# 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): April 13, 2020**

# 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.)** |

**3611 Valley Centre Drive, Suite 500, 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 1.01 Entry into a Material Definitive Agreement.**

**License, Development and Commercialization Agreement**

On April 13, 2020, MEI Pharma, Inc. (the "Company") entered into a License, Development and Commercialization Agreement (the "Agreement") with Kyowa Kirin Co., Ltd. (formerly known as Kyowa Hakko Kirin Co., Ltd.), a Japanese corporation having an office at 1-9-2 Otemachi, Chiyoda-ku, Tokyo 100-0004, Japan ("KKC"), effective as of April 13, 2020 (the "Effective Date"). Pursuant to the terms of the Agreement, the Company and KKC have agreed to terminate the License, Development and Commercialization Agreement dated October 31, 2018 (the "JP Agreement") and to expand the scope of the JP Agreement to collaborate on the development, manufacturing and commercialization of ME-401 (the "Collaboration") globally in accordance with the Agreement.

The Agreement has a term (the "Term") commencing on the Effective Date and continuing in full force and effect, on a country-by-country and product-by-product basis, until the latest of the expiration of the applicable patent, the expiration of regulatory exclusivity or ten years after the date of first commercial sale for such product in such country.

The Company grants to KKC a co-exclusive, sublicensable, payment-bearing license under certain patents and know-how controlled by the Company to develop and commercialize ME-401 and any pharmaceutical product containing ME-401 for all human indications in the U.S., and an exclusive (subject to certain retained rights to perform obligations under the Agreement), sublicensable, payment-bearing, license under certain patents and know-how controlled by the Company to develop and commercialize ME-401 and any pharmaceutical product containing ME-401 for all human indications in countries outside of the United States (the "Ex-US"). KKC grants to the Company a co-exclusive, sublicensable, license under certain patents and know-how controlled by KKC to develop and commercialize ME-401 for all human indications in the U.S., and a co-exclusive, sublicensable, royalty-free, fully paid license under certain patents and know-how controlled by KKC to perform the Company's obligations in the Ex-US under the Agreement.

KKC will be responsible for the development and commercialization of ME-401 in the EX-US and, subject to certain exceptions, will be solely responsible for all costs related thereto. The Company and KKC will co-develop and co-promote ME-401 in the U.S., with the Company booking all revenue from U.S. sales. The Company and KKC will share U.S. profits and costs (including development costs) on a 50-50 basis. The Company will also provide to KKC certain drug supplies necessary for the development and commercialization of ME-401 in the Ex-US pursuant to supply agreements to be entered into on customary terms, with the understanding that KKC will assume responsibility for manufacturing for the Ex-US as soon as practicable.

Under the terms of the Agreement, KKC will pay the Company an initial payment of $100 million within 30 days after the receipt of an invoice from the Company. The Company may earn up to approximately $582.5 million in potential development and commercialization milestone payments, plus royalties on net sales of ME-401 in the Ex-US, which are tiered beginning in the teens.

The Collaboration will be managed by a joint steering committee in which both parties are represented equally, which will serve as a forum for the sharing of information and facilitating communications between the parties regarding development and commercialization activities.

Under the Agreement, each party will maintain ownership of its own technology and intellectual property existing prior to, or outside of, the Collaboration, each party will be the exclusive owner of any and all inventions it solely develops under the Agreement, and the parties shall jointly own any and all inventions developed by the parties jointly under the Agreement.

KKC has the right to terminate the Agreement for convenience upon prior written notice. If either party materially breaches the Agreement, the non-breaching party may terminate the Agreement if the breach is not cured. If either party files or institutes bankruptcy, reorganization, liquidation or receivership proceedings, or assigns a substantial portion of its assets for the benefit of creditors, the other party may terminate the Agreement, provided, that, if such proceeding is involuntary, the other party may terminate the Agreement only if such proceeding is not dismissed. The Company may also terminate the Agreement in the event that KKC challenges any of the Company's licensed patents. The Agreement shall also automatically terminate if KKC fails to make the upfront payment and is terminable by the Company if KKC fails to comply with certain data privacy and security obligations. Each party may terminate the Agreement in connection with an event of force majeure under certain circumstances.

If KKC terminates the Agreement due to an uncured material breach of the Agreement by the Company (or due to the Company's filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings, or the Company's assignment of a substantial portion of its assets for the benefit of creditors), all licenses granted to KKC will immediately terminate and KKC shall cease developing and commercializing ME-401. In the event of such termination, KKC shall either withdraw all regulatory approvals for ME-401 or, with the Company's prior written consent, assign such regulatory approvals and related materials to the Company. If KKC terminates the Agreement for convenience or in connection with a force majeure event, or if the Company terminates the Agreement due to KKC's uncured material breach of the Agreement, KKC's filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings, or KKC's assignment of a substantial portion of its assets for the benefit of creditors, KKC's challenge of any of the Company's licensed patents, KKC's failure to make the upfront payment, KKC's failure to comply with certain data privacy and security obligations, or in connection with a force majeure event, in each such case, all licenses granted to KKC will immediately terminate, KKC shall cease developing and commercializing ME-401, assign all regulatory approvals for ME-401 and related materials to the Company, and assign, or grant the Company an exclusive, royalty-bearing, worldwide, perpetual and irrevocable license to, certain data and technology developed by KKC, for the development and commercialization of ME-401 by the Company.

The foregoing description of the material terms of the Agreement is qualified in its entirety by reference to the complete text of the Agreement, which the Company intends to file, with confidential terms redacted, with the Securities and Exchange Commission as an exhibit to the Company's Annual Report on Form 10-K for the year ending June 30, 2020.

**Item 1.02 Termination of a Material Definitive Agreement.**

On April 13, 2020, the Company and KKC agreed to terminate the License, Development and Commercialization Agreement (JP Agreement), dated October 31, 2018. Pursuant to the terms of the Agreement, the Company and KKC had agreed to collaborate on the development, manufacturing and commercialization of ME-401 in Japan. The JP Agreement was replaced with a broader License, Development and Commercialization Agreement between the two parties, entered into on April 13, 2020.

**Item 8.01 Other Events.**

On April 14, 2020, the Company issued a press release regarding the Agreement, a copy of which is attached as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

**Supplemental Risk Factor**

In light of recent developments relating to the COVID-19 global pandemic, the Company is supplementing the risk factors previously disclosed in Item 1A. of its Annual Report on Form 10-K for the year ended June 30, 2019, as filed with the Securities and Exchange Commission on August 28, 2019, to include the following risk factor under the heading “Risks Related to our Business and Industry”:

***The outbreak of the novel coronavirus disease, COVID-19, or other pandemic, epidemic or outbreak of an infectious disease may materially and adversely impact our business, including our preclinical studies and clinical trials.***

In December 2019, the novel coronavirus disease, COVID-19, was identified in Wuhan, China. This virus has been declared a pandemic and has spread to multiple global regions. The outbreak and government measures taken in response have also had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. In response to the COVID-19 outbreak, “shelter in place” orders and other public health guidance measures have been implemented across much of the United States, Europe and Asia, including in the locations of our offices, clinical trial sites, key vendors and partners. Our clinical development program timelines may be negatively affected by COVID-19, which could materially and adversely affect our business, financial condition and results of operations. Further, due to “shelter in place” orders and other public health guidance measures, we have implemented a work-from-home policy for all staff members excluding those necessary to maintain minimum basic operations. Our increased reliance on personnel working from home may negatively impact productivity, or disrupt, delay or otherwise adversely impact our business.

As a result of the COVID-19 outbreak, or similar pandemics, and related “shelter in place” orders and other public health guidance measures, we have and may in the future experience disruptions that could materially and adversely impact our clinical trials, business, financial condition and results of operations. Potential disruptions include but are not limited to:

- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in initiating or expanding clinical trials, including delays or difficulties with clinical site initiation and recruiting clinical site investigators and clinical site staff;
- increased rates of patients withdrawing from our clinical trials following enrollment as a result of contracting COVID-19 or other health conditions or being forced to quarantine;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures, which may impact the integrity of subject data and clinical study endpoints;
- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines;
- delays or disruptions in preclinical experiments and investigational new drug application-enabling studies due to restrictions of on-site staff and unforeseen circumstances at contract research organizations and vendors;

- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- limitations on our ability to recruit and hire key personnel due to our inability to meet with candidates because of travel restrictions and “shelter in place” orders;
- limitations on employee resources that would otherwise be focused on the conduct of our preclinical studies and clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people; and
- interruption or delays to our sourced discovery and clinical activities.

The COVID-19 pandemic continues to rapidly evolve. The extent to which the outbreak impacts our business, preclinical studies and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease. If we or any of the third parties with whom we engage were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted.

In addition, the trading prices for our common stock and other biopharmaceutical companies have been highly volatile as a result of the COVID-19 pandemic. As a result, we may face difficulties raising capital through sales of our common stock or such sales may be on unfavorable terms.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

| | |
|---|---|
| Exhibit 99.1 | Press release of MEI Pharma, Inc. dated April 13, 2020 relating to License, Development and Commercialization Agreement with Kyowa Kirin Co., Ltd. |

**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.

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

Dated: April 14, 2020

**MEI Pharma and Kyowa Kirin Announce Global License, Development and Commercialization Agreement for ME-401**

- *MEI Pharma and Kyowa Kirin will co-develop and co-promote ME-401 in the U.S.; MEI to book U.S. sales on 50-50 profit and cost sharing*
- *Kyowa Kirin obtains exclusive commercialization rights ex-U.S.; MEI to receive escalating tiered royalty payments on ex-U.S. sales*
- *MEI to receive $100 million in an upfront cash payment and is eligible to receive up to an additional $582.5 million based on the achievement of specified development, regulatory and commercial milestones*
- *MEI to host conference call on April 14 at 8:00 a.m. ET*

SAN DIEGO, and TOKYO, April 14, 2020 – MEI Pharma, Inc. (NASDAQ: MEIP) and Kyowa Kirin Co., Ltd. (Kyowa Kirin, TSE: 4151) today jointly announced that the companies have entered into a global license, development and commercialization agreement to further develop and commercialize MEI's ME-401, an oral, once-daily, investigational drug-candidate, selective for phosphatidylinositol 3-kinase delta (PI3Kd), in clinical development for the treatment of B-cell malignancies. MEI and Kyowa Kirin will co-develop and co-promote ME-401 in the U.S., with MEI booking all revenue from U.S. sales. Kyowa Kirin has exclusive commercialization rights outside of the U.S.

ME-401 is being studied in the ongoing Phase 2 TIDAL clinical trial evaluating patients with relapsed or refractory follicular lymphoma which, subject to results, may support an accelerated approval of a marketing application with the U.S. Food and Drug Administration (FDA). An ongoing Phase 1b study is evaluating ME-401 as a monotherapy and in combination with rituximab (Rituxan®) or zanubrutinib (Brukinsa™) in patients with B-cell malignancies. Also, a Phase 1 study was initiated in 2019 evaluating ME-401 as a monotherapy in patients with indolent B-cell malignancy in Japan.

"This global partnership with Kyowa Kirin is a key step to achieving our goal of broadly developing and commercializing ME-401, optimizing the opportunity to benefit patients across multiple B-cell malignancies inside and outside the U.S., and also building value for our shareholders," said David M. Urso, J.D., chief operating officer & general counsel of MEI Pharma. "The decision to expand our alliance with Kyowa Kirin is based on the successful relationship we've built working together to date under our 2018 Japan license agreement, and the respect we have for Kyowa Kirin and their ability to jointly execute our shared vision of ME-401 in the U.S. and around the world."

"I am delighted to expand our agreement with MEI Pharma for the development and commercialization of ME-401 all over the world," said Tomohiro Sudo, Executive Officer, Director of Strategic Product Planning Department for Kyowa Kirin. "We believe that ME-401 may be an important new treatment option for patients and further enhances our global oncology pipeline."

**About the Global License, Development and Commercialization Agreement**

Under the terms of the agreement, which substantially retains and consolidates the terms of the 2018 license agreement between MEI and Kyowa Kirin to develop and commercialize ME-401 in Japan, MEI will receive a $100 million upfront payment from Kyowa Kirin. MEI is also eligible to receive up to $582.5 million in additional payments from Kyowa Kirin depending on the achievement of certain U.S. and ex-U.S. development, regulatory and commercial milestones.

If approved by FDA in the U.S., MEI and Kyowa Kirin will co-promote ME-401, with MEI booking all revenue from sales. MEI and Kyowa Kirin will share U.S. profits and costs (including development costs) on a 50-50 basis.

Outside the U.S., Kyowa Kirin will have exclusive commercialization rights, lead commercialization and book all revenues from sales of ME-401. Kyowa Kirin will pay MEI escalating tiered royalties on ex-U.S. sales starting in the teens. Kyowa Kirin will be responsible for all incremental ex-U.S. clinical development costs and all ex-U.S. regulatory, CMC and commercial costs.

The companies have agreed to a development plan designed to broadly evaluate ME-401 in patients with various B-cell malignancies, including in combination with other agents.

**Conference Call & Webcast Information (Conducted by MEI)**

When: April 14, 2020, 8:00 a.m. ET
Dial-in: 1-877-879-1183 (International Toll: 1-412-902-6703)
Conference ID: 0809665

Please join the conference call at least 10 minutes early to register. You can access the live webcast under the investor relations section of MEI's website at: www.meipharma.com. A replay of the conference call will be archived under events and webcasts for at least 30 days after the call.

**About ME-401**

MEI-401 is an investigational treatment and not approved by the U.S. Food and Drug Administration (FDA) or other Health Authorities. Clinical development of ME-401 as an oral, once-daily, selective PI3Kd inhibitor for the treatment of B-cell malignancies is ongoing. The U.S. FDA recently granted ME-401 Fast Track designation.

MEI is currently conducting two ongoing studies evaluating ME-401. The first is a Phase 2 clinical trial evaluating ME-401 as a monotherapy for the treatment of adults with relapsed or refractory follicular lymphoma after failure of at least two prior systemic therapies including chemotherapy and an anti-CD20 antibody. Subject to the results, upon completion of the Phase 2 clinical trial, ME-401 is planned to be submitted with the FDA to support an accelerated approval of a marketing application under 21 CFR Part 314.500, Subpart H. The second study is a multi-arm, open-label, Phase 1b dose escalation and expansion trial evaluating ME-401 as a monotherapy and in combination with other therapies or investigational agents in patients with relapsed or refractory B-cell malignancies. Additionally, a Phase 1 study was initiated by Kyowa Kirin in 2019 evaluating ME-401 as a monotherapy in patients with indolent B-cell malignancy in Japan.

**About MEI Pharma**

MEI Pharma, Inc. (Nasdaq: MEIP) is a late-stage pharmaceutical company focused on developing potential new therapies for cancer. Our portfolio of drug candidates contains four clinical-stage assets,

including one candidate in an ongoing global registration trial and another candidate in a Phase 2 clinical trial which may support an accelerated approval marketing application with the U.S. Food and Drug Administration. Each of our 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.

**About Kyowa Kirin**

Kyowa Kirin commits to innovative drug discovery driven by state-of-the-art technologies. The company focuses on creating new value in the four therapeutic areas: nephrology, oncology, immunology/allergy and neurology. Under the Kyowa Kirin brand, employees from 36 group companies across North America, EMEA and Asia/Oceania unite to champion the interests of patients and their caregivers by discovering solutions to address unmet medical needs. You can learn more about the business of Kyowa Kirin 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. 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.*

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