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): September 8, 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)	(I.R.S. 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))

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Item 8.01 Other Events.

On September 8, 2014, Mast Therapeutics, Inc. (the "Company") announced top line results from a Phase 2 clinical study of AIR001 (sodium nitrite) inhalation solution in patients with pulmonary arterial hypertension (PAH). The Company obtained the rights to the AIR001 program through its acquisition of Aires Pharmaceuticals, Inc. in February 2014. In the primary efficacy analysis of the Phase 2 study, all doses showed improvement in median pulmonary vascular resistance (PVR). In the secondary efficacy analysis, all doses showed improvements in the median distances obtained in the 6-minute walk test, including clinically-meaningful improvements at the highest dose level. Additionally, AIR001 was well-tolerated, with no treatment related serious adverse events. In particular, methemoglobin levels remained normal (< 1.5%).

The Phase 2 study was a multi-center, open-label, randomized, parallel-dose study to determine the safety and efficacy of AIR001 in subjects with PAH. Subjects were randomized into one of three treatment arms and treated with AIR001 for 16 weeks: 80 mg once daily after a 2-week "run-in" period of 46 mg once daily; 46 mg four times daily after a 2-week run-in period of 46 mg four times daily; or 80 mg four times daily after a 2-week run-in period of 46 mg four times daily. The primary objective of the study was to evaluate the efficacy of inhaled nebulized AIR001 as determined by change in PVR from baseline to week 16, measured immediately post-completion of AIR001 nebulization. Secondary endpoints included change from baseline to week 16 in: 6 Minute Walk Distance (6MWD) assessed immediately post-completion of AIR001 nebulization (peak), but no more than 40 minutes after completion of AIR001 nebulization; hemodynamic measurements of cardiac output, mean right atrial pressure and pulmonary capillary wedge pressure at peak; N-Terminal Pro-Brain Natriuretic Peptide (NT-proBNP); hemodynamics and 6MWD at trough; and quality of life measures. The study was powered to enroll 90 patients, however, prior to its acquisition by the Company, Aires discontinued the study due to capital constraints. Data is available from 29 patients who enrolled in the study.

Encouraged by the data from the Phase 2 study and data from prior studies of AIR001 in which, to date, more than 120 individuals have received AIR001, and the significant unmet need facing the large number of patients with pulmonary hypertension associated with left heart disease, the Company also announced that it will be pursuing clinical development of AIR001 in patients with pulmonary hypertension associated with left heart disease and plans to support multiple, institution-sponsored Phase 2a studies that will evaluate: (1) acute hemodynamic effects, (2) acute effects versus placebo on maximum oxygen consumption and exercise hemodynamics, and (3) inhaled versus intravenous administration of nitrite, as well as the safety of multiple doses of AIR001, in that patient population.

Forward-Looking Statements

Mast Therapeutics 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 regarding the Company’s development, regulatory and commercialization strategies and plans for its product candidates, including AIR001, as well as the timing of activities related to those plans, including commencement and completion of clinical and nonclinical studies. 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; 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 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 potential for institutional review boards or the FDA or other regulatory agencies to require additional nonclinical or clinical studies prior to initiation of planned clinical study of a product candidate; the risk that, even if clinical studies are successful, the FDA or another regulatory agency may determine they are not sufficient to support a new drug application; 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 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, manufacturing, 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, even if the Company successfully develops a product candidate in one or more indications, it may not realize commercial success with its products and may never generate revenue sufficient to achieve profitability; the risk that the Company is not able to adequately protect its intellectual property rights and prevent competitors from duplicating or developing equivalent versions of its product candidates; 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.

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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.

September 8, 2014

By: /s/ Patrick L. Keran

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