

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): October 19, 2016

Mast Therapeutics, Inc.

(Exact name of Registrant as Specified in Its Charter)

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)

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 8.01 Other Events.

The information attached as 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 BIO Investor Forum on October 19, 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.

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 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-looking statements include, but are not limited to, statements regarding the Company’s development plans for its product candidates, the Company’s business plans and objectives, and its anticipated results of operations and financial condition. 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 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 the Company may be required to repay its remaining outstanding debt obligation on an accelerated basis and/or at a time that could be detrimental to the Company’s financial condition, operations and/or business strategy; the impact of significant reductions in the Company’s operations on its ability to execute its business strategy or maintain compliance with laws and regulations relating to public companies; completion of a more detailed analysis of EPIC study data and announcement of additional data from the study; uncertainties inherent in the conduct of clinical studies and the risk that the Company’s product candidates may not demonstrate adequate safety, efficacy or tolerability in one or more clinical studies and that their clinical development will take longer and be more expensive than anticipated; the potential for the Company to significantly delay, reduce or discontinue current and/or planned development activities or sell or license its assets at inopportune times if it is unable to raise sufficient additional capital as needed; that the Company is not the sponsor of the ongoing Phase 2 clinical studies of AIR001 and has limited to no control over the conduct of those studies, including whether they will be completed on anticipated timelines, or at all; the Company’s dependence on third parties to assist with important aspects of development of the Company’s product candidates, including the conduct of its clinical studies, the manufacture and supply of its clinical trial material and, if approved, commercial product, and the conduct of regulatory activities, 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 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, the Company 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

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: October 19, 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, October 19, 2016



Corporate Overview

October 19, 2016

Safe Harbor Statement

This presentation includes forward-looking statements about our business prospects, financial position, and development of investigational new drugs for therapeutic use in humans. Any statement that is not a statement of historical fact should be considered a forward-looking statement. Because forward-looking statements relate to the future, they are subject to inherent risks, uncertainties and changes in circumstances that are difficult to predict. Actual events or performance may differ materially from our expectations indicated by these forward-looking statements due to a number of factors, including, but not limited to, our ability to raise additional capital as needed and continue as a going concern; results of pending and future clinical and nonclinical studies, the timeline for product development activities; failure to obtain regulatory approval of our product candidates; our dependency on third parties to conduct clinical studies and supply or manufacture clinical trial material; our ability to repay outstanding debt as payments come due; our ability to establish and protect proprietary rights related to our product candidates; and other risks and uncertainties more fully described in our press releases and our filings with the SEC, including our quarterly report on Form 10-Q filed with the SEC on August 9, 2016 and our current report on Form 8-K filed with the SEC on September 26, 2016.

We caution you not to place undue reliance on any of these forward-looking statements, which speak only as of the date of this presentation. We do not intend to update any forward-looking statement included in this presentation to reflect events or circumstances arising after the date of the presentation, except as may be required by law.

Product Candidate Pipeline

AIR001*

Preclinical

Phase 1

Phase 2

Phase 3

Heart Failure (HFpEF)

Published / Primary Endpoint Met

Pulmonary Hypertension
(Incl. cohort of HFpEF-PH)

Enrolling / Interim results expected Q4

INABLE-HFpEF

Recruiting

INDIE-HFpEF



Enrolling

Vepoloxamer*

Preclinical

Phase 1

Phase 2

Phase 3

Ischemic Stroke

Phase 2-ready

AIR001 Program Heart Failure

Objective: Improve exercise tolerance and hemodynamics in HFpEF patients

Multiple Phase 2 Studies Ongoing

AIR001 Overview

➤ AIR001 is nitrite* for intermittent inhalation

- An inhaled investigational new treatment for heart failure patients, exploiting a *novel* NOS-independent pathway
- Delivered via proprietary handheld nebulizer
- Activity includes dilation of blood vessels and reduced inflammation
 - Not limited to role as nitric oxide donor, as nitrite has direct mitochondrial oxygen-sparing activity
- Hemodynamic benefits include reductions in:
 - Pulmonary capillary wedge pressure
 - Right atrial pressure
 - Mean pulmonary arterial pressure
- Safety data available in approximately 175 subjects (generally well-tolerated)



* Note: Nitrite is a different molecule and has separate activity compared to organonitrates or nitric oxide.

AIR001 Development History

- **Mast purchased Aires Pharmaceuticals, Inc. in 2014, including rights to AIR001 program**
 - Prior to the acquisition, AIR001 development in pulmonary hypertension (PH) was supported by \$35M of venture capital
 - Until 2012, AIR001 program was the subject of a \$250M option and license agreement with Novartis Pharmaceuticals (terminated for strategic reasons)

- **Following the acquisition, Mast redirected development of AIR001 to focus on heart failure with preserved ejection fraction (HFpEF)**
 - More applicable hemodynamic benefits
 - Preferable competitive landscape

AIR001 Clinical Development Plan

➤ Heart Failure with Preserved Ejection Fraction (HFpEF)

- Responsible for ~50% of heart failure hospitalizations
- No approved medications

➤ AIR001 is being tested in three separate institutional-sponsored Phase 2 studies at prestigious institutions:

- Phase 2 study in HFpEF-PH (ClinicalTrials.gov: NCT01431313)
- Phase 2 INABLE study in HFpEF (ClinicalTrials.gov: NCT02713126)
- Phase 2 INDIE study in HFpEF (ClinicalTrials.gov: NCT02742129)
 - a 100-patient study by Heart Failure Clinical Research Network with significant support from a grant from the NHLBI/NIH

AIR001 Prior Clinical Studies (Normal Healthy Volunteers & PH)

➤ **Three Phase 1 studies**

- Established Maximum Tolerated Dose
- Acute improvements in hypoxia-induced pulmonary hypertension
- No drug-drug interaction with sildenafil

➤ **Phase 2a study in Pulmonary Arterial Hypertension (n=29)**

- Well-tolerated; no treatment-related serious adverse events
- Improvements seen in median pulmonary vascular resistance (PVR) and median distances in 6-minute walk test
- Methemoglobin levels remained normal (<1.5%)

➤ **Phase 2 study in PH (n=50)**

- Interim results (n=6; HFpEF-PH) presented at 2016 ATS
 - AIR001 administration significantly lowered central pressures
 - Increase in pulmonary artery compliance observed with no significant decrease in systemic blood pressures or change in heart rate
- Additional interim results submitted for publication, expected Q4 2016

AIR001 Clinical Studies in HFpEF

AIR001

Preclinical

Phase 1

Phase 2

Phase 3

Heart Failure (HFpEF)

Published / Primary Endpoint Met

(n=30)

Pulmonary Hypertension
(Inc. cohort of HFpEF-PH)

Enrolling / Interim results expected Q4

(n=20)

INABLE-HFpEF

Recruiting

(n=68)

INDIE-HFpEF

Enrolling

(n=100)



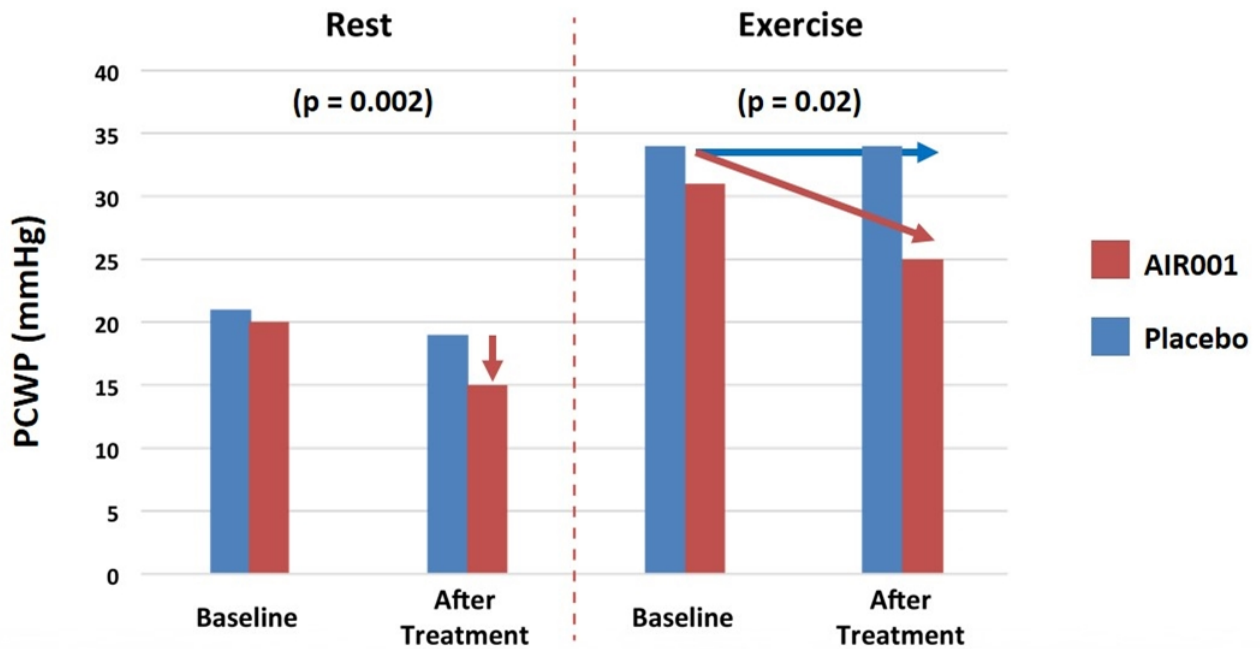
Phase 2a Study in HFpEF (n=30)

- **Investigated effects of AIR001 administration on resting and exercise hemodynamics in patients with HFpEF**
- **Primary endpoint met**
 - AIR001 demonstrated statistically significant ($p=0.02$) decrease in pulmonary capillary wedge pressure (PCWP) during exercise compared to placebo
- **AIR001 significantly lowered right atrial pressure ($p=0.05$)**
- **AIR001 significantly lowered mean pulmonary artery pressure at rest ($p=0.007$)**
- **AIR001 significantly improved pulmonary artery compliance ($p=0.046$)**
- **AIR001 was generally well-tolerated, with no treatment-related serious adverse events**

Source: Inhaled Sodium Nitrite Improves Rest and Exercise Hemodynamics in Heart Failure With Preserved Ejection Fraction
Barry A Borlaug, Vojtech Melenovsky and Katlyn E Koepp, *Circulation Research*; July 25, 2014
DOI: <http://dx.doi.org/10.1161/CIRCRESAHA.116.305>

Phase 2a Study in HFpEF (n=30)

- Primary endpoint of exercise pulmonary capillary wedge pressure (PCWP) was significantly improved with AIR001 compared with placebo
 - Effects observed both at rest and during exercise



Source: Inhaled Sodium Nitrite Improves Rest and Exercise Hemodynamics in Heart Failure With Preserved Ejection Fraction
Barry A Borlaug, Vojtech Melenovsky and Katlyn E Koeppe, *Circulation Research*; July 25, 2014
DOI: <http://dx.doi.org/10.1161/CIRCRESAHA.116.301161>



Phase 2 Study (HFpEF Cohort of PH)

- **Single-center, open label study to evaluate the effect of AIR001 in a dose escalation manner on the change in pulmonary vascular resistance (PVR) in subjects with pulmonary hypertension undergoing right heart catheterization**
- **Planned for patients (n=50) with a diagnosis of pulmonary hypertension, 20 of which are diagnosed with HFpEF**
- **Primary endpoint:**
 - Change in pulmonary vascular resistance (from time zero and at 15, 30, and 45 minutes of nebulization)
- **Patient enrollment ongoing – publication / interim results expected Q4 2016**

Phase 2 Study in HFpEF (“INABLE”)

- **Investigator-sponsored Phase 2 study**
- **Single-center, randomized, interventional study to evaluate whether AIR001 improves clinical responses and tolerability of exercise training (ET)**
- **Patients with a diagnosis of HFpEF (n=68)**
 - Patients will undergo 12 weeks of cardiac rehabilitation including ET; randomized to AIR001 or placebo inhalation solution through the training period
- **Primary endpoint:**
 - Change in exercise capacity as measured by peak oxygen consumption
- **Patient recruitment initiated**

Phase 2a Study in HFpEF (“INDIE”)

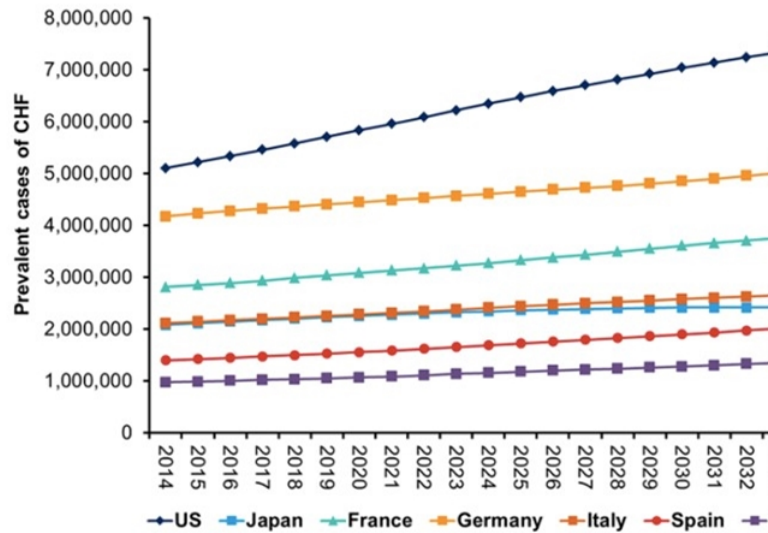
- **Ongoing study, conducted by the Heart Failure Clinical Research Network (HFN) with significant support from a grant awarded by the NHLBI/NIH**
 - HFN consists of premier clinical centers; established to expedite clinical research on treatments and strategies to improve the management of acute and chronic heart failure
- **Randomized, double-blind, placebo-controlled crossover study to evaluate the effect of AIR001 on peak exercise capacity**
- **Patients with a diagnosis of HFpEF (n=100)**
- **Primary endpoint:**
 - Peak oxygen consumption (VO_2) after four weeks of treatment with nebulized inhaled AIR001 or placebo (assessed by CPET performed at peak drug levels)
- **Results expected Q4 2017**
 - First patient dosed July 2016



Heart Failure Market Opportunity

Heart failure is a leading cause of morbidity and mortality among the elderly worldwide

- Approx. 5.7M individuals in the U.S. have clinical heart failure
- HF is the primary diagnosis in >1 million hospitalizations per year and medical costs are projected to rise to \$53 billion in the U.S. by 2030
- ~50% of HF hospitalizations are for HFpEF & prevalence of HFpEF is expected to increase
- No approved medications



AIR001 IP and Market Protections

- **Patent applications filed in major markets cover various methods of therapeutic use of inhaled inorganic nitrite, including its use for treating HFpEF**
 - Patents issued would have a term until February 2034

- **Approval for HFpEF may result in data and/or marketing exclusivity:**
 - 3 years market exclusivity in the US (New Use Exclusivity)
 - 6 years data exclusivity and 2 years of market exclusivity in Canada
 - 8 years data exclusivity and 2 years of market exclusivity in Europe
 - 8 years of data exclusivity in Japan

- **Exclusive right to purchase I-nebs from Philips for use with an inhaled nitrite or inhaled NO-donating compound for HFpEF**

- **Expected exclusivity for the combination of AIR001 and its delivery system**
 - Other medications to alter pulmonary pressures include the delivery device in FDA and EMA labels and are approved only with the specified proprietary device

Vepoloxamer Status Update

- **Prior study in sickle cell disease did not meet primary & secondary endpoints**
 - SCD is extremely complex, involving numerous pathophysiologies
 - Inflammation, tissue ischemia, vaso-occlusion, hemolysis, hypoxia, nitric oxide depletion, organ damage, anemia and pain
 - Given disease complexity, it may be too difficult to correlate improved blood flow with clinical outcomes in a clinical setting

- **Will evaluate partnership opportunities for ischemic stroke (phase 2-ready)**
 - Vepoloxamer has demonstrated improved thrombolysis and perfusion in the clinical setting
 - Vepoloxamer has demonstrated improved survival in MCAO stroke models
 - Perfusion can be *more directly measured* and may be *more translatable* to clinical outcomes in stroke patients
 - Objective: Accelerate recanalization, improve perfusion, and reduce injury

Vepoloxamer for Ischemic Stroke

- **Nonclinical Studies;** In combination with fibrinolytic agents, vepoloxamer shortened time to thrombolysis, improved post-lysis perfusion and expanded the treatment window for t-PA
- **Clinical Studies;** Vepoloxamer was well-tolerated in healthy volunteers and individuals with sickle cell disease at similar or higher doses than are anticipated for use in stroke
- **Funding; SBIR grant awarded by National Institute of Neurological Disorders and Stroke/NIH in August 2016**
 - Working with leading stroke researchers at Henry Ford Health System
 - Evaluate the effect of combination treatment with tPA on infarct volume and functional outcome in a nonclinical model
 - Study expected to be completed July 2017
- **Vepoloxamer is covered by an issued composition of matter patent that does not expire until 2035 (U.S. 9,403,941)**
- **Evaluating partnership opportunities; no internal spend forecasted for 2017**

MSTX Financial Overview

- **Cash/investments at 8/31/2016: \$30.3 million**
 - \$10.6 million in principal debt payments made in Sep. & Oct. 2016; outstanding principal debt balance of \$3.7M
- **Estimated 2017 Operating Expenses: ~\$8 – 9 million***

MSTX News and Future Plans

- **Focused on clinical development of AIR001 for HFpEF**
 - Supporting three investigator-sponsored Phase 2 clinical studies at prestigious research institutions
 - Interim results from HFpEF-PH study expected Q4 2016
 - Results from 100-patient INDIE study expected Q4 2017

- **Actively evaluating partnering and licensing opportunities;**
 - AIR001 (heart failure)
 - Vepoloxamer program (all acute ischemic indications)
 - Unique, 388-patient sickle cell disease database



