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Mast Therapeutics, Inc.
Form 8-K
June 06, 2016

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): June 6, 2016

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

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(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 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 June 6, 2016, Mast Therapeutics, Inc. (the “Company”) updated the anticipated timing for announcement of top-line data from the Company’s Phase 3 clinical study of vepoloxamer in patients with sickle cell disease, known as the EPIC study. The Company currently expects to complete database lock in July and report top-line data shortly thereafter. The delay does not reflect on the quality or integrity of the results or conduct of the study. Rather, validation of the multitude of data points generated by the study and quality assurance/quality control procedures have taken longer than previously anticipated.

Forward-Looking Statements

Mast Therapeutics cautions you that statements in this report that are not a description of historical fact are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements may be identified by the use of words referencing future events or circumstances such as “expect,” “intend,” “plan,” “anticipate,” “believe,” and “will,” among others. Examples of forward-looking statements in this report include the statements regarding anticipated timing of clinical study database lock and announcement of top-line data. Forward-looking statements should not be read as guarantees of future performance or results because they involve the Company’s beliefs and assumptions based on currently available information and are subject to significant known and unknown risks and uncertainties that may cause actual performance and results to differ materially from expectations indicated by the forward-looking statements. Some of the factors that could cause actual performance or results to differ include, without limitation: the potential for additional delays in EPIC study closeout procedures, including blinded data validation and quality assurance/quality control procedures; the Company’s dependence on third parties such as clinical research organizations (CROs) to assist it conducting its clinical studies, including study close-out procedures, and the risk that such third parties may fail to perform as expected leading to delays in product candidate development or approval; risks associated with the Company’s ability to manage operating expenses and obtain additional capital as needed; the Company’s potential inability to continue as a going concern if it does not raise additional capital as needed; the risk that the Company may be required to repay its outstanding debt obligations on an accelerated basis and/or at a time that could be detrimental to its financial condition, operations and/or business strategy, including prepayment of \$10 million of the principal balance of its debt facility if results from EPIC are not positive and/or are not available on or before July 31, 2016; the potential for the Company to significantly delay, reduce or discontinue current and/or planned development, regulatory and commercial-readiness activities or sell or license its assets at inopportune times if it is unable to raise sufficient additional capital as needed; and other risks and uncertainties more fully described in the Company’s press releases and periodic filings with the Securities and Exchange Commission.

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 Securities Exchange Act of 1934, as amended, 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 hereunto duly authorized.

Mast Therapeutics, Inc.

Date: June 6, 2016 By: /s/ Brandi L. Roberts
Brandi L. Roberts
Chief Financial Officer and Senior Vice President