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): December 31, 2015

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 1.01 Entry into a Material Definitive Agreement.

Effective as of December 31, 2015, Mast Therapeutics, Inc. (the "Company") entered into an amendment (the "Second Amendment") to the Loan and Security Agreement, dated August 11, 2015, as amended by the First Amendment thereto dated September 28, 2015 (together, the "Loan Agreement"), with Hercules Technology III, L.P. and Hercules Technology Growth Capital, Inc. (together, "Hercules"). The Second Amendment extended to January 31, 2016 the deadline for the Company's vepoloxamer and AIR001 programs to achieve the clinical development milestones required to avoid prepayment to Hercules on April 30, 2016 of \$10 million of the principal balance under the Loan Agreement.

A copy of the Second Amendment is attached hereto as Exhibit 10.1 and incorporated herein by reference.

Item 2.02 Results of Operations and Financial Condition.

On January 7, 2016, the Company announced that its cash, cash equivalents and investment securities were approximately \$41 million as of December 31, 2015.

Item 7.01 Regulation FD Disclosure.

On January 7, 2016, the Company issued a press release that announced the Company's cash, cash equivalents and investment securities as of December 31, 2015 and provided a business update. A copy of the press release is furnished as Exhibit 99.1 hereto.

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.

In accordance with General Instruction B.2. of Form 8-K, the information in Items 2.02 and 7.01 of this report and Exhibit 99.1 to this report shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference in any of the Company's filings under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any incorporation language in such a filing, except as expressly set forth by specific reference in such a filing.

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: January 7, 2016

By: /s/ Brandi L. Roberts

Brandi L. Roberts Chief Financial Officer and Senior Vice President

Exhibit Index

Description
Second Amendment to Loan and Security Agreement, dated as of December 31, 2015, among Mast Therapeutics, Inc., Hercules Technology
III, L.P. and Hercules Technology Growth Capital, Inc.
Press release dated January 7, 2016

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SECOND AMENDMENT TO LOAN AND SECURITY AGREEMENT

THIS SECOND AMENDMENT (this "<u>Amendment</u>") to the Loan and Security Agreement, dated as of August 11, 2015, as previously amended pursuant to that certain First Amendment thereto dated as of September 28, 2015 (as so amended, the "<u>Loan Agreement</u>"), is made by and among MAST THERAPEUTICS, INC., a Delaware corporation ("<u>Borrower</u>"), HERCULES TECHNOLOGY GROWTH CAPITAL, INC., a Maryland corporation, as administrative agent ("<u>Agent</u>"), and the lender party hereto ("<u>Lender</u>"), and shall be effective as of December 31, 2015.

RECITALS

A. Borrower, Agent and Lender are parties to the Loan Agreement.

B. The parties wish to amend the Loan Agreement, as provided herein.

C. The Loan Agreement may be amended pursuant to Section 11.3(b) thereof by the written agreement of Borrower, Agent and Lender (which, for the avoidance of doubt, is the Required Lender).

AGREEMENT

NOW, THEREFORE, for valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

DEFINED TERMS

. Capitalized terms used but not defined herein (including in the recitals) shall have the meanings assigned to such terms in the Loan Agreement.

SECTION 2. <u>Amendments to Loan Agreement</u>. Subject to all of the terms and conditions set forth in this Amendment, the parties hereby agree to the following amendments to the Loan Agreement:

(A) The definition of "Second Advance Prepayment Conditions" in Section 1.1 of the Loan Agreement is hereby amended to replace the date "December 31, 2015" with "January 31, 2016" in clauses (a) and (b) thereof.

SECTION 3. <u>Effect on Loan Documents</u>. Except as specifically amended herein, all Loan Documents shall continue to be in full force and effect and are ratified and confirmed in all respects. The execution, delivery and effectiveness of this Amendment shall not operate as a waiver of any right, power or remedy of any Lender or Agent under any of the Loan Documents, and it shall not constitute a waiver of any provision of the Loan Documents. Any reference to the Loan Agreement in any other Loan Document shall be a reference to the Loan Agreement as amended by this Amendment.

SECTION 4. <u>Representations and Warranties</u>. Borrower represents and warrants to Agent and Lender as follows:

(A) Borrower's execution, delivery and performance of this Amendment, (i) has been duly authorized by all necessary corporate action of Borrower, (ii) will not result in the creation or imposition of any Lien upon the Collateral or the Intellectual Property, other than Permitted Liens and the Liens created by the Loan Documents, (iii) does not violate any provisions of Borrower's Certificate of Incorporation, bylaws, or any law, regulation, order, injunction, judgment, decree or writ to which Borrower is subject, and (iv) does not violate any contract or agreement or require the consent or approval of any other Person which has not already been obtained. The individual or individuals executing this Amendment are duly authorized to do so.

(B) This Amendment has been duly executed and delivered on Borrower's behalf by its duly authorized officer, and constitutes Borrower's legal, valid and binding obligations, enforceable in accordance with its terms, subject to bankruptcy, reorganization, insolvency, moratorium and other similar laws affecting the

enforcement of creditors' rights generally and the exercise of judicial discretion in accordance with general principles of equity.

SECTION 5. Governing Law. This Amendment shall be governed by, and construed in accordance with, the law of the State of California.

COUNTERPARTS

. This Amendment may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Delivery by facsimile, .pdf or other electronic imaging means of an executed counterpart of a signature page to this Amendment shall be effective as delivery of an original executed counterpart of this Amendment. Agent may also require that any such documents and signatures delivered by facsimile, .pdf or other electronic imaging means be confirmed by a manually signed original thereof; <u>provided</u> that the failure to request or deliver the same shall not limit the effectiveness of any document or signature delivered by facsimile, .pdf or other electronic imaging means.

[Remainder of page intentionally blank]

IN WITNESS WHEREOF, the parties hereto have caused this Amendment to be duly executed and delivered by their respective proper and duly authorized officers as of the day and year first above written.

BORROWER:

MAST THERAPEUTICS, INC.

By: <u>/s/ Brandi Roberts</u> Name: Brandi Roberts Title: Chief Financial Officer

AGENT:

HERCULES TECHNOLOGY GROWTH CAPITAL, INC.

By: <u>/s/ Ben Bang</u> Name: Ben Bang Title: Associate General Counsel

LENDER:

HERCULES TECHNOLOGY III, L.P.

By: Hercules Technology SBIC Management, LLC, its General Partner

By: Hercules Technology Growth Capital, Inc., its Manager

By: <u>/s/ Ben Bang</u> Name: Ben Bang Title: Associate General Counsel

[Second Amendment to Loan and Security Agreement]



MAST THERAPEUTICS PROVIDES BUSINESS UPDATE

- Enrollment in largest-ever interventional Phase 3 trial in sickle cell disease has surpassed 90%; top-line data anticipated Q2 2016
- Enrollment in Phase 2a study of AIR001 in HFpEF is complete; top-line data expected this month
- Company ended 2015 with approximately \$41M in cash, cash equivalents and investment securities

SAN DIEGO – January 7, 2016 – <u>Mast Therapeutics, Inc.</u> (NYSE MKT: MSTX), a biopharmaceutical company developing novel, clinical-stage therapies for sickle cell disease and heart failure today provided a business update.

- The Company reported that patient enrollment in the pivotal Phase 3 "<u>EPIC</u>" study of its lead product candidate, vepoloxamer (MST-188), in sickle cell disease recently surpassed the 90% mark. The Company expects to complete patient enrollment in February. Consistent with prior guidance, the Company expects to report top-line results in the second quarter of 2016.
- The Company also reported that dosing in its special population pharmacokinetics study of vepoloxamer in subjects with varying degrees of renal insufficiency is scheduled to begin today. This study will support the Company's New Drug Application submission to the U.S. Food and Drug Administration and provide guidance for proper dosing of vepoloxamer in sickle cell disease.
- The Company also announced that patient enrollment is complete in a placebo-controlled Phase 2a study of AIR001 designed to measure its effect on cardiovascular hemodynamics in patients suffering from heart failure with preserved ejection fraction (HFpEF). Top-line results from this 30patient, investigator-sponsored study are expected to be available this month. Preliminary results from an initial cohort of patients enrolled in a second investigator-sponsored Phase 2a study of AIR001 in HFpEF patients have been submitted for presentation at a scientific conference in May.
- The Company also is progressing with its Phase 2 study of vepoloxamer for the treatment of chronic heart failure, which is testing a new formulation of vepoloxamer designed to be more suitable for heart failure patients. The Company currently has 5 study sites open in the United States and Australia and plans to open additional sites in the first quarter of 2016.
- As of December 31, 2015, the Company had cash, cash equivalents and investment securities of approximately \$41 million.

"We are pleased to report that more than 90% of the planned 388 patients have been enrolled in EPIC, the largest sickle cell crisis intervention study ever conducted," stated Brian M. Culley, Chief Executive Officer. "Participation in EPIC has been outstanding with more than 75 sites in 14 countries and more than two-thirds of those sites located in the U.S. We expect to complete enrollment next month and after the final enrolled patient's 30-day observation period, the process of blinded data review and quality control will begin, leading thereafter to database lock and unblinding of the study data."

"In addition, we have made important progress with the development of AIR001 for HFpEF and look forward to receiving results from two ongoing Phase 2a studies, the first of which is expected to occur this month," continued Mr. Culley.

About Mast Therapeutics

Mast Therapeutics, Inc. is a publicly traded biopharmaceutical company headquartered in San Diego, California. The Company is leveraging its <u>MAST</u> (<u>Molecular Adhesion and Sealant Technology</u>) <u>platform</u>, 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 <u>EPIC</u> 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. More information can be found on the Company's web site at <u>www.masttherapeutics.com</u>. (Twitter: <u>@MastThera</u>)

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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 vepoloxamer and AIR001, and anticipated timing of achievement of development milestones, such as commencement and completion of clinical studies or regulatory activities, and of announcement of study data. 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 the Company's product candidates and the risk that its product candidates, including vepoloxamer, may not demonstrate adequate safety, efficacy or tolerability in one or more such studies, including EPIC; 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, 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; delays in clinical study closeouts, including blinded data review and quality assurance procedures; the risk that, even if current and planned clinical studies are successful, the FDA or other regulatory agencies 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 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 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, even if the Company successfully develops a product candidate in one or more indications, it may not realize commercial success and may never achieve profitability; the risk that the Company is not able to adequately protect its intellectual property rights, through patents or otherwise, and prevent competitors from duplicating or developing equivalent versions of its product candidates or that the use or manufacture of its products or product candidates 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 Securities and Exchange Commission. The Company's public filings with the Securities and Exchange Commission are available at www.sec.gov.

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 Ioana C. Hone (ir@mastthera.com) 858-552-0866 Ext. 303

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