Mast Therapeutics, Inc.
Form 8-K
January 06, 2015

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): January 6, 2015

Mast Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	001-32157	84-1318182
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)
12390 El Camino Real, Suite 150, San Diego, California		92130
(Address of principal executive offices)		(Zip Code)

Registrant s telephone number, including area code: 858-552-0866

Not Applicable

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:

[ ] 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))

Top of the Form

Item 2.02 Results of Operations and Financial Condition.

On January 6, 2015, Mast Therapeutics, Inc. (the "Company") announced that its cash, cash equivalents and investment securities were over $57 million as of December 31, 2014.

Item 8.01 Other Events.

On January 6, 2015, the Company provided an update on its pivotal Phase 3 study of vepoloxamer (MST-188) in sickle cell disease as well as milestones for its other development programs anticipated in 2015. The update included the following:

- 130 patients have been randomized to the EPIC study;
- The Company has opened almost 70 EPIC study sites in ten countries, with more than 50 of those sites located in the U.S.;
- The Company plans to initiate enrollment in an open-label extension study of vepoloxamer in EPIC subjects, referred to as EPIC-E, during the first half of 2015 to expand its existing safety database with respect to repeat exposure to vepoloxamer;
- The Company continues to expect to complete enrollment in EPIC by the end of 2015 and to anticipate announcing top-line results of the study in the first quarter of 2016; and
- During 2015, the Company also expects to: announce data from a non-clinical, repeat-dose study of vepoloxamer in heart failure and from its first nonclinical study of vepoloxamer in embolic stroke; initiate enrollment in a Phase 2 clinical study of vepoloxamer in acute decompensated heart failure; and report preliminary data from one or more Phase 2a studies of AIR001 in patients suffering heart failure with preserved ejection fraction (HFpEF).

The information set forth under Item 2.02 is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") and is not to be incorporated by reference into any filing of the registrant, whether made before or after the date hereof, regardless of any general incorporation language in any such filing.

The Company makes no admission as to the materiality of any information in this report, which is summary information intended to be considered in the context of the Company’s filings with the U.S. Securities and Exchange Commission (the “SEC”), including its Annual Report on Form 10-K filed on March 26, 2014, Quarterly Report on Form 10-Q filed on October 31, 2014, and other public announcements that the Company makes, by press release or otherwise, from time to time. The Company undertakes no duty or obligation to publicly update or revise the information contained in this report, although it may do so from time to time as it believes is appropriate. Any such updating may be made through the filing of other reports or documents with the SEC, through press releases, or through other public disclosure.

Forward-Looking Statements

Mast Therapeutics cautions you that statements included in this report that are not a description of historical fact are forward-looking statements that are based on the Company’s current expectations and assumptions. Such forward-looking statements include, but are not limited to, statements regarding the EPIC study and the Company’s development, regulatory and commercialization strategies and plans for its product candidates, including vepoloxamer in sickle cell disease, arterial disease, heart failure, and AIR001, as well as the timing of activities related to those

plans, including commencement and completion of clinical and nonclinical studies. Among the factors that could cause or contribute to material differences between the Company's actual results and the expectations indicated by the forward-looking statements are risks and uncertainties that include, but are not limited to: the uncertainty of outcomes in ongoing and future studies of its product candidates and the risk that its product candidates may not demonstrate adequate safety, efficacy or tolerability in one or more such studies, including in the EPIC study; delays in the commencement or completion of clinical studies, including as a result of difficulties in obtaining regulatory agency agreement on clinical development plans or clinical study design, opening trial sites, enrolling study subjects, manufacturing sufficient quantities of clinical trial material, completing manufacturing process development activities, being subject to a "clinical hold," and/or suspension or termination of a clinical study, including due to patient safety concerns or lack of funding; the potential for institutional review boards or the FDA or other regulatory agencies to require additional nonclinical or clinical studies prior to initiation of planned clinical study of a product candidate; the risk that, even if clinical studies are successful, the FDA or another regulatory agency may determine they are not sufficient to support a new drug application; the potential that even if clinical studies of a product candidate in one indication are successful, clinical studies in another indication may not be successful; the Company's reliance on contract research organizations (CROs), contract manufacturing organizations (CMOs), and other third parties to assist in the conduct of important aspects of development of its product candidates, including clinical studies, manufacturing, and regulatory activities for its product candidates and that such third parties may fail to perform as expected; the Company's ability to obtain additional funding as needed on a timely basis or on acceptable terms, or at all; the potential for the Company to delay, reduce or discontinue current and/or planned development activities, including clinical studies, partner its product candidates at inopportune times or pursue less expensive but higher-risk and/or lower return development paths if it is unable to raise sufficient additional capital as needed; the risk that the FDA and regulatory agencies outside of the U.S. do not grant marketing approval of a product candidate, on a timely basis, or at all; the risk that, even if the Company successfully develops a product candidate in one or more indications, it may not realize commercial success with its products and may never generate revenue sufficient to achieve profitability; the risk that the Company is not able to adequately protect its intellectual property rights and prevent competitors from duplicating or developing equivalent versions of its product candidates; and other risks and uncertainties more fully described in the Company's periodic filings with the SEC and press releases.

You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date they are made. Mast Therapeutics does not intend to revise or update any forward-looking statement set forth in this report to reflect events or circumstances arising after the date hereof, except as may be required by law. This caution is made under the safe harbor provisions of Section 21E of the Exchange Act and Section 27A of the Securities Act of 1933, as amended.

Top of the Form

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.

Mast Therapeutics, Inc.

January 6, 2015

By: /s/ Patrick L. Keran

Name: Patrick L. Keran
Title: President and Chief Operating Officer