

Mast Therapeutics, Inc.
Form 8-K
February 10, 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): February 7, 2014

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.)

12390 El Camino Real, Suite 150, San Diego, California
(Address of principal executive offices)

92130
(Zip Code)

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(858) 552-0866

Registrant's telephone number, including area code

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(b))
- .. 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 1.01. Entry into a Material Definitive Agreement.

Merger Agreement

On February 7, 2014, Mast Therapeutics, Inc. (the Company) and its wholly-owned subsidiary AP Acquisition Sub, Inc., a Delaware corporation (Merger Sub), entered into an Agreement and Plan of Merger (the Merger Agreement) with Aires Pharmaceuticals, Inc., (Target) and a stockholders representative (the Stockholders Representative). Pursuant to the Merger Agreement, the Company will acquire Target, a privately held pharmaceutical company focused on the development of inhaled sodium nitrite. The Merger Agreement provides that at the effective time of the Merger (the Effective Time), Merger Sub will be merged with and into Target (the Merger), with Target continuing as the surviving corporation and a wholly-owned subsidiary of the Company.

Under the terms of the Merger Agreement, at the Effective Time, each outstanding share of Target capital stock (other than shares held by stockholders of Target who have properly demanded appraisal rights for their shares in accordance with Delaware law) will be converted into the right to receive from the Company, in the aggregate, such number of unregistered shares of the Company s common stock, par value \$0.001 (Common Stock) as is equal to (i) the product of Target s net cash immediately prior to the Effective Time multiplied by 1.5, (ii) divided by the price that is the average of the closing price per share of Common Stock during the 10 trading day period immediately preceding the closing date of the Merger (the Merger Consideration). Approximately 80% of the shares that constitute the Merger Consideration (the Holdback Amount) will be held back from issuance for a period of six months from the Effective Time for the benefit of the Company to satisfy the indemnification obligations of Target s stockholders pursuant to the Merger Agreement. Based on the average of the closing prices per share of Common Stock for the 10-day period ending February 7, 2014 and the Company s estimate of Target s net cash immediately prior to the Effective Time, the Company expects that the Merger Consideration will be approximately 6,000,000 shares of Common Stock.

The shares of Common Stock constituting the Merger Consideration will be issued by the Company in reliance on the exemptions provided by Section 4(a)(2) of the Securities Act of 1933, as amended (the Securities Act), and Regulation D promulgated thereunder and in reliance on similar exemptions under applicable state laws.

The parties have made customary representations, warranties and covenants in the Merger Agreement, including among other things, covenants that Target shall, during the period from the date of the Merger Agreement until the closing date of the Merger (the Closing Date), (a) maintain its corporate existence; (b) use its reasonable best efforts to preserve intact its present business organization; (c) maintain its books and records in accordance with current practice, and to use its reasonable best efforts to maintain in full force and effect all authorizations and policies; and (d) use its reasonable best efforts to conduct its business in such a manner that on the Closing Date the representations and warranties of Target contained in the Merger Agreement shall be true and correct, as though such representations and warranties were made on and as of such date; and (e) Target shall use its reasonable best efforts to cause all of the conditions to the obligations of the Company and Merger Sub to be satisfied as soon as practicable following the date of the Merger Agreement. Additionally, Target agrees that it shall not, (i) adopt or propose any amendment to its organizational documents; (ii) declare, or pay any dividend or other distribution with respect to any of its securities; (iii) issue or authorize for issuance any securities, or make any change in any issued and outstanding securities, or redeem, purchase or otherwise acquire any securities, other than with respect to the issuance of securities upon the exercise of its stock option and warrants; (iv) mortgage, pledge or permit to become subject to liens (other than permitted liens) any properties or assets of the Company; (v) be party to (A) any merger, acquisition, consolidation, recapitalization, liquidation, dissolution or similar transaction involving Target or (B) any purchase of all or any substantial portion of the assets or securities of Target; (vi) (A) other than file income tax returns for calendar year 2012, file any tax return or amendment to any tax return unless copies of such tax return or amendment have first been delivered to the Company for its review and approval at a reasonable time prior to filing, (B) except as required by applicable law, make or change any material election in respect of taxes or adopt or change any accounting method in respect of taxes, or (C) enter into any closing agreement, settle any claim or assessment in respect of taxes, or consent

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to any extension or waiver of the limitation period applicable to any claim or assessment in respect of taxes; (vii) enter into any severance or termination arrangement with any employee or consultant which include any covenants, obligations or liabilities that will continue or survive on or after the Closing, other than as set forth in the Merger Agreement; (viii) incur any indebtedness, or make any capital expenditures or commit to make any capital expenditures which, in any one case exceeds \$10,000 or which in the aggregate exceed \$30,000; (ix) enter into or renew any material contract, other than as set forth in the Merger Agreement; (x) modify any of Target's insurance policies in effect on the date of the Merger Agreement; (xi) waive, release, assign, settle or compromise any material claims, settle any proceeding or initiated proceeding; (xii) sell, lease, transfer or assign any material property or assets of Target, other than as set forth in the Merger Agreement; (xiii) amend any of Target's benefit plans unless required by applicable law or requested by the Company; (xiv) delay or

postpone the payment of accounts payable or other liabilities, in each case, outside the ordinary course of business, consistent with past practice, make any change in its accounting principles or practices or the methods by which such principles or practices are applied for financial reporting purposes (except as required by GAAP), or write down or write up (or fail to write down or write up in accordance with GAAP consistent with past practice) the value of any inventories or revalue any of their respective assets other than in the ordinary course of business consistent with past practice and in accordance with GAAP; or (xv) agree, whether in writing or otherwise, to do any of the foregoing.

Pursuant to the Merger Agreement, the Company, on the one hand, and the stockholders of Target on the other, will indemnify and hold the other harmless as a result of the breach of the representations, warranties and covenants in the Merger Agreement. To provide a fund for payment to the Company in respect of its indemnification rights, the Holdback Amount will be held back for a period of six months following the Effective Time. Subject to certain limited exceptions, no claim for indemnification of losses by the Company shall be made unless the aggregate amount of losses exceeds \$50,000, in which case the Company shall be entitled to seek compensation for all losses without regard to such limitation. Subject to certain exceptions, the Merger Agreement provides for a maximum limit on indemnification by the stockholders of Target equal to the Holdback Amount.

The consummation of the Merger is subject to certain customary conditions, including, without limitation, (a) the approval of the Merger Agreement and the transactions contemplated thereunder by Target's stockholders; (b) the absence of any legal prohibitions on the closing of the Merger; (c) subject to certain exceptions, the continued accuracy of the Company's and Target's representations and warranties as of the Effective Time; (d) the absence of any circumstance or event since the date of the Merger Agreement that has had or would reasonably be expected to have, individually or in the aggregate, a material adverse effect on Target; (e) Target's stock option plan shall have been terminated; (f) Target's stock options and capital stock equivalents shall have been terminated; (g) certain of Target's agreements and plans shall have terminated; (h) certain employees of Target shall have entered into separation agreements and/or releases providing for the termination of such employees' employment effective immediately prior to the Effective Time; (i) certain employees of Target shall have entered into offer letters and/or remain employed by Target immediately prior to the closing of the Merger; and (j) and the Company shall have received approval from the NYSE MKT LLC of its additional listing application with respect to the shares constituting the Merger Consideration.

Under the Merger Agreement, each of the Company and Target has certain rights to terminate the Merger Agreement and the Merger, including (a) by mutual written consent of either party, (b) by either party if the Merger has not been consummated on or prior to February 28, 2014, subject to certain exceptions; (c) by the Company, if the required Target stockholder approval is not obtained; (d) by either party if a governmental authority shall have issued an order or taken any other action, in each case having the effect of permanently restraining, enjoining or otherwise prohibiting the Merger, subject to certain exceptions; or (e) by either party if there has been a breach of any representation, warranty, covenant or agreement on the part of the other party set forth in this Agreement, which breach (i) causes certain closing conditions to not be met and (ii) shall not have been cured within 10 calendar days following receipt by the breaching party of written notice of such breach from the other party.

The Company expects that five of Target's current employees, including its chief medical officer, will continue with the surviving corporation following the closing of the Merger. Three of those employees will continue on a transitional basis, for two to four months post-closing. The Company plans to enter into an offer letter agreement with Target's chief medical officer prior to the closing date, which agreement will govern the initial terms of his employment with Target post-closing.

Stockholder Agreement

On February 7, 2014, promptly following the execution of the Merger Agreement, the Company and stockholders holding all of the outstanding shares of the preferred stock and approximately 90% of the Common Stock of Target each (i) entered into a stockholder agreement (the "Stockholder Agreement") and (ii) delivered a written consent of the

stockholders of Target (which constitutes the required vote under the Merger Agreement) approving the Merger Agreement, the ancillary documents, the Merger and the transactions contemplated thereby. Each Stockholder Agreement became effective as of February 7, 2014. Pursuant to the terms and conditions of the Stockholder Agreement each stockholder signatory thereto has agreed to, among other items (i) not transfer the shares of Common Stock issued as Merger Consideration (the Merger Shares) held by such stockholder for a period of six months from closing date of the Merger, subject to certain exceptions, (ii) not transfer the Target s shares held by such stockholder, subject to certain exceptions, (iii) vote the Target s shares held by such stockholder at any meeting of Target stockholders or written consent of Target stockholders to approve the Merger Agreement and the Merger and the transactions contemplated thereby, and against any other acquisition proposal and also grant an irrevocable proxy to the Target s officers to vote such shares in the same manner, and (iv) grant an irrevocable proxy to the Company s officers to vote the Merger Shares held by such stockholder at any meeting of the Company stockholders or written consent of the Company stockholders

in the same manner, which proxy shall terminate on the earlier of the termination of the Merger Agreement and the 30-month anniversary of the closing date of the Merger. The transfer restrictions and proxy with respect to Target's shares held by the stockholder terminate on the earlier of the termination of the Merger Agreement or the Effective Date. The Stockholder Agreement shall terminate automatically on the termination of the Merger Agreement.

The Stockholder Agreement also provides for certain covenants and representations and warranties, including those relied on by the Company in connection with issuing the Merger Shares in reliance on Section 4(a)(2) of the Securities Act and Regulation D thereunder. Additionally, the Stockholder Agreement provides that the stockholder releases the Company and Target from claims relating to Target, but excluding claims under the Merger Agreement.

Description of the AIR001 Program

Target's lead product candidate is AIR001 (sodium nitrite) inhalation solution. AIR001 is an 80 mg/mL solution of sodium nitrite in a sterile phosphate buffer solution for nebulization. Nitrite is a physiological signaling molecule with roles in intravascular endocrine nitric oxide (NO) production, hypoxic vasodilation, signaling, and cytoprotection after ischemia-reperfusion. Nitrite serves as the largest physiologic reservoir of NO and can be converted to NO independent of nitric oxide synthase (NOS) activity. Nitrite mediated NO formation has been shown to have multiple vasoprotective characteristics, including inhibition of endothelial cell apoptosis, inhibition of platelet aggregation and adhesion, inhibition of leukocyte chemotaxis, and inhibition of smooth muscle cell proliferation and migration. Results of nitrite use in monocrotoline and hypoxic animal models of pulmonary hypertension have demonstrated improved remodeling both in the pulmonary vasculature and right ventricle.

To date, Target's development of AIR001 has been focused primarily on WHO (World Health Organization) Group 1 pulmonary hypertension, or pulmonary arterial hypertension (PAH), and Target had initiated two phase 2 studies of AIR001 in that setting. Prior to execution of the Merger Agreement, Target terminated and began the process of closing those studies. After the Merger, the Company will continue the closing process. Though the terminated studies did not complete enrollment, assuming the closing of the Merger, the Company expects data from subjects who completed the protocol-specified 16 weeks of treatment (approximately 20 subjects) in the second quarter of 2014.

The Company has not defined its development strategy for AIR001 and, other than potentially supporting an extension of an ongoing study at the University of Pittsburgh (described below), does not have plans to initiate immediately any clinical or nonclinical studies involving AIR001. Over the three to nine months following the Merger, the Company plans to meet with clinical and regulatory experts in pulmonary hypertension and heart failure to define the optimal development strategy for AIR001. However, the Company is considering working with the University of Pittsburgh to expand an ongoing phase 2a clinical study sponsored by the university, which currently is evaluating whether AIR001 can reduce pulmonary vascular resistance in subjects with WHO Group 1 and WHO Group 3 PH, to evaluate whether AIR001 can reduce wedge pressure and right atrial pressure in WHO Group 2, or patients with PH with left heart disease. The Company believes that, with its support, data from that study could be available as early as summer 2015.

The Company currently estimates that, during the 12-month period following the Merger, the costs of the AIR001 program, including costs associated with the wind-down of Target's clinical studies in PAH, costs to support the University of Pittsburgh's clinical study, and Target personnel costs, will be approximately \$2.0 million. The Company currently expects that Target's net cash at closing will exceed the Company's estimated 12-month post-closing expenses for the AIR001 program. However, as noted above, the Company will be refining its development strategy for AIR001 over the next few months and expects that its initial plans and, therefore, its estimated costs for the program, will change.

Forward-Looking Statements

Mast Therapeutics cautions you that statements included in this report, including under Description of the AIR001 Program, 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 number of shares of Common Stock that constitutes the Merger Consideration and the Company's development plans for AIR001, as well as the cost and 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 potential that the closing of the Merger may be delayed and/or the Merger Agreement may be terminated pursuant to its terms and the Company will not acquire Target on a timely basis or at all; the potential that the number of shares of Common Stock that constitutes the Merger Consideration will be greater or less than the Company's estimated amount as a result of differences between the Company's estimate of and Target's actual net cash immediately prior to the Effective Time and/or volatility in the closing sales prices of the Common Stock; the potential for delays in the commencement or completion of nonclinical and 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 other regulatory agencies to require additional nonclinical or clinical studies in addition to those that the Company includes in its development plan, which likely would increase the total time and cost of development; the risk that clinical studies are not successfully executed and/or do not successfully demonstrate the safety or efficacy of the investigational drug; the risk that, even if clinical studies are successful, the FDA

determines they are not sufficient to support a new drug application; the risk that even if clinical studies of an investigational drug 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 nonclinical and clinical studies and regulatory activities, 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, 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 Company is not able to adequately protect its intellectual property rights relating to the AIR001 program, if acquired, and prevent competitors from duplicating or developing equivalent versions of the drug; 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 hereof. 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 Exchange Act.

Item 3.02. Unregistered Sales of Equity Securities.

The information set forth in Item 1.01 of this report related to the issuance of shares of the Company's common stock is hereby incorporated by reference under this Item 3.02.

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.

February 10, 2014

Mast Therapeutics, Inc.

By: /s/ Patrick L. Keran

Name: Patrick L. Keran

Title: President and Chief Operating Officer