
**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): May 6, 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))
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Item 2.02 Results of Operations and Financial Condition.

On May 6, 2016, Mast Therapeutics, Inc. issued a press release announcing its financial results for the three months ended March 31, 2016. 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 Item 2.02 of this report and Exhibit 99.1 hereto 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: May 6, 2016

By: /s/ Brandi L. Roberts

Brandi L. Roberts

Chief Financial Officer and Senior Vice President

Exhibit Index

**Exhibit
Number**

Description

99.1 Press release dated May 6, 2016



MAST THERAPEUTICS REPORTS FIRST QUARTER 2016 FINANCIAL RESULTS AND RECENT HIGHLIGHTS

- **Completed enrollment in Phase 3 EPIC study of vepoloxamer in sickle cell disease**
- **Announced positive top-line results from Phase 2a study of AIR001 in patients with heart failure with preserved ejection fraction (HFpEF)**
- **AIR001 selected by Heart Failure Clinical Research Network (HFN) for multicenter, randomized, double-blind, placebo-controlled Phase 2 study in ~100 patients with HFpEF**
- **Continued progress with ongoing Phase 2 study of vepoloxamer in chronic heart failure**

SAN DIEGO – May 6, 2016 – Mast Therapeutics, Inc. (NYSE MKT: MSTX), a biopharmaceutical company developing novel, clinical-stage therapies for sickle cell disease and heart failure, today reported financial results for the first quarter ended March 31, 2016.

“The first quarter of 2016 was a productive one for Mast. Not only did we complete enrollment in our Phase 3 EPIC study of vepoloxamer in sickle cell disease, but also we announced positive data from a Phase 2a study of AIR001 in patients with heart failure with preserved ejection fraction conducted at Mayo Clinic, and the selection of AIR001 for a double-blind, placebo-controlled Phase 2 study in approximately 100 patients with HFpEF to be conducted at premier U.S. clinical centers that make up the HFN,” stated Brian M. Culley, Chief Executive Officer.

“With 388 patients, the EPIC study was the largest placebo-controlled study in sickle cell disease ever concluded and should provide many insights into the activity of vepoloxamer in this indication. Importantly, vepoloxamer has the potential to become the first and only approved therapy for shortening the duration of a sickle cell vaso-occlusive crisis and we are working diligently toward generating top-line results, which we expect to announce this quarter,” continued Mr. Culley. “Meanwhile, we are advancing our two heart failure programs. Our 150-patient Phase 2 study of vepoloxamer in chronic heart failure is ongoing, with ten study sites now open, and the HFN’s 100-patient Phase 2 study of AIR001 in HFpEF is expected to begin in the third quarter of 2016.”

First Quarter 2016 Operating Results

The Company’s net loss for the first quarter of 2016 was \$11.2 million, or \$0.06 per share (basic and diluted), compared to a net loss of \$9.6 million, or \$0.06 per share (basic and diluted), for the same period in 2015.

Research and development expenses for the first quarter of 2016 were \$7.9 million, an increase of \$1.9 million, or 30%, compared to \$6.0 million for the same period in 2015. The increase was due mainly to increases of \$0.9 million in external nonclinical study fees and expenses, \$0.5 million in external clinical study fees and expenses, and \$0.3 million in personnel expenses.

The increase in external nonclinical study fees and expenses was due primarily to increased costs related to preparation for a new drug application for vepoloxamer (\$0.5 million) and research-related manufacturing for vepoloxamer (\$0.5 million), offset by a decrease in research-related manufacturing for AIR001 (\$0.1 million). The increase in external clinical study fees and expenses was due primarily to increased costs related to the Phase 2 study of vepoloxamer in heart failure (\$0.5 million) and the EPIC study (\$0.3 million), offset by a decrease

related to discontinuation of a Phase 2 study of vepoloxamer in acute limb ischemia, which the Company began to wind-down in the third quarter of 2015 (\$0.3 million).

Selling, general and administrative (SG&A) expenses for the first quarter of 2016 were \$2.8 million, a decrease of \$0.8 million, or 21%, compared to \$3.6 million for the same period in 2015. SG&A expenses for the first quarter of 2015 included \$0.4 million of severance expenses and \$0.3 million of share-based compensation resulting from the termination of employment of the Company's former president and chief operating officer in February 2015 and the acceleration of stock option vesting pursuant to the terms of his option agreements.

Interest expense for the first quarter of 2016 was \$0.5 million, which was related to the Company's debt facility. There was no interest expense for the first quarter of 2015.

About Mast Therapeutics

Mast Therapeutics, Inc. is a publicly traded biopharmaceutical company headquartered in San Diego, California. The Company is developing two clinical-stage investigational new drugs for serious or life-threatening diseases and conditions. Vepoloxamer, the Company's lead product candidate, is in Phase 3 clinical development for the treatment of vaso-occlusive crisis in patients with sickle cell disease and in Phase 2 clinical development for the treatment of patients with heart failure. Enrollment in the Company's 388-patient Phase 3 study of vepoloxamer in patients with sickle cell disease, known as the EPIC study, was completed in February 2016. Enrollment in the Company's Phase 2 study of vepoloxamer in patients with chronic heart failure is ongoing. AIR001, the Company's second product candidate, is in Phase 2 clinical development for the treatment of patients with heart failure with preserved ejection fraction (HFpEF). Enrollment in a Phase 2a study of AIR001 in patients with HFpEF is ongoing and AIR001 was recently selected by the Heart Failure Clinical Research Network for evaluation in a 100-patient, multicenter, randomized, double-blind, placebo-controlled, Phase 2 study in patients with HFpEF. More information can be found on the Company's web site at www.masttherapeutics.com. (Twitter: @MastThera)

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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 within the meaning of the Private Securities Litigation Reform Act of 1995 that are based on the Company's current expectations and assumptions. Such forward-looking statements may be identified by the use of forward-looking words such as "expect," "intend," "plan," "anticipate," "believe," among others, and include, but are not limited to, statements relating to prospects for successful development and commercialization of the Company's product candidates, including vepoloxamer for the treatment of vaso-occlusive crisis of sickle cell disease, and anticipated timing of achievement of development milestones, such as commencement and completion of clinical studies and announcement of study data. There are a number of factors that could cause or contribute to material differences between actual events or results and the expectations indicated by the forward-looking statements. These factors include, but are not limited to: the inherent uncertainty of outcomes in ongoing and future studies of the Company's product candidates and the risk that its product candidates may not demonstrate adequate safety, efficacy or tolerability in one or more such studies, including vepoloxamer in the Phase 3 "EPIC" study; risks associated with the Company's ability to manage operating expenses and obtain additional capital as needed; the Company's potential inability to continue as a going concern if it does not raise additional capital as needed; 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, including the prepayment of \$10 million of the principal balance of its debt facility if results from the EPIC study are not positive; the potential for the Company to significantly delay, reduce or discontinue current and/or planned development and commercial-readiness activities or sell or license its assets at inopportune times if it is unable to raise sufficient additional capital as needed; delays in clinical study closeouts, including blinded data review and quality control and assurance procedures; the risk that, even if EPIC study results are positive, the FDA may require a second Phase 3 study or other clinical or nonclinical studies to demonstrate substantial evidence of vepoloxamer's effectiveness for sickle cell patients or to provide additional safety and tolerability data or that the FDA may require changes to manufacturing controls or processes that could delay filing of a new drug application; 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; 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 dependence on third parties to assist with important aspects of development of its product candidates, including conduct of its clinical studies and supply and manufacture of clinical trial material, and, if approved, commercial product, and the risk that such third parties may fail to perform as expected, leading to delays in product candidate development or approval or inability to meet market demand for approved products, if any; 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 obtain and maintain effective patent coverage or other market exclusivity protections for its products, if approved, without infringing 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:

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[Tables to Follow]

Mast Therapeutics, Inc.
Condensed Consolidated Statements of Operations
(In thousands, except per share data)

	Three months ended	
	March 31,	
	(Unaudited)	
	2016	2015
Total net revenue	\$ —	\$ —
Operating expenses:		
Research and development	7,875	6,042
Selling, general and administrative	2,835	3,578
Depreciation and amortization	32	30
Total operating expenses	10,742	9,650
Loss from operations	(10,742)	(9,650)
Interest and other (expense)/income, net	(465)	34
Net loss	\$ (11,207)	\$ (9,616)
Net loss per share – basic and diluted	\$ (0.06)	\$ (0.06)
Weighted average shares – basic and diluted	178,115	159,459

Mast Therapeutics, Inc.
Balance Sheet Data
(In thousands)

	March 31,		December 31,
	2016		2015
Cash, cash equivalents and investment securities	\$	37,089	\$ 40,981
Working capital		15,580	19,079
Total assets		50,145	54,217
Total liabilities		29,465	30,328
Stockholders' equity		20,680	23,889