Mast Therapeutics, Inc.
Form 8-K
March 07, 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): March 7, 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, including at the Cowen and Company 36th Annual Health Care Conference on March 7, 2016.

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 and furnishing 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 24, 2015, Quarterly Report on Form 10-Q filed on November 12, 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

The Company cautions you that statements included 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 that are based on the Company's current expectations and assumptions. Such forward-looking statements may be identified by the use of forward-looking words such as "intend," "plan," anticipate," "believe," "expect," among others, and include, but are not limited to, statements regarding the Company's development, regulatory and commercialization strategies and plans for its investigational 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. 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 inherent uncertainty of outcomes in ongoing and future studies of the Company's product candidates and the risk that its product candidates may not demonstrate adequate safety, efficacy or tolerability in one or more such studies, including vepoloxamer in the ongoing EPIC study; delays in the commencement or completion of clinical studies, including the Phase 2 study of vepoloxamer in heart failure, and the ongoing and planned Phase 2 studies of

AIR001, 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; delays in clinical study closeouts, including blinded data review and quality assurance procedures, that may delay announcement of study results; risks associated with the fact that the Company is not the sponsor of the ongoing or currently planned Phase 2 studies of AIR001 in heart failure and has no control over the protocol for or conduct of the studies, including whether the ongoing study will be completed or the planned study be commenced on anticipated timelines, or at all; the risk that, even if the EPIC study achieves statistical significance in the primary endpoint, the FDA or another regulatory authority may determine it does not demonstrate sufficient magnitude of clinical relevance or provide adequate safety and tolerability data to provide the basis for submission of a new drug application; the potential for institutional review boards or the FDA or other regulatory agencies to require additional clinical or nonclinical studies prior to initiation of a planned clinical study; the potential that even if clinical studies of a product candidate in one indication are successful, clinical studies in another indication may not be successful; the Company's dependence on third parties to assist with important aspects of development of its product candidates, including conduct of its clinical studies and supply and manufacture of clinical trial material, and, if approved, commercial product and the risk that such third parties may fail to perform as expected; 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 harmful to its financial

condition and/or ability to pursue its business strategy; risk associated with the Company's ability to manage operating expenses and/or obtain additional funding to support its operations, if 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 or partner its product candidates 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 and obtains regulatory approval for a product candidate, 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 and other market exclusivity protections for its products, if approved, without infringing the proprietary rights of others; 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 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: March 7, 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, March 7, 2016 |

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