
**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): October 31, 2018

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

Delaware
(State or other jurisdiction of
incorporation or organization)

000-50484
(Commission
File Number)

51-0407811
(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))

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 October 31, 2018, MEI Pharma, Inc. (the “Company”) entered into a License, Development and Commercialization Agreement (the “Agreement”) with Kyowa Hakko Kirin Co., Ltd (“KHK”). Pursuant to the terms of the Agreement, the Company and KHK have agreed to collaborate on the development, manufacturing and commercialization of ME-401 in Japan (the “Collaboration”).

The Agreement has a term (the “Term”) commencing on the effective date and continuing until the later of the date (i) of expiration of the applicable patents in Japan, (ii) of expiration of regulatory exclusivity in Japan or (iii) that is 10 years after the first commercial sale in Japan.

During the Term, the Company grants to KHK an exclusive (subject to certain retained rights to perform obligations under the Agreement), sublicenseable, payment-bearing, license under and to 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 Japan. KHK will be primarily responsible for the development of ME-401 in Japan and, subject to certain exceptions, will be solely responsible for all costs related thereto. The Company will be primarily responsible for the development of ME-401 outside Japan and will be solely responsible for all costs related thereto. The Company will also provide to KHK certain drug supplies necessary for the development of ME-401 and, upon commercialization, for the manufacturing of ME-401 pursuant to supply agreements to be entered into on customary terms, subject to KHK’s option to assume responsibility for manufacturing in certain circumstances.

Under the terms of the Agreement, KHK will pay the Company an initial payment of \$10 million within 30 days after the date of the Agreement, or within 30 days after the receipt of relevant tax forms from the Company. The Company may earn up to approximately \$87.5 million in potential development and sales milestone payments, plus royalties on net sales of ME-401 in Japan, which are tiered and in the mid-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 activities and commercialization.

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 with regard to ME-401, and the parties shall jointly own any and all inventions developed by the parties jointly with regard to ME-401. KHK will grant to the Company a non-exclusive, sublicenseable, royalty-free, fully paid, perpetual license under KHK’s applicable technology as necessary for the Company to develop and commercialize ME-401.

KHK has the right to terminate the Agreement for convenience upon 180 days’ prior written notice. If either party materially breaches the Agreement, the non-breaching party may terminate the Agreement, if the breach is not cured within 90 days (30 days in the event of payment-related breach) of receiving written notice of the breach. If either party files or institutes bankruptcy, reorganization, liquidation or receivership proceedings, or assigns a substantial portion of the 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 within 90 days of the filing. The Company may also terminate the Agreement in the event that KHK challenges any of the licensed patents. The Agreement shall also automatically terminate if KHK fails to make the upfront payment and is terminable by the Company if KHK 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 KHK 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 the assets for the benefit of creditors), all licenses granted to KHK will immediately terminate and KHK shall cease developing and commercializing ME-401. In the event of such termination, KHK shall either withdraw all regulatory approvals for ME-401 in Japan or, with the Company's prior written consent, assign such regulatory approvals and related materials to the Company. If KHK terminates the Agreement for convenience or in connection with a force majeure event, or if the Company terminates the Agreement due to KHK's uncured material breach of the Agreement, KHK's filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings, or KHK's assignment of a substantial portion of the assets for the benefit of creditors, KHK's challenge of any of the Company's licensed patents, KHK's failure to make the upfront payment, KHK'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 KHK will immediately terminate, KHK shall cease developing and commercializing ME-401 in Japan, assign all regulatory approvals for ME-401 in Japan and related materials to the Company, and grant the Company an exclusive, royalty-free, fully paid, worldwide, perpetual and irrevocable license to certain data and technology developed by KHK, 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 Quarterly Report on Form 10-Q for the quarter ending December 31, 2018.

Item 8.01 Other Events

On November 5, 2018, 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit 99.1 [Press release of MEI Pharma, Inc. dated November 5, 2018](#)

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: November 5, 2018

**KYOWA KIRIN****MEI Pharma and Kyowa Hakko Kirin Announce License Agreement to Develop and Commercialize ME-401 in Japan***MEI to Receive \$10 Million Upfront Payment, Plus Milestones and Tiered Royalty Payments*

SAN DIEGO, and TOKYO, November 5, 2018 – MEI Pharma, Inc. (NASDAQ: MEIP) and Kyowa Hakko Kirin Co., Ltd. (Tokyo: 4151, “Kyowa Hakko Kirin”), today announced the execution of a license agreement granting Kyowa Hakko Kirin exclusive rights to develop and commercialize ME-401 in Japan (“License Agreement”). ME-401 is MEI’s phosphatidylinositol 3-kinase (“PI3K”) delta inhibitor being developed by MEI for the treatment of patients with B-cell malignancies. MEI is planning to initiate a Phase 2 study to evaluate patients with follicular lymphoma that is intended to support an accelerated approval marketing application with the U.S. Food and Drug Administration.

Under the terms of the License Agreement, MEI will receive a \$10 million upfront payment and is eligible to receive additional development and commercialization milestones totaling up to \$87.5 million. MEI is also eligible to receive tiered double-digit royalties extending into the mid-teens. The agreement grants Kyowa Hakko Kirin exclusive rights to ME-401 to develop and commercialize ME-401 in Japan. The initial indication for development and regulatory approval under the agreement is relapsed or refractory follicular lymphoma.

“Kyowa Hakko Kirin is a well-regarded leader in the development and commercialization of hematology and oncology therapies in Japan,” said David M. Urso, J.D., Chief Operating Officer of MEI Pharma. “This agreement is important for MEI as an opportunity to expand the development of ME-401 as a potential best-in-class PI3K delta inhibitor outside of the U.S. and is consistent with our strategy to optimize value through partnering opportunities abroad while developing capabilities for domestic commercialization.”

“I am delighted to enter into an agreement with MEI Pharma for the development and commercialization of ME-401 in Japan,” said Wataru Murata, Executive Officer, Director of Corporate Strategy & Planning Department. “We believe that ME-401 will be an important drug candidate in our oncology pipeline.”

Kyowa Hakko Kirin plans to initiate a Phase 1 study in Japan in 2019.

About ME-401

ME-401 is an investigational oral phosphatidylinositol 3-kinase (“PI3K”) delta inhibitor; PI3K delta is often overexpressed in cancer cells and plays a key role in the proliferation and survival of hematologic cancer cells. ME-401 displays high selectivity for the PI3K delta isoform and has distinct pharmaceutical properties from other PI3K delta inhibitors. It is being clinically evaluated in patients with various B-cell malignancies. MEI is initiating a Phase 2 study to evaluate the efficacy, safety, and tolerability of ME-401 as a single agent in patients with follicular lymphoma after failure of at least two prior systemic therapies including chemotherapy and an anti-CD20 antibody. The Phase 2 study is intended to support an accelerated approval marketing application with the U.S. Food and Drug Administration.

About MEI Pharma

MEI Pharma, Inc. (Nasdaq: MEIP) is a San Diego-based pharmaceutical company focused on leveraging its extensive development and oncology expertise to identify and advance new therapies for cancer. The Company's portfolio of drug candidates includes pracinostat, an oral HDAC inhibitor that is partnered with Helsinn Healthcare, SA. Pracinostat has been granted Breakthrough Therapy Designation from the U.S. Food and Drug Administration for use in combination with azacitidine for the treatment of patients with newly diagnosed acute myeloid leukemia (AML) who are unfit for intensive chemotherapy. Pracinostat is also being developed in combination with azacitidine for the treatment of patients with high and very high-risk myelodysplastic syndrome (MDS). MEI Pharma's clinical development pipeline also includes ME-401, a highly differentiated oral PI3K delta inhibitor currently in a Phase 1b study in patients with relapsed refractory follicular lymphoma or CLL, and voruciclib, an oral, selective CDK inhibitor shown to suppress MCL1, a known mechanism of resistance to BCL2 inhibitors. The Company is also developing ME-344, a novel mitochondrial inhibitor currently in an investigator-initiated study in combination with bevacizumab evaluating patients with HER2-negative breast cancer. Pracinostat, ME-401, ME-344 and voruciclib are investigational agents and are not approved for use in the U.S. For more information, please visit www.meipharma.com.

About Kyowa Hakko Kirin Co., Ltd.

Kyowa Hakko Kirin Co., Ltd. is a research-based life sciences company, with special strengths in biotechnologies. In the core therapeutic areas of oncology, nephrology and immunology/allergy, Kyowa Hakko Kirin leverages leading-edge biotechnologies centered on antibody technologies, to continually discover innovative new drugs and to develop and market those drugs world-wide. In this way, the company is working to realize its vision of becoming a Japan-based global specialty pharmaceutical company that contributes to the health and wellbeing of people around the world. You can learn more about the business at: www.kyowa-kirin.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; 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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