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Mast Therapeutics, Inc.
Form 8-K
April 23, 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): April 21, 2015

Mast Therapeutics, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction

001-32157

84-1318182
(IRS Employer

of Incorporation)

(Commission File Number) Identification No.)

3611 Valley Centre Drive, Suite 500,

San Diego, CA
(Address of Principal Executive Offices)

92130
(Zip Code)

Registrant's Telephone Number, Including Area Code: (858) 552-0866

Not Applicable

(Former Name or Former Address, if Changed Since Last Report)

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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 Instructions 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))
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Item 8.01 Other Events.

On April 21, 2015, Mast Therapeutics, Inc. (the “Company”) announced that enrollment in its Phase 3 clinical study of vepoloxamer (MST-188) in sickle cell disease, known as the EPIC study, had surpassed the halfway mark and that it anticipates reporting top-line results from the EPIC study in the first quarter of 2016. The Company also announced the following about the EPIC study as of April 20, 2015:

- 205 sickle cell patients had been randomized to the EPIC study.
- The Company had opened more than 70 EPIC sites in ten countries, with more than two-thirds of those sites located in the U.S.
- The Company anticipates opening new EPIC sites in at least four additional countries.
- More than 70% of the EPIC sites had enrolled at least one subject and 75% of those sites had enrolled two or more subjects.
- A majority of EPIC subjects have come from the U.S. study sites.
- The average age of EPIC subjects is 14 years old.
- Approximately 20% of EPIC subjects are 18 years and older.

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 24, 2015 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. 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 clinical studies, including EPIC, and the risk that vepoloxamer may not demonstrate adequate safety, efficacy or tolerability in the EPIC study or other ongoing or future clinical studies; delays in the completion of clinical studies, including as a result of difficulties in 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; delays in reporting data from completed clinical studies; 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 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.

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 thereunto duly authorized.

Mast Therapeutics, Inc.

Date: April 23, 2015 By: /s/ Brandi L. Roberts
Brandi L. Roberts
Chief Financial Officer and Senior Vice President