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): July 2, 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.)**

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

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

3611 Valley Centre Drive, Suite 500, San Diego, California 92130
(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 (*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 July 2, 2020, MEI Pharma, Inc., a late-stage pharmaceutical company focused on advancing potential new therapies for cancer (the "Company"), and Helsinn Healthcare SA, a Swiss pharmaceutical group focused on building quality cancer care and rare diseases products, issued a press release announcing that an interim futility analysis of the ongoing Phase 3 study of pracinostat in combination with azacitidine in patients with acute myeloid leukemia ("AML") who are unfit to receive standard intensive chemotherapy, undertaken by the study Independent Data Monitoring Committee, has demonstrated it was unlikely to meet the primary endpoint of overall survival compared to the control group and as a result will discontinue the study. Pending further evaluation, patients currently enrolled in other pracinostat studies will continue treatment. A copy of the press release 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., and Helsinn Healthcare SA, dated July 2, 2020 relating to the Phase 3 study of pracinostat.

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: July 2, 2020

Helsinn Group and MEI Pharma Discontinue the Phase 3 Study with Pracinostat in AML after Completing Interim Analysis

Lugano, Switzerland and San Diego, USA, July 2, 2020 – Helsinn, a Swiss pharmaceutical group focused on building quality cancer care and rare diseases products, and MEI Pharma, Inc. (Nasdaq: MEIP), a late-stage pharmaceutical company focused on advancing potential new therapies for cancer, today announce that an interim futility analysis of the ongoing Phase 3 study of pracinostat in combination with azacitidine in patients with AML who are unfit to receive standard intensive chemotherapy, undertaken by the study Independent Data Monitoring Committee ("IDMC"), has demonstrated it was unlikely to meet the primary endpoint of overall survival compared to the control group. Based on the outcome of the interim analysis, the decision was made to discontinue the recruitment of patients and end the study. The decision was based on a lack of efficacy and not on safety concerns. Pending further evaluation, patients currently enrolled in other pracinostat studies will continue treatment.

About AML

Acute Myeloid Leukemia (AML) is a disorder of the blood and bone marrow caused by the uncontrolled proliferation of an abnormal hematopoietic cell of myeloid lineage. This results in a high circulating number of immature blood cells and replacement of normal bone marrow by malignant cells. AML has various subtypes, which are based on the type of cell from which the leukemia developed. It is typically a disease of older patients, with a median age at diagnosis of 67 years. Whilst the cure rate with intensive chemotherapy for AML patients who are 60 or younger is 35 to 40%, the rate is poor in older patients, typically not exceeding 15%.

About Pracinostat

Pracinostat is an oral histone deacetylase ("HDAC") inhibitor that is being investigated in combination with azacitidine for the treatment of adults with newly diagnosed acute myeloid leukemia ("AML") who are unfit for standard intensive chemotherapy. It is also being evaluated in a Phase II study in patients with high or very high-risk myelodysplastic syndromes ("MDS"). The U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) have granted Orphan Drug Designation for pracinostat in combination with azacitidine for the treatment of patients with newly diagnosed AML who are ≥75 years of age or unfit for intensive chemotherapy. In addition, the FDA has granted Breakthrough Therapy Designation to the combination treatment.

In August 2016, Helsinn and MEI Pharma entered an exclusive license, development and commercialization agreement for pracinostat in AML and other potential indications. The agreement provides that Helsinn is primarily responsible for development and commercialization costs for pracinostat in AML and other indications, including MDS.

Pracinostat is an investigational agent and is not approved for commercial use in the U.S. or any other country worldwide.

About the Helsinn Group

Helsinn is a privately-owned Swiss Pharma Company which, since 1976, has been improving the lives of patients, guided by core family values of respect, integrity and quality. The Group has an extensive portfolio of marketed innovative cancer and rare disease therapies, a robust drug development pipeline and ambitions to further accelerate its growth through in-licensing and acquisition to address unmet medical needs. Helsinn operates a unique integrated licensing business model, achieving success with over 80 long-standing partners in 190 countries, who share our values. The Group's pharmaceutical business, (Helsinn Healthcare) is headquartered in Lugano, Switzerland with operating subsidiaries in the U.S. (Helsinn Therapeutics US) and China (Helsinn Pharmaceuticals China) which market the Group's products directly in these countries. The Group has additional operating subsidiaries in Switzerland (Helsinn Advanced Synthesis, an active pharmaceutical ingredient manufacturer) and Ireland (Helsinn Birex Pharmaceuticals, a drug product manufacturer). Helsinn Investment Fund was created to enhance the future of healthcare by providing funding and strategic support to innovative companies.

Helsinn Group plays an active and central role in promoting social transformation in favor of people and the environment. Corporate social responsibility is at the heart of everything we do which is reinforced in the company's strategic plan by a commitment to sustainable growth.

To learn more about Helsinn Group please visit www.helsinn.com

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 four clinical-stage assets, including ME-401, currently in an ongoing Phase 2 clinical trial which may support an accelerated approval marketing application with the U.S. Food and Drug Administration. 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.

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.

For more information:

Helsinn Group Media Contact:

Paola Bonvicini
Group Head of Communication
Lugano, Switzerland
Tel: +41 (0) 91 985 21 21
Email: Info-hhc@helsinn.com
For more information, please visit www.helsinn.com and follow us on Twitter, LinkedIn and Vimeo

MEI Pharma

David A. Walsey
VP of IR and Corporate Communications
Tel: 858-369-7104
investor@meipharma.com

Jason I. Spark

Canale Communications for MEI
Tel: 619-849-6005
jason@canalecomm.com