Mast Therapeutics, Inc.
Form 8-K
February 01, 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): February 1, 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.

On February 1, 2016, Mast Therapeutics, Inc. (the "Company") issued a press release announcing the selection of its product candidate AIR001 by the Heart Failure Clinical Research Network (HFN) for evaluation in a Phase 2 study in patients with heart failure with preserved ejection fraction (HFpEF) known as the Inorganic Nitrite Delivery to Improve Exercise Capacity in HFpEF (INDIE-HFpEF) study. A copy of the press release is furnished as Exhibit 99.1 hereto.

Item 8.01 Other Events.

The HFN is providing the platform to conduct the INDIE-HFpEF study and the HFN's Coordinating Center will be the sponsor of the study. The Company plans to provide the test materials, nebulizers, regulatory and technical support, as well as financial support at milestones over the course of the study of approximately $3 million. The Company expects to enter into a contract with the HFN's Coordinating Center in the coming weeks and that the Coordinating Center will submit an Investigational New Drug application to the U.S. Food and Drug Administration for clearance to conduct the study in the first quarter of 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.

The information set forth under Item 7.01 and in Exhibit 99.1 is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and is not to be incorporated by reference into any filing of the registrant, whether made before or after the date hereof, regardless of any general incorporation language in any such filing.

Forward-Looking Statements

The Company cautions you that statements included in this report 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 relating to the commencement of the INDIE-HFpEF study and the Company's support of that study. 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: that the Company is not the sponsor of the INDIE-HFpEF study and has no control over the protocol for or conduct of the study, including whether the study will commence or be completed on anticipated timelines, or at all; delays in the commencement or completion of the INDIE-HFpEF study, including as a result of difficulties in obtaining regulatory clearance or institutional review board approval, 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 third parties for the manufacture and supply of test material and nebulizers for use in the INDIE-HFpEF study and the risks the Company may not be able to supply such material or devices for the study on a timely basis, or at all, or may incur significant unanticipated expenses in connection with procuring sufficient quantities; the risk that AIR001 may not demonstrate adequate safety, efficacy or tolerability in the INDIE-HFpEF study; the Company's ability to obtain and maintain effective patent coverage and other market exclusivity protections for its products without infringing on the proprietary rights of others; 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; the Company's ability to obtain additional funding on a timely basis or on acceptable terms, or at all; the Company's ability to complete development of and successfully commercialize its product candidates and achieve profitability; 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: February 1, 2016 By: /s/ Brandi L. Roberts
Brandi L. Roberts
Chief Financial Officer and Senior Vice President

Exhibit Index

Exhibit Number	Description
99.1	Press release dated February 1, 2016