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

Date of Report (Date of earliest event reported): March 24, 2022

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

Delaware	000-50484	51-0407811
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. 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

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 (*see* General Instruction A.2. below):

☐ 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	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 8.01. Other Events

On March 24, 2022, MEI Pharma, Inc. (the "Company") and Kyowa Kirin Co., Ltd issued a press release announcing a recent meeting with the U.S. Food Drug Administration (FDA) to discuss the pursuit of a marketing authorization for zandelisib, a phosphatidylinositol-3-kinase ("PI3K") inhibitor drug candidate, via the accelerated approval pathway under 21 CFR Part 314.500, Subpart H, based on data generated by the single arm Phase 2 TIDAL study.

A copy of the above referenced press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release dated March 24, 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, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

MEI PHARMA, INC.

Date: March 24, 2022

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

MEI Pharma and Kyowa Kirin Provide Regulatory Update on Zandelisib Following Meeting with the FDA

– MEI to Host Zandelisib Program Update Webcast Today at 4:30 p.m. Eastern Time –

SAN DIEGO and TOKYO, Japan – March 24 and 25, 2022– MEI Pharma, Inc. (NASDAQ: MEIP) and Kyowa Kirin Co., Ltd. (Kyowa Kirin, TSE: 4151), today provided an update after a recent meeting with the U.S. Food Drug Administration (FDA) to discuss the pursuit of a marketing authorization for zandelisib, a phosphatidylinositol-3-kinase ("PI3K") inhibitor drug candidate, via the accelerated approval pathway under 21 CFR Part 314.500, Subpart H, based on data generated by the single arm Phase 2 TIDAL study. In the meeting, the FDA informed the companies of its position that a randomized trial is now needed to adequately assess drug efficacy and safety of PI3K inhibitor drug candidates, including zandelisib. Based on this view, the agency discouraged a filing based on the Phase 2 TIDAL study data and emphasized that the companies continue efforts with the ongoing, randomized Phase 3 COASTAL study as planned. Accordingly, in line with the FDA's recommendation, the companies do not plan to submit an FDA marketing application based on the single arm Phase 2 TIDAL study. In addition, while the FDA stated that safety on the 60 mg intermittent schedule appears reasonable, it recommended continued dose exploration to further support the current dose and regimen.

"The FDA's current position on the assessment of benefit and risk of PI3K inhibitors solely based on single arm studies appears to have evolved, as evidenced by the position the FDA communicated at the recent meeting on zandelisib, and the upcoming ODAC meeting scheduled for April 21, 2022 to discuss whether randomized data should be required for the class of PI3K inhibitors to demonstrate appropriate evidence of efficacy and safety," said Daniel P. Gold, Ph.D., president and chief executive officer of MEI Pharma. "Clearly, the outcome of our recent FDA meeting is a disappointing development. Nonetheless we will continue to focus on the ongoing Phase 3 COASTAL study as we consider options that provide the most expeditious approval pathway utilizing randomized data, and which we believe will demonstrate the potential of zandelisib to help patients. Today's announcement in no way diminishes our conviction to the development of zandelisib and the promise of its emerging clinical profile. Based on current projections, MEI believes we have sufficient cash for operations to complete the COASTAL study enrollment in 2024."

Dr. Gold continued: "In partnership with Kyowa Kirin, we remain committed to the ultimate potential of zandelisib to address important medical needs as a single agent or in combination with other therapies providing physicians, and their patients, important new treatment options. We plan on completing evaluation of the Phase 2 TIDAL study, and look forward to sharing final data later this year to further advance an understanding of zandelisib's clinical utility."

“Our dialogue with the FDA has updated our understanding of the evolving regulatory view of the PI3K inhibitor drug class. With this knowledge, we can focus our efforts to advance the COASTAL program,” said Yoshifumi Torii, Ph.D., Executive Officer, Vice President, Head of R&D of Kyowa Kirin. “Our teams around the world have made steady progress to enroll patients and give us important momentum. Together with MEI Pharma, we will continue to work with the investigators, patients, and advocacy organizations to drive continued progress.”

About 21 CFR Part 314.500, Subpart H

Under 21 CFR Part 314.500, Subpart H, a drug candidate may be eligible for accelerated approval if it is intended to treat a serious or life-threatening disease or condition, and the product would provide meaningful therapeutic benefit over existing treatments. Under accelerated approval, a product may be approved based on adequate and well-controlled clinical studies establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality and that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefits. As a condition of approval, the FDA may require that a sponsor receiving accelerated approval perform adequate and well-controlled post-marketing clinical studies to verify the predicted clinical benefit.

The FDA historically granted accelerated approval to PI3K inhibitors under 21 CFR Part 314.500, Subpart H for relapsed or refractory follicular and marginal zone lymphomas. Such approvals were granted with the expectation that confirmatory Phase 3 studies producing randomized data would follow the approval. Generally the FDA has expressed a preference for randomized trials however, the recent meeting with the FDA was the first instance that the agency informed the companies that data from a single arm study, such as the Phase 2 TIDAL clinical study, would not be adequate to evaluate benefit and risk under 21 CFR Part 314.500, Subpart H and that a randomized study is required to support a potential accelerated approval.

About Zandelisib

Zandelisib, a selective PI3KÎ´ inhibitor, is an investigational cancer treatment being developed as an oral, once-daily, treatment for patients with B-cell malignancies. Clinical trials are investigating the efficacy and safety of zandelisib as a single agent and in combination with other modalities while administered on an Intermittent Dosing Regimen (IDT). The IDT leverages molecular and biologic properties specific to zandelisib.

In November 2021, MEI Pharma announced data from ongoing Phase 2 TIDAL study (NCT03768505) evaluating zandelisib as a single agent for follicular lymphoma (FL) patients who received at least two prior systemic therapies. Zandelisib demonstrated a 70.3% objective response rate (ORR) as determined by Independent Review Committee (IRC) assessment in the primary efficacy population (n=91). In addition, 35.2% of patients achieved a complete response. At the time of the data cutoff, the data were insufficiently mature to accurately estimate duration of response (DOR). In line with previously reported data from the Phase 1B

study, zandelisib was generally well tolerated. With 9.4 months (range: 0.8-24) median duration of follow-up in the total study population (n=121), interim data demonstrated a discontinuation rate due to any drug related adverse event of 9.9%. Patients enrolled in the study will continue to be followed for safety and DOR.

Ongoing zandelisib studies include the cohort in TIDAL evaluating patients with R/R marginal zone lymphoma (MZL) and continuing follow up in the cohort of the study evaluating patients with R/R FL. Also ongoing is the Phase 3 COASTAL study (NCT04745832) comparing zandelisib plus rituximab to standard of care chemotherapy plus rituximab, in patients with R/R FL or MZL who received more than one prior line of therapy, which must have included an anti-CD20 antibody in combination with chemotherapy or lenalidomide. COASTAL is intended to support marketing applications in the U.S. and globally.

Other ongoing studies include a Phase 2 pivotal study in Japan (NCT04533581) in patients with indolent B-cell non-Hodgkin's lymphoma (iNHL) without small lymphocytic lymphoma (SLL), lymphoplasmacytic lymphoma (LPL), and Waldenström's macroglobulinemia (WM) conducted by Kyowa Kirin.

In March 2020, the FDA granted zandelisib Fast Track designation for the treatment of adult patients with R/R follicular lymphoma who have received at least two prior systemic therapies. In November 2021, the FDA granted zandelisib Orphan Drug designation for the treatment of patients with follicular lymphoma.

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 will 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.

Conference Call and Webcast

MEI Pharma will host a conference call and webcast on March 24, 2022 at 4:30pm Eastern Time. 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 call. The event is also available via a live audio webcast at this link, and on the Investors section of MEI's website at https://www.meipharma.com/investors/events-calendar. A replay of the webcast will be archived on MEI's website for at least 30 days following the event.

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.

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 more than 70-year heritage, 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 and on Twitter @KyowaKirin_US and 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 statements regarding the results of our clinical trials of zandelisib, the anticipated timing of our submission of an FDA marketing application for zandelisib, the anticipated timing of the disclosure of the final study data for our Phase 2 TIDAL trial, the timing and success of enrollment for our Phase 3 COASTAL trial, our projected financial position and our expected cash runway, the overall advancement of our product candidates in clinical trials and our plans to continue development of our product candidates. We may in some cases use terms such as "predicts," "believes," "potential," "continue," "anticipates," "estimates," "expects," "plans," "intends," "may," "could," "might," "likely," "will," "should" or other words that convey uncertainty of the future events or outcomes to identify these forward-looking statements. 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 of our product candidates, or the failure to obtain such approval, of our product candidates; uncertainties or differences in interpretation in clinical trial results; the risk that our clinical trials are discontinued or delayed for any reason, including for safety, tolerability, enrollment, manufacturing or economic reasons; 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 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. to these forward-looking statements.

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