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Mast Therapeutics, Inc.
Form 8-K
September 20, 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): September 20, 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 2.04 Triggering Events That Accelerate or Increase a Direct Financial Obligation or an Obligation under an Off-Balance Sheet Arrangement.

On September 20, 2016, Mast Therapeutics, Inc. (the “Company”) announced top-line results from its Phase 3 clinical study of its investigational new drug vepoloxamer in individuals with sickle cell disease experiencing vaso-occlusive crisis (VOC). The trial, known as EPIC, did not meet its primary efficacy endpoint of demonstrating a statistically significant reduction in the mean duration of VOC (82 hours in the vepoloxamer group compared to 78 hours in the placebo group in the intent-to-treat population (p=0.09)). There were no statistically significant differences between the treatment groups in the intent-to-treat population across the two secondary efficacy endpoints, rate of re-hospitalization for vaso-occlusive crisis and the occurrence of acute chest syndrome. Consistent with previously conducted studies, vepoloxamer was generally well tolerated with no statistically significant differences in treatment-related serious adverse events in the vepoloxamer group compared to the control group. No deaths occurred on the study.

As a result of the reported top-line results from EPIC, in accordance with the terms and conditions of its Loan and Security Agreement with Hercules Capital, Inc. and Hercules Technology III, L.P. (together, “Hercules”), as amended, the Company is required to prepay to Hercules within three business days an amount equal to \$10 million of the principal balance of the loan and all unpaid fees and expenses accrued. The Company plans to make the prepayment to Hercules and to continue to repay the remaining principal balance in equal monthly installments of principal and interest on the first business day of each month through the scheduled maturity date of January 1, 2019.

Item 8.01 Other Events.

The information set forth under Item 2.04 of this Current Report on Form 8-K regarding the top-line results of EPIC is incorporated by reference in this Item 8.01. In addition, Company management plans to discuss the following on the conference call to be held on September 21, 2016 at 8:00 a.m. ET / 5:00 a.m. PT:

- The Company plans to analyze additional data from the EPIC study as well as perform an interim analysis of its ongoing clinical study of vepoloxamer in chronic heart failure in order to inform its business strategy and capital needs. However, based on the EPIC data reviewed to date, the Company expects it will terminate all clinical development of vepoloxamer.
- While the Company evaluates its options, the Company intends to implement significant cost-saving measures to its vepoloxamer development programs immediately and to continue development of AIR001, in particular by supporting ongoing, investigator-sponsored Phase 2 clinical studies of AIR001 in heart failure with preserved ejection fraction.
- The Company expects that its operating expenses for the next fifteen months will be significantly lower than previously anticipated.
- The Company is in discussions with Hercules regarding the details of the \$10 million prepayment that was triggered by announcement of top-line EPIC results.

The information contained in this report is summary information that is 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 14, 2016, Quarterly Report on Form 10-Q filed on August 9, 2016, 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 in this report that are not a description of historical facts 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 include are not limited to, statements regarding the Company’s development plans for its product candidates, the Company’s business plans and objectives, and its anticipated results of operations and financial condition. 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 Company’s need for additional funding to continue to operate as a going concern; risks associated with the Company’s ability to manage operating expenses and obtain additional capital as needed; uncertainty related to the Company’s ability to comply with the terms and conditions under its debt facility and risk that, in addition to the \$10 million prepayment required within three days of announcement of negative EPIC results, the Company may be required to repay its remaining outstanding debt obligations on an accelerated basis and/or at a time that could be detrimental to the Company’s financial condition, operations and/or business strategy;

the impact of significant reductions in the Company's operations on its ability to develop its product candidates or maintain compliance with laws and regulations relating to public companies; completion of a more detailed analysis of EPIC study data and announcement of additional data from the study; uncertainties inherent in the conduct of clinical studies and the risk that the Company's product candidates may not demonstrate adequate safety, efficacy or tolerability in one or more clinical studies; 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; that the Company is not the sponsor of the ongoing Phase 2 clinical studies of AIR001 and has no control over the conduct of those studies, including whether they will be completed on anticipated timelines, or at all; the Company's dependence on third parties to assist with important aspects of development of the Company's product candidates, including the conduct of its clinical studies, the manufacture and supply of its clinical trial material and, if approved, commercial product, and the conduct of regulatory activities, including preparation of new drug applications, and the risk that such third parties may fail to perform as expected leading to delays in product candidate development, regulatory approval, commercial launch and/or inability to meet future market demand for any approved products; 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, the Company may not realize commercial success and may never achieve profitability; the risk that the Company is not able to obtain and maintain effective patent coverage or other market exclusivity protections for its products, if approved, or that the use or manufacture of the Company's products may infringe the proprietary rights of others; and other risks and uncertainties more fully described in the Company's press releases and periodic filings with the SEC.

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 hereunto duly authorized.

Mast Therapeutics, Inc.

Date: September 20, 2016 By: /s/ Brandi L. Roberts
Brandi L. Roberts
Chief Financial Officer and Senior Vice President