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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

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**FORM 8-K**

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**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**

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**Mast Therapeutics, Inc.**

(Exact name of Registrant as Specified in Its Charter)

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**Delaware**  
(State or Other Jurisdiction  
of Incorporation)

**001-32157**  
(Commission File Number)

**84-1318182**  
(IRS Employer  
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 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**

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99.1 Press release dated February 1, 2016



## **MAST THERAPEUTICS' AIR001 SELECTED BY THE HEART FAILURE CLINICAL RESEARCH NETWORK FOR EVALUATION IN A 100-PATIENT MULTICENTER PHASE 2 STUDY**

**SAN DIEGO – February 1, 2016** – Mast Therapeutics, Inc. (NYSE MKT: MSTX), a biopharmaceutical company developing novel, clinical-stage therapies for sickle cell disease and heart failure, today reported that its product candidate AIR001, a sodium nitrite solution being developed for treatment of heart failure with preserved ejection fraction (HFpEF), has been selected by the Heart Failure Clinical Research Network (HFN) for evaluation in a 100-patient, multicenter, randomized, double-blind, placebo-controlled, Phase 2 clinical trial known as the Inorganic Nitrite Delivery to Improve Exercise Capacity in HFpEF (INDIE-HFpEF) study.

The HFN is made up of premier clinical centers located across North America and was established to expedite clinical research on treatments and strategies to improve the management of acute and chronic heart failure. The HFN is providing the platform to conduct the INDIE-HFpEF study. Mast Therapeutics will provide test materials, nebulizers, and regulatory, technical, and additional financial support. The Company expects to complete a contract with the HFN's Coordinating Center, which will be the sponsor of the study, in the coming weeks.

The collaborative scientific leadership for the study will include Dr. Barry Borlaug, the Principal Investigator, and the investigators from the HFN Regional Coordinating Centers.

“Given the results from prior clinical studies of AIR001, including decreases in right atrial and pulmonary capillary wedge pressures, as well as improvements observed in pulmonary vascular resistance and cardiac lusitropy, AIR001 may further demonstrate its potential benefit to patients with heart failure and preserved ejection fraction in this study,” stated Edwin L. Parsley, D.O., Chief Medical Officer of Mast Therapeutics, Inc. “We have assisted with the study development and will support training on AIR001 and nebulizer devices, as well as assist in the submission of an institutional Investigational New Drug application, which we anticipate will occur in the first quarter of this year.”

“We appreciate the HFN's recognition of the study of AIR001 in heart failure as an appropriate area of investigation and the opportunity to work with them,” stated Brian M. Culley, Chief Executive Officer of Mast Therapeutics, Inc. “With their help, we expect to accelerate efforts to define the potential efficacy of AIR001 and hopefully provide a viable and much-needed treatment option for patients who have heart failure with preserved ejection fraction, as currently there are no proven effective therapeutic agents available for this large patient population.”

### **About the Heart Failure Clinical Research Network (HFN)**

The primary goal of the HFN is to conduct multiple clinical trials to evaluate treatments and strategies to improve management of acute and chronic heart failure. The HFN provides a unique platform for collaborative research by bringing together many premier centers across North America. HFN is composed of nine Regional Coordinating Centers and their affiliated sites, whose investigators provide scientific leadership in the collaborative development of the HFN's scientific agenda. HFN is recognized for robust enrollment in heart failure clinical trials and high scientific productivity. The goal of partnering with HFN is to accelerate research and medical innovation, and provide early results that may improve public health. More information can be found on the HFN's website, <https://www.hfnetwork.org/>.

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## About AIR001

AIR001 is a sodium nitrite solution for intermittent inhalation via nebulization. Nitrite is a direct vasodilator and can be recycled *in vivo* to form nitric oxide (NO) independent of the classical NO synthase (NOS) pathway. Nitrite mediated NO formation has several beneficial effects, including dilation of blood vessels and reduction of inflammation and undesirable cell growth. Generation of NO from sodium nitrite is not dependent upon endothelial function and is enhanced in the setting of tissue hypoxia and acidosis, conditions in which NOS activity typically is depressed. In early clinical studies, AIR001 demonstrated positive hemodynamic effects with reductions observed in right atrial pressure and pulmonary capillary wedge pressure, as well as improvements in mean pulmonary artery pressures, cardiac output, and exercise tolerance as measured by six minute walk distance. Mast Therapeutics obtained the AIR001 program through its acquisition of privately-held Aires Pharmaceuticals, Inc. in 2014.

## About Mast Therapeutics

Mast Therapeutics, Inc. is a publicly traded biopharmaceutical company headquartered in San Diego, California. The Company is leveraging its MAST (Molecular Adhesion and Sealant Technology) platform, derived from over two decades of clinical, nonclinical and manufacturing experience with purified and non-purified poloxamers, to develop vepoloxamer (also known as MST-188), its lead product candidate, for serious or life-threatening diseases and conditions typically characterized by impaired microvascular blood flow and damaged cell membranes. The Company is also developing AIR001, a sodium nitrite solution for inhalation via nebulization, for the treatment of heart failure with preserved ejection fraction (HFpEF).

Vepoloxamer is an investigational new drug being evaluated in a pivotal Phase 3 study called EPIC for the treatment of vaso-occlusive crisis in patients with sickle cell disease and in a Phase 2 study for the treatment of patients with chronic heart failure. AIR001 is an investigational new drug being evaluated in two institution-sponsored Phase 2a studies in patients with HFpEF and recently was selected by the Heart Failure Clinical Research Network for an approximately 100-patient, placebo-controlled Phase 2 study in patients with HFpEF. More information can be found on the Company's web site at [www.masttherapeutics.com](http://www.masttherapeutics.com). (Twitter: [@MastThera](https://twitter.com/MastThera))

Mast Therapeutics™ and the corporate logo are trademarks of Mast Therapeutics, Inc.

## Forward Looking Statements

Mast Therapeutics cautions you that statements included in this press release 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 may include, but are not limited to, statements relating to prospects for successful development and commercialization of the Company's investigational drugs, including AIR001, and anticipated timing of achievement of development milestones, such as commencement of clinical studies or progress with regulatory activities. 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; the Company's reliance on third parties for the manufacture and supply of test material and nebulizer devices 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 uncertainty of outcomes in ongoing and future studies of the Company's product candidates and the risk that its product candidates, including AIR001, may not demonstrate adequate safety, efficacy or tolerability in one or more such studies, including INDIE-HFpEF; 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. The Company's public filings with the Securities and Exchange Commission are available at [www.sec.gov](http://www.sec.gov).

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You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date when made. Mast Therapeutics does not intend to revise or update any forward-looking statement set forth in this press release to reflect events or circumstances arising after the date hereof, except as may be required by law.

Contact:

**Mast Therapeutics**

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