



## MEI Pharma Reports Fiscal Year 2022 Results and Operational Highlights

*-MEI Begins Fiscal Year 2023 with \$153 Million in Cash-*

*- Conference Call Today at 5:00 p.m. Eastern Time -*

**SAN DIEGO – September 8, 2022** – 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, 2022.

"This past fiscal year was marked by progress on multiple fronts, including the first patient dosed in our Phase 3 COASTAL study, strong zandelisib data reported from the global Phase 2 TIDAL study, reporting of data from our voruciclib and ME-344 programs, and key appointments to our executive team and board of directors," said Daniel P. Gold, Ph.D., president and chief executive officer of MEI Pharma. "Further, we remain well capitalized with \$153 million to advance our pipeline and continue operations for about two years."

Dr. Gold continued: "Despite a strong start to the fiscal year, our successes have been tempered by changes to the FDA's approach to accelerated approvals, as now encapsulated by the FDA's Project FrontRunner, which largely has closed the pathway to marketing authorization based on data from a single-arm study like our Phase 2 TIDAL study. However, the FDA emphasized that we and our partner, Kyowa Kirin, should continue efforts to evaluate zandelisib in our ongoing randomized Phase 3 COASTAL study. We remain confident in zandelisib's potential to benefit patients with B-cell malignancies as we continue evaluating zandelisib's unique profile, particularly in combination with other therapies, to provide physicians and their patients new treatment options for cancer."

### Expected Drug Candidate Pipeline Developments

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

- Report complete data from the follicular lymphoma cohort in the Phase 2 TIDAL study by year-end 2022.
- Dose the first patient in the Phase 2 CORAL study evaluating zandelisib plus Venclexta® (venetoclax) and rituximab in patients with chronic lymphocytic leukemia by year-end 2022.
- Provide an update from the Phase 1b study cohort evaluating zandelisib plus Brukinsa® (zanubrutinib) at an upcoming scientific congress.



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

- Dose the first patient cohort of voruciclib in combination with Venclexta (venetoclax) in patients with acute myeloid leukemia by year-end 2022 in the Phase 1 study.

*ME-344 – Tumor selective mitochondrial inhibitor*

- Initiate a Phase 1b study evaluating ME-344 plus Avastin®(bevacizumab) in relapsed colorectal cancer patients in the first half of calendar year 2023.

### **Fiscal Year 2022 and Recent Select Drug Candidate Pipeline Highlights**

*Zandelisib*

- In July 2022, MEI Pharma and Kyowa Kirin announced publication in The Lancet Oncology of data from the Phase 1b clinical study of zandelisib in patients with relapsed or refractory B-cell malignancy.
- In June 2022, MEI Pharma and Kyowa Kirin presented ongoing clinical data on zandelisib at both the American Society of Clinical Oncology (ASCO) Annual Meeting 2022 and European Hematology Association (EHA) 2022 Hybrid Congress.
- In March 2022, after meeting with the FDA, MEI Pharma and Kyowa Kirin announced they no longer plan to submit an FDA marketing application under the accelerated approval pathway using the single arm TIDAL study.
- In November 2021, MEI Pharma and Kyowa Kirin first reported data from the ongoing global Phase 2 TIDAL study evaluating zandelisib as a single agent in patients with relapsed or refractory follicular lymphoma. The data demonstrate:
  - Overall response rate of 70.3% in the primary efficacy population; the complete response rate was 35.2%.
  - 9.9% of patients discontinued therapy due to a drug related adverse event.
  - As of the data cutoff date, the data were not sufficiently mature to accurately estimate the final duration of response in the FL primary efficacy population. At that time, the median follow-up time for response was 8.4 months.



- In November 2021, MEI Pharma and Kyowa Kirin announced that the U.S. Food and Drug Administration granted orphan-drug designation to zandelisib for the treatment of follicular lymphoma.
- In August 2021, MEI Pharma and Kyowa Kirin announced the first patient dosed in the Phase 3 COASTAL study evaluating zandelisib plus rituximab in patients with relapsed or refractory indolent Non-Hodgkin B-cell lymphoma.

#### *Voruciclib*

- In November 2021, MEI reported data from the Phase 1 dose-escalation study of voruciclib, an oral CDK9 inhibitor, in patients with relapsed or refractory B-cell malignancies or acute myeloid leukemia at the American Society of Hematology annual meeting.

#### *ME-344*

- In April 2022, MEI reported preclinical data at the American Association for Cancer Research evaluating the combination of ME-344 with venetoclax in standard-of-care-resistant acute myeloid leukemia (AML) cell lines and relapsed or refractory (R/R) AML patient samples.

#### **Fiscal Year 2022 and Recent Corporate Highlights**

- During fiscal year 2022, MEI announced several additions to its management team. In June 2022, MEI appointed Anne Frese as Senior Vice President, Chief People Officer. In February 2022, MEI appointed Alejandro Ricart, M.D., as Senior Vice President, Clinical Development, and Yomara Gomez-Naiden as Senior Vice President, Quality. In July 2021, MEI appointed Tina C. Beamon, J.D. as Chief Compliance Officer.
- In December 2021, MEI completed a public offering of common stock resulting in net proceeds to the Company of approximately \$48.7 million.
- In November 2021, MEI appointed Sujay Kango to its Board of Directors.

#### **Fiscal Year 2022 Financial Results**

- As of June 30, 2022, MEI had \$153.3 million in cash, cash equivalents, and short-term investments with no outstanding debt.



- For the year ended June 30, 2022, net cash used in operations was \$48.7 million, compared to \$52.4 million for 2021. The decrease primarily related to changes in working capital.
- Research and development expenses were \$85.6 million for the year ended June 30, 2022, compared to \$69.4 million for 2021. The increase was primarily related to increased development costs associated with zandelisib, increased drug manufacturing costs, and increased consulting fees to support clinical trial activities.
- General and administrative expenses were \$30.5 million for the year ended June 30, 2022, compared to \$24.4 million for 2021. The increase primarily related to increased personnel costs, professional services costs, and general corporate overhead expenses incurred during 2022.
- MEI recognized revenues of \$40.7 million for the year ended June 30, 2022, compared to \$34.8 million for 2021. The increase in revenue related to increased reimbursement of expenses from Kyowa Kirin due to research and development activity related to zandelisib.
- Net loss was \$54.5 million, or \$0.44 per share, for the year ended June 30, 2022, compared to net loss of \$41.3 million, or \$0.37 per share for 2021. MEI had 133,152,045 shares of common stock outstanding as of June 30, 2022, compared with 112,614,643 shares as of June 30, 2021.
- The adjusted net loss for the year ended June 30, 2022, excluding non-cash expenses related to changes in the fair value of the warrants (a non-GAAP measure), was \$75.2 million, compared to an adjusted net loss of \$59.4 million for 2021.

### **Conference Call and Webcast**

MEI Pharma will host a conference call with simultaneous webcast today, September 8, 2022, 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](http://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](http://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 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.*

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**MEI PHARMA, INC.**

**BALANCE SHEETS**

(In thousands, except per share amounts)

	June 30,	
	<u>2022</u>	<u>2021</u>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 15,740	\$ 8,543
Short term investments	137,512	144,883
Total cash, cash equivalents and short-term investments	153,252	153,426
Unbilled receivables	10,044	7,582
Prepaid expenses and other current assets	3,830	3,809
Total current assets	167,126	164,817
Intangible assets, net	9,054	7,774
Property and equipment, net	1,660	1,507
Total assets	<u>\$ 177,840</u>	<u>\$ 174,098</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 7,918	\$ 6,355
Accrued liabilities	10,820	8,402
Deferred revenue	4,834	4,526
Operating lease liability	871	928
Total current liabilities	24,443	20,211
Deferred revenue, long-term	90,610	74,696
Operating lease liability, long-term	8,771	7,370
Warrant liability	1,603	22,355
Total liabilities	125,427	124,632
Stockholders' equity:		
Preferred stock, \$0.01 par value; 100 shares authorized; none outstanding	-	-
Common stock, \$0.0000002 par value; 226,000 shares authorized; 133,152 and 112,615 shares issued and outstanding at June 30, 2022 and 2021, respectively	-	-
Additional paid-in-capital	426,572	369,171
Accumulated deficit	(374,159)	(319,705)
Total stockholders' equity	52,413	49,466
Total liabilities and stockholders' equity	<u>\$ 177,840</u>	<u>\$ 174,098</u>



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

	Years Ended June 30,		
	2022	2021	2020
Revenue	\$ 40,697	\$ 34,796	\$ 27,756
Operating expenses:			
Cost of revenue	-	1,408	2,671
Research and development	85,641	69,398	34,065
General and administrative	30,540	24,414	16,717
Total operating expenses	116,181	95,220	53,453
Loss from operations	(75,484)	(60,424)	(25,697)
Other income (expense):			
Change in fair value of warrant liability	20,752	18,122	(22,870)
Interest and dividend income	284	510	1,395
Other income	(6)	486	-
Income tax expense	-	(8)	(1)
Net loss	\$ (54,454)	\$ (41,314)	\$ (47,173)
Net loss:			
Basic	\$ (54,454)	\$ (41,314)	\$ (47,173)
Diluted	\$ (62,500)	\$ (68,708)	\$ (47,173)
Net loss per share:			
Basic	\$ (0.44)	\$ (0.37)	\$ (0.52)
Diluted	\$ (0.50)	\$ (0.60)	\$ (0.52)
Shares used in computing net loss per share:			
Basic	124,473	112,527	91,080
Diluted	125,142	114,481	91,080

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

	Years Ended June 30,		
	2022	2021	2020
Net loss:	\$ (54,454)	\$ (41,314)	\$ (47,173)
Add: Change in fair value of warrant liability	(20,752)	(18,122)	22,870
Adjusted net loss:	\$ (75,206)	\$ (59,436)	\$ (24,303)