Mast Therapeutics, Inc.
Form 8-K
September 12, 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 12, 2016

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)	(IRS Employer Identification No.)
3611 Valley Centre Drive, Suite 500, San Diego, CA		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 (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))

Item 7.01 Regulation FD Disclosure.

The information furnished in Exhibit 99.1 to this report, which relates to Mast Therapeutics, Inc. (the "Company") and its development programs, may be presented from time to time by the Company at various investor and analyst meetings.

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.

In accordance with General Instruction B.2. of Form 8-K, the information in Item 7.01 of this report and Exhibit 99.1 hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference in any of the Company's filings under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any incorporation language in such a filing, except as expressly set forth by specific reference in such a filing.

By filing this report, including the information contained in Exhibit 99.1 attached hereto, the Company makes no admission as to the materiality of any information in this report. The information contained in Exhibit 99.1 hereto 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, including in Exhibit 99.1 attached hereto, 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-look statements include, but are not limited to, statements regarding the Company's development, regulatory and commercialization strategies and plans for its investigational new drugs, vepoloxamer (also known as MST-188) and AIR001, as well as the timing of activities and events related to those plans, including commencement and completion of clinical studies, announcements of study results, submission of applications to regulatory authorities for marketing approval, and product launch, and prospects for clinical, regulatory and commercial success. 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 inherent uncertainty of outcomes in clinical studies and the risk that the Company's product candidates may not demonstrate adequate safety, efficacy or tolerability in one or more such studies, including vepoloxamer in the EPIC study; 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; uncertainties related to future feedback from the FDA regarding the development of vepoloxamer, including the risks that the FDA may determine another Phase 3 study or other clinical or nonclinical studies are necessary to demonstrate vepoloxamer's development and/or safety for the treatment of patients with sickle cell disease or may require changes to manufacturing controls or processes, any of which could delay filing of a new drug application, significantly increase the cost of vepoloxamer's development and/or ultimately lead to denial of regulatory approval of vepoloxamer; 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 it may be required to repay its 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, 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; delays in the commencement or completion of clinical studies, including the EPIC study, the Phase 2 study of vepoloxamer in heart failure, and the Phase 2 studies of AIR001 in HFpEF, 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 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 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 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; 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 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 12, 2016 By:/s/ Brandi L. Roberts
Brandi L. Roberts
Chief Financial Officer and Senior Vice President

Exhibit Index

Exhibit Number	Description
99.1	Mast Therapeutics, Inc. corporate presentation, September 12, 2016