Mast Therapeutics, Inc.
Form 8-K
May 09, 2014

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): May 9, 2014

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.)**

12390 El Camino Real, Suite 150,

San Diego, California **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:

¨ 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 8.01. Other Events.

The information attached as Exhibit 99.1 to this report relating to Mast Therapeutics, Inc. (the Company) and its lead product candidate, MST-188, 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 filed with this report.

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 26, 2014, Quarterly Report on Form 10-Q filed on May 5, 2014 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 included in this report, including in Exhibit 99.1 attached hereto, that are not a description of historical facts are forward-looking statements that are based on the Company s current expectations and assumptions. Such forward-looking statements include, but are not limited to, statements regarding the Company s development, regulatory and commercialization strategies and plans for MST-188 in sickle cell disease, arterial disease and heart failure, as well as the timing of activities related to those plans. 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 uncertainty of outcomes in ongoing and future studies of its product candidates and the risk that its product candidates may not demonstrate adequate safety, efficacy or tolerability in one or more such studies, including MST-188 in the EPIC study and the phase 2 clinical study in acute lower limb ischemia; the potential for delays in the commencement or completion of clinical studies, 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 clinical trial material, completing manufacturing process development activities, and being subject to a clinical hold ; the risk of suspension or termination of a clinical study, including due to lack of adequate funding or patient safety concerns; the potential for institutional review boards or the FDA or regulatory agencies outside of the U.S. to require additional nonclinical or clinical studies prior to initiation of phase 2 clinical studies of MST-188 in any particular indication in which the Company determines to develop MST-188, including heart failure, which likely would increase the total time and cost of development in the indication; the risk that clinical studies of the Company s product candidates are not successfully executed and/or do not successfully demonstrate the drug s safety or efficacy; the risk that, even if clinical studies are successful, the FDA or a regulatory agency outside of the U.S. determines they are not sufficient to support a new drug application; the risk 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 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, and regulatory activities for its product candidates and that such third parties may fail to perform as expected; the Company s ability to obtain additional

funding 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, partner its product candidates at inopportune times or pursue less expensive but higher-risk and/or lower return development paths 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 the Company is not able to adequately protect its intellectual property rights relating to the MAST platform or MST-188 and prevent competitors from duplicating or developing equivalent versions of its product candidates; the risk that, even if the Company successfully develops and obtains marketing approval for its product candidates, it may not realize commercial success with its products and may never generate revenue sufficient to achieve profitability; 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.

May 9, 2014

By: /s/ Patrick L. Keran
Name: Patrick L. Keran
Title: President and Chief Operating Officer

Exhibit Index

Exhibit No.	Description
99.1	Summary of the development history of MST-188, May 2014