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Mast Therapeutics, Inc.
Form 8-K
July 25, 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): July 22, 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

(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 1.01 Entry into a Material Definitive Agreement.

On July 22, 2016, Mast Therapeutics, Inc. (the “Company”) entered into an amendment (the “Fourth Amendment”) to the Loan and Security Agreement, dated August 11, 2015, as amended by the First Amendment thereto dated September 28, 2015, the Second Amendment thereto dated December 31, 2015, and the Third Amendment thereto dated February 25, 2016 (collectively, the “Loan Agreement”) with Hercules Technology III, L.P. and Hercules Capital, Inc. (together, “Hercules”). As previously disclosed, the Loan Agreement provides for a \$15 million debt facility, \$5 million of which was funded to the Company in August 2015 and \$10 million of which was funded to the Company in September 2015 (the “Second Advance”). As of July 25, 2016, the principal balance of the loan was approximately \$14.6 million.

Under the Loan Agreement, as amended by the Fourth Amendment, on or before October 14, 2016, the Company must demonstrate, to the reasonable satisfaction of Hercules, positive results from its Phase 3 clinical study of vepoloxamer in patients with sickle cell disease, known as the EPIC study (the “Second Advance Prepayment Condition”), or prepay to Hercules \$10 million of the principal balance of the loan and any accrued but unpaid fees and expenses (the “Second Advance Prepayment”), without any prepayment penalty. In the event that the Second Advance Prepayment Condition is not satisfied, the Second Advance Prepayment would be due on October 14, 2016; provided, however, that if the Company issues a public announcement of EPIC results that do not satisfy the Second Advance Prepayment Condition before October 14, 2016, the Company is required to make the Second Advance Prepayment promptly, but in any case, within three business days of the public announcement.

If the Company achieves the Second Advance Prepayment Condition, is not required to make the Second Advance Prepayment, and no event of default under the Loan Agreement has occurred, the Company may resume making interest-only payments and further payments against the principal balance will be deferred until March 1, 2017. If the interest-only period resumes and is extended to March 1, 2017, then the scheduled maturity date under the Loan Agreement will be extended from January 1, 2019 to October 1, 2019. In accordance with the Fourth Amendment, the Company paid an additional facility charge of \$75,000.

Except as specifically amended by the Fourth Amendment, the Loan Agreement remains in full force and effect.

A copy of the Fourth Amendment is filed herewith as Exhibit 10.1 and is incorporated herein by reference. The foregoing description of the Fourth Amendment does not purport to be complete and is qualified in its entirety by reference to such exhibit.

Item 2.02 Results of Operations and Financial Condition.

The Company estimates that, as of June 30, 2016, its cash, cash equivalents and investment securities was \$35.1 million and its working capital was \$10.5 million. During the three months ended June 30, 2016, the Company sold an aggregate of 17,024,743 shares of its common stock under its “at the market” equity offering program for aggregate gross proceeds of \$6.7 million and an estimated \$6.5 million in net proceeds, after deducting sales agent commission and discounts and other offering costs.

All estimated amounts as of and for the period ended June 30, 2016 are preliminary and actual results may differ.

Item 8.01 Other Events.

On July 25, 2016, the Company provided guidance on the anticipated timing for announcement of top-line data from the EPIC study. The Company expects to report top-line data in September 2016. The Company believes that the additional time needed to lock the study database does not reflect on the quality or integrity of the results or conduct

of the study. Rather, validation of the multitude of data points and quality assurance/quality control procedures have taken longer than the Company previously anticipated. Allocation of key resources to the database lock process for longer than initially anticipated has affected the planned timing of submission of the new drug application (NDA) for vepoloxamer. The Company will provide an updated timeline on the NDA submission after the results of the EPIC study and its pre-NDA meeting with the U.S. Food and Drug Administration.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

The list of exhibits called for by this Item is incorporated by reference to the Exhibit Index immediately following the signature page of this report.

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; 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 sufficient 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 October 14, 2016; the inherent uncertainty outcomes in clinical studies, including EPIC, and the risk that vepoloxamer may not demonstrate adequate safety, efficacy or tolerability in patients with sickle cell disease; the risk that, even if EPIC results are positive, the FDA or other regulatory agencies may determine they are not sufficient to support a new drug application; 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; 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: July 25, 2016 By: /s/ Brandi L. Roberts
Brandi L. Roberts
Chief Financial Officer and Senior Vice President

Exhibit Index

Exhibit

Number Description

10.1 Fourth Amendment to Loan and Security Agreement, dated as of July 22, 2016, among Mast Therapeutics, Inc., Hercules Technology III, L.P. and Hercules Capital, Inc.