UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(D)
of the Securities Exchange Act of 1934

December 5, 2022
Date of report (Date of earliest event reported)

MEI Pharma, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**000-50484**	**51-0407811**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

11455 El Camino Real, Suite 250 **San Diego, California**	**92130**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code (858) 369-7100

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, $0.00000002 par value	MEIP	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter)

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 5.07 Submission of Matters to a Vote of Security Holders.

On December 6, 2022, MEI Pharma, Inc. (the "Company") announced that the Company's 2022 Annual Meeting of Stockholders (the "Annual Meeting") has been adjourned to January 5, 2023 at 9:00 a.m. Pacific Time. The record date for the adjourned Annual Meeting continues to be October 13, 2022.

The Company's stockholders and proxyholders will be able to attend and participate in the reconvened Annual Meeting online, be deemed to be present in person and vote their shares electronically, and submit questions prior to and during the reconvened Annual Meeting by visiting https://meetnow.global/MTGT7UU and entering their control number found on the proxy card they previously received for the Annual Meeting. This information is also displayed on the current Annual Meeting's website.

On December 5, 2022, the Company issued two press releases announcing important information about the Company and its plans moving forward. Because this information was released so soon before the Annual Meeting, the Company's management and board of directors decided to propose an adjournment of the Annual Meeting to give the Company's stockholders a chance to consider this information.

The vote results for the proposal to adjourn, the only proposal able to be acted upon, were as follows:

Votes For
85,187,224

This material may be deemed to be solicitation material in respect of the Annual Meeting to be reconvened on January 5, 2023. In connection with the Annual Meeting, the Company filed a definitive proxy statement with the SEC on October 27, 2022. BEFORE MAKING ANY VOTING DECISIONS, STOCKHOLDERS ARE URGED TO READ THE DEFINITIVE PROXY STATEMENT AND ANY OTHER RELEVANT DOCUMENTS FILED WITH THE SEC, BECAUSE THEY CONTAIN IMPORTANT INFORMATION ABOUT THE ANNUAL MEETING. No changes have been made in the proposals to be voted on by stockholders at the Annual Meeting. The Company's proxy statement and any other materials filed by the Company with the SEC can be obtained free of charge at the SEC's website at sec.gov or at www.edocumentview.com/MEIP.

Item 8.01 Other Events.

On December 5, 2022, MEI Pharma, Inc. (the "Company") and Kyowa Kirin Co., Ltd. issued a joint press release announcing that after receiving the most recent guidance from a late November meeting with the U.S. Food and Drug Administration (FDA), the companies are discontinuing global development of zandelisib outside of Japan for B-cell malignancies.

Additionally, on December 5, 2022, the Company announced that it plans to initiate a realignment of its clinical development efforts following the discontinuation of global development outside Japan of its PI3Kd inhibitor, zandelisib.

On December 6, 2022, the Company issued a press release announcing the adjournment of the Annual Meeting.

Copies of the press releases are filed herewith as Exhibits 99.1, 99.2 and 99.3 and are incorporated into this Item 8.01 by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release issued by MEI Pharma, Inc. and Kyowa Kirin Co., Ltd, dated December 5, 2022.
99.2	Press Release issued by MEI Pharma, Inc., dated December 5, 2022.
99.3	Press Release issued by MEI Pharma, Inc., dated December 6, 2022.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Company has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

MEI PHARMA, INC.

Dated: December 8, 2022

By: /s/ Daniel P. Gold
Name: Daniel P. Gold
Title: Chief Executive Officer

MEI Pharma and Kyowa Kirin Announce Discontinuation of Zandelisib Development Outside of Japan Following Recent FDA Meeting

SAN DIEGO and TOKYO, December 5 and 6, 2022 — MEI Pharma, Inc. (Nasdaq: MEIP), a pharmaceutical company focused on advancing new therapies for cancer, and Kyowa Kirin Co., Ltd. (Kyowa Kirin, TSE: 4151), a Japan-based global specialty pharmaceutical company creating innovative medical solutions utilizing the latest biotechnology, today announced that after receiving the most recent guidance from a late November meeting with the U.S. Food and Drug Administration (FDA), the companies are discontinuing global development of zandelisib outside of Japan for B-cell malignancies. Kyowa Kirin is continuing the ongoing clinical trials including Phase 2 MIRAGE study evaluating Japanese patients with relapsed or refractory indolent B-cell non-Hodgkin lymphomas and will explore the potential for a submission to Japanese health authorities based on data from the MIRAGE and TIDAL clinical trials.

“Based on the most recent guidance received from the FDA at a late November meeting, we have jointly decided with Kyowa Kirin to discontinue development of zandelisib outside of Japan. We are very disappointed to share this decision in light of our belief in the potential of zandelisib to benefit patients and meet the ongoing need for new options to treat relapsed or refractory indolent non-Hodgkin lymphomas,” said Daniel P. Gold, Ph.D., president and chief executive officer of MEI Pharma. “However, in light of FDA’s guidance, we no longer believe clinical development can be completed within a time period that would support further investment, or with sufficient certainty of the regulatory requirements to justify continued global development efforts.”

“We share MEI’s disappointment in making this decision,” said Yoshifumi Torii, Ph.D., executive officer, vice president, head of R&D division of Kyowa Kirin. “However, given the Phase 2 data we previously announced on zandelisib, we still see potential to continue the program in Japan to address unmet patient needs. We are continuing the Japanese clinical trials including Phase 2 MIRAGE trial and will consult the PMDA to understand the potential it offers for a regulatory submission.”

In March 2022, MEI Pharma and Kyowa Kirin reported the outcome of an end of Phase 2 meeting with the FDA wherein the agency discouraged a filing based on the single-arm Phase 2 TIDAL trial evaluating zandelisib in patients with relapsed or refractory follicular lymphoma. At this meeting, the FDA stated that a randomized trial should be used to support an initial zandelisib registration in patients with indolent non-Hodgkin lymphoma and, accordingly, data generated from single arm studies such as the Phase 2 TIDAL trial are insufficient to adequately assess the risk/benefit of PI3K inhibitors evaluating indolent non-Hodgkin lymphoma. At that time the FDA emphasized that the companies continue efforts with the ongoing randomized Phase 3 COASTAL trial evaluating patients with relapsed or refractory follicular or marginal zone lymphomas. Subsequently, at an April 2022 meeting of the FDA Oncology Drugs Advisory Committee, the committee voted that future approvals of PI3K inhibitors for hematologic malignancies should be supported by randomized data.

In late November 2022, MEI Pharma and Kyowa Kirin met with the FDA in a follow-up meeting to the March 2022 end of Phase 2 meeting. At this meeting, FDA provided further guidance regarding the design and statistical analysis for the COASTAL trial. Following the November meeting, the companies concluded that a clinical trial consistent with the recent FDA guidance, including modification of the COASTAL trial, would likely not be feasible to complete within a time period that would support further investment. As a result, global development of zandelisib for indolent forms of non-Hodgkin lymphoma, except for Japan, is being discontinued.

The discontinuation of zandelisib development outside of Japan is a business decision based on the most recent regulatory guidance from the FDA and is not related to the zandelisib clinical data generated to date. Kyowa Kirin is continuing the ongoing clinical trials including Phase 2 MIRAGE trial evaluating Japanese patients with relapsed or refractory indolent B-cell non-Hodgkin lymphomas and will explore submitting the MIRAGE and TIDAL trials for marketing authorization in Japan. MIRAGE is a Phase 2 trial, similar in design to the global Phase 2, single-arm, TIDAL trial. In November 2022 Kyowa Kirin and MEI announced positive topline data from the Phase 2 MIRAGE trial. MEI and Kyowa Kirin plan to immediately start winding-down ongoing clinical studies outside of Japan, including the Phase 3 COASTAL trial and the Phase 2 CORAL trial evaluating patients with relapsed or refractory chronic lymphocytic leukemia. Depending on the achievement of certain regulatory and commercial milestones in Japan, MEI may be eligible for additional payments from Kyowa Kirin under the current agreement. MEI may also be entitled to royalties on any sales of zandelisib in Japan.

About zandelisib

Zandelisib, a selective PI3Kd inhibitor, is an investigational cancer treatment being developed as an oral, once-daily, treatment for patients with B-cell malignancies.

In April 2020, MEI and Kyowa Kirin entered a global license, development, and commercialization agreement to further develop and commercialize zandelisib. MEI and Kyowa Kirin were to co-develop and co-promote zandelisib in the U.S., with MEI booking all revenue from the U.S. sales. Kyowa Kirin has exclusive commercialization rights outside of the U.S.

About MEI Pharma

MEI Pharma, Inc. (Nasdaq: MEIP) is a pharmaceutical company focused on developing potential new therapies for cancer. MEI Pharma's portfolio of drug candidates includes clinical stage candidates with differentiated mechanisms of action intended to address unmet medical needs and 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.

About Kyowa Kirin

Kyowa Kirin strives to create and deliver novel medicines with life-changing value. As a Japan-based global specialty pharmaceutical company with a heritage of more than 70 years, the company applies cutting-edge science, including expertise in antibody research and engineering, to address the needs of patients across multiple therapeutic areas such as nephrology, oncology, immunology/allergy and neurology. Across its four regions – Japan, Asia Pacific, North America and EMEA/International – Kyowa Kirin focuses on its purpose, to make people smile, and is united by its shared values of commitment to life, teamwork, innovation and integrity. Learn more about the Company at www.kyowakirin.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 including, without limitation, statements regarding: MEI's plans to discontinue development of zandelisib, wind down the currently ongoing clinical studies of zandelisib being conducted by MEI, , the potential, safety, efficacy, and regulatory and clinical progress of our 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 ability to successfully wind down the currently ongoing clinical studies of zandelisib; our ability to negotiate a termination of the existing zandelisib global development and commercialization agreement between MEI and Kyowa Kirin and negotiate a license agreement for Japan; our failure to successfully commercialize 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.


Contacts

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MEI Pharma Initiates Strategic Realignment

– Company continuing development efforts on its two early clinical-stage oncology assets: voruciclib and ME-344 –

– MEI expects existing cash sufficient to fund through clinical data milestones for voruciclib and ME-344 –

SAN DIEGO, December 5, 2022 – MEI Pharma, Inc. (Nasdaq: MEIP), a clinical-stage pharmaceutical company focused on advancing new therapies for cancer, today announced that it plans to initiate a realignment of its clinical development efforts following the discontinuation of global development outside Japan of its PI3K delta inhibitor, zandelisib. As part of the realignment, the company plans to streamline its organization towards the development of two earlier clinical-stage assets, voruciclib and ME-344. Following completion of the workforce reductions, MEI expects its existing cash, cash equivalents and marketable securities will be sufficient to fund operations through clinical data milestones for both voruciclib and ME-344. The company further announced that it has engaged Torreya Partners as financial advisor to help explore additional strategic opportunities.

"In light of the determination we made with our global partner, Kyowa Kirin, to discontinue development of zandelisib outside of Japan after a recent meeting with FDA, we have had to make some tough decisions. We intend to continue development of our earlier-stage clinical assets, streamline MEI's operations towards these efforts, and consider additional strategic opportunities," said Daniel P. Gold, Ph.D., president and chief executive officer of MEI Pharma. "As we move forward with the planned development of voruciclib and ME-344, two investigational candidates representing potential treatments for various hematological and solid tumor cancers, I want to express my deep gratitude to the MEI team. I am very proud of our work, and the simply exemplary efforts, to develop zandelisib. I also want to recognize the collaborative efforts of our partner, Kyowa Kirin, and sincerely thank all the healthcare providers and patients that contributed to zandelisib's development."

Expected Drug Candidate Pipeline Developments

Voruciclib – Oral cyclin-dependent kinase 9 (CDK9*)* inhibitor for the treatment of B-cell malignancies and acute myeloid leukemia, as well as solid tumors.

- After initiating dosing of the first patient in November, continue advancing the dosing of patient cohorts evaluating voruciclib in combination with Venclexta® (venetoclax) in patients with acute myeloid leukemia in the ongoing Phase 1 study.
    - Provide a clinical data update in CY2023.
- Continue preclinical evaluation of the role CDK9 in cMYC regulation in solid tumors expressing KRAS mutations to support potential clinical development as a treatment for solid tumors.

ME-344 – Tumor selective mitochondrial inhibitor for the treatment of solid tumors.

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

Strategic Realignment Overview

MEIP plans to streamline its organization towards the continued clinical development of voruciclib and ME-344. As a result, it plans to initiate a staggered workforce reduction, initially representing approximately 30% of the current workforce in connection with the wind down of the zandelisib development program outside of Japan, which costs are shared with Kyowa Kirin, our global development partner. Following completion of the zandelisib wind down and associated workforce reductions, MEI expects that, along with any additional workforce reductions to be determined to fully align resources going forward, its existing cash, cash equivalents and marketable securities will be sufficient to fund operations through clinical data milestones for both voruciclib and ME-344.

About Voruciclib

Voruciclib is an orally administered Cyclin-dependent kinase 9 (CDK9) inhibitor being clinically investigated for hematological malignancies. Potential applications in solid tumors are also being actively explored. CDK9 has important functions in cell cycle regulation, including the modulation of two therapeutic targets in cancer: myeloid leukemia cell differentiation protein ("MCL1") and the MYC proto-oncogene protein ("MYC") which regulates cell proliferation and growth. Voruciclib is currently being evaluated in a Phase 1b trial evaluating dose and schedule in patients with acute myeloid leukemia ("AML") and B-cell malignancies. Applications in solid tumors are also being considered where MYC is dysregulated.

About ME-344

ME-344 is a tumor selective mitochondrial inhibitor drug candidate targeting the OXPHOS pathway involved in the production of adenosine triphosphate, or ATP, in the mitochondria. It is in clinical development to treat solid tumors. Although clinical investigation of ME-344 has demonstrated single agent activity in patients with solid tumors, using it in combination with other cancers therapies is thought to hold more significant potential for patients. Data reported at the 2018 ASCO conference from an investigator-initiated, multi-center, randomized study of ME-344 in combination with the VEGF inhibitor bevacizumab (Avastin®) in women with demonstrated biologic activity in the ME-344 treatment group supporting further clinical investigation.

About MEI Pharma

MEI Pharma, Inc. (Nasdaq: MEIP) is a pharmaceutical company focused on developing potential new therapies for cancer. MEI Pharma's portfolio of drug candidates includes clinical stage candidates with differentiated mechanisms of action intended to address unmet medical needs and 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 including, without limitation, statements regarding: the potential, safety, efficacy, and regulatory and clinical progress of voruciclib, ME-344 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; the sufficiency of our cash, cash equivalents and short-term investments to fund our operations through clinical data milestones for both voruciclib and ME-344; our ability to recognize the anticipated benefits of our planned strategic realignment; and our ability to identify and enter into potential future strategic opportunities. 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 develop 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 realize the anticipated benefits of our planned strategic realignment; our inability to identify and enter into potential future strategic opportunities; 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.

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MEI Pharma Announces Adjournment of Annual Meeting of Stockholders

SAN DIEGO, December 6, 2022 — MEI Pharma, Inc. (Nasdaq: MEIP), a pharmaceutical company focused on advancing new therapies for cancer, announced today that its annual meeting of stockholders has been adjourned to January 5, 2023, at 9:00 a.m. Pacific Time. The record date for the adjourned annual meeting continues to be October 13, 2022.

MEI Pharma stockholders and proxyholders will be able to attend and participate in the reconvened annual meeting online, be deemed to be present in person and vote their shares electronically, and submit questions prior to and during the reconvened annual meeting by visiting https://meetnow.global/MTGT7UU and entering their control number found on the proxy card they previously received for the annual meeting. This information is also displayed on the current meeting's website.

On December 5, 2022, MEI issued two press releases announcing important information about the company and its plans moving forward. Because this information was released so soon before the annual meeting, MEI's management and board of directors decided to propose an adjournment of the annual meeting to give MEI's stockholders a chance to consider this information.

Stockholders who have previously submitted a proxy or otherwise voted do not need to take any action and all previously submitted proxies will be voted at the adjourned annual meeting unless properly revoked.

Our Board of Directors continues to recommend that stockholders vote "FOR" proposals one through five.

Important Information

This material may be deemed to be solicitation material in respect of the Annual Meeting to be reconvened on January 5, 2023. In connection with the Annual Meeting, the Company filed a definitive proxy statement with the SEC on October 27, 2022. BEFORE MAKING ANY VOTING DECISIONS, STOCKHOLDERS ARE URGED TO READ THE DEFINITIVE PROXY STATEMENT AND ANY OTHER RELEVANT DOCUMENTS FILED WITH THE SEC, BECAUSE THEY CONTAIN IMPORTANT INFORMATION ABOUT THE ANNUAL MEETING. No changes have been made in the proposals to be voted on by stockholders at the Annual Meeting. The Company's proxy statement and any other materials filed by the Company with the SEC can be obtained free of charge at the SEC's website at sec.gov or at www.edocumentview.com/MEIP.

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