# 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): September 5, 2017**

# 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))

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 Agreement***

On September 5, 2017, MEI Pharma, Inc. (the "Company") entered into a License Agreement (the "Agreement") with Presage Biosciences, Inc. ("Presage"). Under the terms of the Agreement, Presage grants to the Company exclusive worldwide rights to develop, manufacture and commercialize Voruciclib, a clinical-stage, oral and selective cyclin-dependent kinase (CDK) inhibitor, and related compounds. In exchange, the Company will pay Presage near-term payments of up to $2.9 million and additional potential payments of up to $181 million upon the achievement of certain development, regulatory and commercial milestones. With respect to the first indication, an incremental $2.0 million payment, due upon dosing the first subject in the first registration trial will be owed to Presage, for total payments of $4.9 million up to receipt of marketing approval of the first indication by the U.S., E.U. or Japan. The Company will also pay mid-single-digit tiered royalties on the net sales of any product successfully developed. As an alternative to milestone and royalty payments related to countries in which the Company sublicenses product rights, the Company will pay to Presage a tiered percent (which decreases as product development progresses) of amounts received from such sublicensees.

The Agreement has a term commencing on the effective date and continuing, on a country-by-country basis, until the later of the date (i) of expiration of patents licensed by Presage to the Company in such country, or (ii) of expiration of regulatory exclusivity in such country.

The Company will be solely responsible for the global commercialization of products and shall be solely responsible for the costs related thereto.

The Company has the right to terminate the Agreement upon 90 days' prior written notice. If at any time following the second anniversary of the effective date, the Company has not taken certain actions towards the development of Voruciclib (other than for regulatory reasons or a need to manufacture clinical trial material) and there are no other related products or compounds for which material development activities are being undertaken, or with respect to which material commercialization activities are being undertaken, by the Company for a period of at least 18 months, Presage may terminate this Agreement upon written notice to the Company.

If either party materially breaches the Agreement, the non-breaching party may terminate the Agreement, if the breach is not cured within 60 days of receiving written notice of the breach.

If either party files or institutes bankruptcy, reorganization, liquidation or receivership proceedings, is the subject of involuntary bankruptcy proceedings, or assigns a substantial portion of the assets for the benefit of creditors, the other party may terminate the Agreement, if such proceeding is not dismissed within 60 days of the filing. Presage may also terminate the Agreement in the event that the Company challenges any of the licensed patents.

If the Agreement is terminated by the Company (other than as a result of an uncured material breach of the Agreement by Presage), the parties have an obligation, at Presage's election, to negotiate in good faith an agreement by which the Company would grant an exclusive worldwide license to the patents and know how developed by the Company in connection with the development and commercialization of products and the Company shall transition the development of products to Presage and wind down any commercialization of products over a 12 month period. The Agreement also provides the Company with certain rights in connection with a termination of the Agreement resulting from the bankruptcy, reorganization, liquidation or receivership of Presage, including a right of first refusal in connection with the proposed sale of Presage's rights and interest in products to a third party.

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 ended September 30, 2017.

**Item 8.01 Other Events**

On September 5, 2017, 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

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|---|---|
| Exhibit 99.1 | Press release of MEI Pharma, Inc. dated September 5, 2017 |

**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: September 6, 2017

## Exhibit Index

| Exhibit No. | Description |
| --- | --- |
| 99.1 | Press release of MEI Pharma, Inc. dated September 5, 2017 |

**Exhibit 99.1**

**MEI Pharma Announces Exclusive License Agreement with Presage Biosciences for Voruciclib, An Oral, Selective CDK Inhibitor**

**Clinical-Stage Asset in Validated Class of Drugs with Demonstrated Value**

**Potent Inhibitor of CDK9, 4/6 & 1, Potential to Overcome Resistance to BCL-2 Inhibitors**

**Opportunity in Combination with Venetoclax in CLL, Other Hematologic Indications**

San Diego and Seattle, September 5, 2017 — MEI Pharma, Inc. (Nasdaq: MEIP), an oncology company focused on the clinical development of novel therapies for cancer, today announced that it has entered into a license agreement with Presage Biosciences, Inc. for voruciclib, a clinical-stage, oral and selective cyclin-dependent kinase (CDK) inhibitor. Under the terms of the agreement, MEI Pharma receives exclusive worldwide rights to develop, manufacture and commercialize voruciclib. In exchange, Presage will receive near-term payments of $2.9 million and additional potential payments of up to $181 million upon the achievement of certain development, regulatory and commercial milestones. Presage will also receive mid-single-digit tiered royalties on the net sales of any product successfully developed.

“We are very excited by this opportunity to add voruciclib to our growing pipeline of clinical-stage oncology drug candidates,” said Daniel P. Gold, Ph.D., President and Chief Executive Officer of MEI Pharma. “Voruciclib is a selective CDK inhibitor, a class of drugs that has recently demonstrated significant clinical and commercial value, and is differentiated by its potent inhibition of CDK9. This is an attractive asset that comes with an established clinical safety profile, along with compelling pre-clinical data showing suppression of MCL1, a known mechanism of resistance to BCL2 inhibitors, and synergy with the FDA-approved BCL2 inhibitor venetoclax. We believe this provides a clear and efficient clinical development path forward in combination with venetoclax. We appreciate that Presage put their trust in us to execute this plan and we are eager to get started.”

Voruciclib (formerly P1446A) has been tested in more than 70 patients in multiple Phase 1 studies and has been associated with manageable side effects consistent with other drugs in its class, including nausea, vomiting and diarrhea. In pre-clinical studies, voruciclib alone induces cell death in multiple patient-derived chronic lymphocytic leukemia (CLL) samples . In addition, voruciclib shows dose-dependent suppression of MCL1 at concentrations achievable with doses that appeared to be generally well tolerated in the Phase 1 studies. Studies have shown that MCL1 is an established resistance mechanism to the B-cell lymphoma 2 (BCL2) inhibitor venetoclax (marketed as Venclexta™) .

“Voruciclib is a promising drug candidate with the potential to overcome mechanisms of drug resistance and significantly improve patient outcomes,” said David Johnson, Chairman of Presage. “The management team at MEI Pharma has a proven track record in oncology therapeutic development and we believe they have the clinical, regulatory and CMC expertise to maximize the value of this asset. This transaction also enables us to focus our attention on identifying and advancing additional drug candidates and combinations using our powerful CIVO™ intratumoral microdosing platform.

There are currently two CDK inhibitors approved by the U.S. Food and Drug Administration, palbociclib (marketed as Ibrance®) and ribociclib (marketed as Kisqali®), both oral, selective CDK 4/6 inhibitors approved for the treatment of hormone receptor-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer in combination with hormonal therapy. A third, abemaciclib, was recently granted priority review by the FDA.

**About Presage Biosciences**

Presage Biosciences is an oncology company pioneering a new drug development approach to assess novel drugs and drug combinations directly in patient tumors with its patented CIVO™ intratumoral microdosing platform. The CIVO platform is a drug development tool intended to simultaneously assess responses to multiple drugs or drug combinations directly in a single solid tumor while still in a patient’s body. Presage is using CIVO to develop a portfolio of promising oncology therapies to advance to the clinic. Presage also partners with oncology-focused pharmaceutical companies through strategic alliances to provide data to discover effective drug combinations. Presage is privately held and based in Seattle. For more information, visit www.presagebio.com.

**About MEI Pharma**

MEI Pharma, Inc. (Nasdaq: MEIP) is a San Diego-based oncology company focused on the clinical development of novel 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 Ib study in patients with relapsed/refractory CLL or follicular lymphoma, 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-sponsored study in combination with bevacizumab for the treatment of 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.

*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 ability to obtain sufficient funds to progress our clinical trials; risks relating to our collaboration agreement with Helsinn; changes in general economic conditions; costs and delays in the development and/or FDA approval, or the failure to obtain such approval, of our product candidates; our failure to satisfy foreign regulatory approval requirements; uncertainties or differences in interpretation in clinical study 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; our failure to successfully commercialize our product candidates; the effect of unfavorable pricing regulations, third-party reimbursement practices and health care regulations on our products; competitive factors; our reliance on third party clinical research organizations, suppliers and manufacturers; 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; 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; data security 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.*