drug candidates, including zandelisib. At this FDA meeting, the agency discouraged a planned filing based on the Phase 2 TIDAL study data and emphasized that the company continues efforts with the ongoing, randomized Phase 3 COASTAL study as planned. Accordingly, in line with the FDA's recommendation, the company reported it no longer plans to submit an FDA marketing application based on the single arm Phase 2 TIDAL study.

On February 7, 2022, we announced the expansion of our management team with the addition of two experienced industry executives: Alejandro Ricart, M.D., joined as senior vice president, clinical development, a role reporting to Richard Ghalie, M.D., chief medical officer, and Yomara Gomez-Naiden joined as senior vice president, quality, reporting to Daniel P. Gold, Ph.D., chief executive officer.

Expected Drug Candidate Pipeline Developments

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

Provide a more complete report of the Phase 2 TIDAL data announced on November 30, 2021 at upcoming medical meetings in 2022.

Initiate CORAL, a Phase 2 study evaluating zandelisib plus venetoclax and rituximab in patients with chronic lymphocytic leukemia in the first half of calendar year 2022.

Provide an update from the arm of a Phase 1b study evaluating zandelisib plus zanubrutinib at an upcoming scientific congress in 2022.

Report updated data from the Phase 2 TIDAL study arm in follicular lymphoma intended for an upcoming scientific congress in the fourth calendar year quarter of 2022.

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

Initiate Phase 1b study evaluating voruciclib in combination with Venclexta® (venetoclax) in patients with acute myeloid leukemia mid calendar year 2022.

ME-344 – Tumor selective mitochondrial inhibitor

Initiate a Phase 1b study of ME-344 in relapsed colorectal cancer by the end of calendar year 2022.

Third Quarter Fiscal Year 2022 Financial Results

As of March 31, 2022, MEI had \$169.0 million in cash, cash equivalents, and short-term investments with no outstanding debt.

For the quarter ended March 31, 2022, cash used in operations was \$17.0 million, compared to \$15.6 million used in operations for the quarter ended March 31, 2021. The increase in cash used in operations reflects increased development activity in 2022 and changes in working capital balances.

Research and development expenses were \$22.3 million for the quarter ended March 31, 2022, compared to \$17.9 million for the quarter ended March 31, 2021. The increase was primarily related to costs to support ongoing zandelisib studies, and expenses related to voruciclib and ME-344.

General and administrative expenses were \$8.9 million for the quarter ended March 31, 2022, compared to \$6.2 million for the quarter ended March 31, 2021. The increase primarily relates to personnel costs, professional services and general corporate expenses.

MEI recognized revenue of \$9.7 million for the quarter ended March 31, 2022, compared to \$8.1 million for the quarter ended March 31, 2021. The increase in recognized revenue relates to the partial satisfaction of the research and development obligations under the license agreement with Kyowa Kirin.

Net loss was \$8.7 million, or \$.07 per share, for the quarter ended March 31, 2022, compared to net loss of \$25.6 million, or \$.23 per share for the quarter ended March 31, 2021. The Company had 133,152,045 shares of common stock outstanding as of March 31, 2022, compared with 112,591,778 shares as of March 31, 2021.

The adjusted net loss for the quarter ended March 31, 2022, excluding non-cash expenses related to changes in the fair value of the warrants (a non-GAAP measure), was \$21.5 million, compared to an adjusted net loss of \$16.4 million for the quarter ended March 31, 2021.

Figures for the quarter ended March 31, 2021 and year ended June 30, 2021 shown above and in the following

tables for revenue, net loss, net loss per share, and adjusted net loss reflect the previously announced restatement of certain of the Company's historical financial statements, which was completed today.

Restatement of the Company's 2021 Quarterly Periods

As disclosed in the Current Report on Form 8-K filed with the Securities and Exchange Commission (the "SEC") on May 13, 2022, the Company determined that it made certain errors in the manner in which it recognized revenue from its License, Development, and Commercialization Agreement with Kyowa Kirin Co., Ltd. (the "KKC Commercialization Agreement"), with the result that revenue was overstated in some quarters and understated in other quarters in the Company's financial statements during 2020 and 2021. The errors relate to the appropriate timing and amounts of revenue recognized over time under the cost-to-cost method associated with the KKC Commercialization Agreement. These errors and the required restatement had no effect on the Company's previously reported operating expenses, cash flows or cash and short-term investments. The cumulative effect of these errors was a misstatement of deferred revenue and accumulated deficit of \$3.9 million. As a result, the Company restated its previously filed annual and quarterly financial statements for periods from June 30, 2020 forward, which were included in the Annual Report on Form 10-K/A for the fiscal year ended June 30, 2021 and Quarterly Reports of Form 10-Q/A for the quarters ended September 30, 2021 and December 31, 2021, filed with the SEC today. For more information concerning the restatement, please see those filings.

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](https://twitter.com/MEI_Pharma) and on [LinkedIn](https://www.linkedin.com/company/meipharma).

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 including, without limitation, statements regarding: the potential, safety, efficacy, and regulatory and clinical progress of zandelisib and our other product candidates, including the anticipated timing for initiation of clinical trials and release of clinical trial data and our expectations surrounding potential regulatory submissions, approvals and timing thereof, our business strategy and plans; and the sufficiency of our cash, cash equivalents and short-term investments to fund our operations. 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; the availability or appropriateness of utilizing the FDA's accelerated approval pathway for our product candidates; final data from our pre-clinical studies and completed clinical trials may differ materially from reported interim data from ongoing studies and trials; 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; adverse effects on the Company's business as a result of the restatement of our previously issued financial statements; 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.

Non-GAAP Financial Measures

To supplement our consolidated financial statements, which are prepared and presented in accordance with generally accepted accounting principles in the United States ("GAAP"), we provide investors with a non-GAAP financial measure, adjusted net loss, which we believe is helpful to our investors. We use adjusted net loss for financial and operational decision-making purposes and as a means to evaluate period-to-period comparisons. We believe this non-GAAP financial measure provides useful information about our operating results, enhances the overall understanding of past financial performance and future prospects and allows for greater transparency with respect to metrics used by our management in its financial and operational decision-making.

The presentation of adjusted net loss is not meant to be considered in isolation or as a substitute for net loss, the directly comparable financial measure prepared in accordance with GAAP. While we believe adjusted net loss is an important tool for financial and operational decision-making and for evaluating our own operating results over different periods of time, we urge investors to review the reconciliation of this financial measures to the comparable GAAP financial measures included below, and not to rely on any single financial measure to evaluate our business.

We define adjusted net loss, adjusted to exclude non-cash expenses related to changes in the fair value of the warrants. We have presented adjusted net loss because we believe excluding the non-cash expenses related to changes in the fair value of warrants can produce a useful measure for period-to-period comparisons of our business.

MEI PHARMA, INC.		
CONDENSED BALANCE SHEETS		
(In thousands, except per share amounts)		
	March 31, 2022	June 30, 2021
	(unaudited)	(As Restated)
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 11,112	\$ 8,543
Short-term investments	157,930	144,883
Total cash, cash equivalents and short-term investments	169,042	153,426
Unbilled receivable	8,446	7,582
Prepaid expenses and other current assets	5,978	3,809
Total current assets	183,466	164,817
Operating lease right-of-use asset	9,524	7,774
Property and equipment, net	1,439	1,507
Total assets	<u>\$ 194,429</u>	<u>\$ 174,098</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 8,257	\$ 6,355
Accrued liabilities	10,082	8,402
Deferred revenue	4,789	4,526
Operating lease liabilities	828	928

Total current liabilities	23,956	20,211
Deferred revenue, long-term	91,920	74,696
Warrant liability	9,211	7,370
Operating lease liabilities, long-term	1,536	22,355
Total liabilities	126,623	124,632
Stockholders' equity:		
Preferred stock, \$0.01 par value; 100 shares authorized; none outstanding	-	-
Common stock, \$0.00000002 par value; 226,000 shares authorized; 133,152 and 112,615 shares issued and outstanding at March 31, 2022 and June 30, 2021, respectively	-	-
Additional paid-in-capital	425,902	369,171
Accumulated deficit	(358,096)	(319,705)
Total stockholders' equity	67,806	49,466
Total liabilities and stockholders' equity	\$ 194,429	\$ 174,098

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

	Three Months Ended March 31,		Nine Months Ended March 31,	
	2022	2021 (As Restated)	2022	2021 (As Restated)
Revenue	\$ 9,694	\$ 8,109	\$ 29,283	\$ 27,342
Operating expenses:				
Cost of revenue	-	405	-	1,408
Research and development	22,318	17,884	63,802	53,104
General and administrative	8,934	6,215	24,769	17,780
Total operating expenses	31,252	24,504	88,571	72,292
Loss from operations	(21,558)	(16,395)	(59,288)	(44,950)
Other income:				
Change in fair value of warrant liability	12,773	(9,272)	20,819	11,035
Interest and dividend income	60	58	78	497
Other income (expense)	-	(13)	-	482
Net loss	\$ (8,725)	\$ (25,622)	\$ (38,391)	\$ (32,936)
Net loss:				
Basic	\$ (8,725)	\$ (25,622)	\$ (38,391)	\$ (32,936)
Diluted	\$ (8,725)	\$ (25,622)	\$ (46,437)	\$ (53,243)
Net loss per share:				
Basic	\$ (0.07)	\$ (0.23)	\$ (0.32)	\$ (0.29)
Diluted	\$ (0.07)	\$ (0.23)	\$ (0.38)	\$ (0.47)
Shares used in computing net loss per share:				
Basic	133,056	112,557	121,591	112,505
Diluted	133,056	112,557	122,482	113,991

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,	
	2022	2021 (As Restated)	2022	2021 (As Restated)
Net loss	\$ (8,725)	\$ (25,622)	\$ (38,391)	\$ (32,936)
Add: Change in fair value of warrant liability	(12,773)	9,272	(20,819)	(11,035)
Adjusted net loss	<u>\$ (21,498)</u>	<u>\$ (16,350)</u>	<u>\$ (59,210)</u>	<u>\$ (43,971)</u>

View source version on businesswire.com: <https://www.businesswire.com/news/home/20220520005450/en/>

David A. Walsey

MEI Pharma

Tel: 858-369-7104

investor@meipharma.com

Jason I. Spark

Canale Communications for MEI

Tel: 619-849-6005

jason.spark@canalecomm.com

Source: MEI Pharma, Inc.

ORIGINAL NASDAQ-SMALL:MEIP Business Wire