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): November 12, 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 2.02 Results of Operations and Financial Condition.

On November 12, 2015, Mast Therapeutics, Inc. issued a press release announcing its financial results for the three and nine months ended September 30, 2015. 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.

The information set forth under Item 2.02 and in Exhibit 99.1 is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and is not to be incorporated by reference into any filing of the registrant, whether made before or after the date hereof, regardless of any general incorporation language in any such 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: November 12, 2015

By: /s/ Brandi L. Roberts

Brandi L. Roberts Chief Financial Officer and Senior Vice President

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99.1 Press release dated November 12, 2015

Description



MAST THERAPEUTICS REPORTS THIRD QUARTER 2015 FINANCIAL RESULTS

Conference Call Scheduled Today at 4:30pm ET / 1:30pm PT

SAN DIEGO – November 12, 2015 – <u>Mast Therapeutics, Inc.</u> (NYSE MKT: MSTX), a clinical-stage biopharmaceutical company leveraging its molecular adhesion and sealant technology (MAST) platform to develop novel therapies for sickle cell disease, heart failure and stroke, today reported financial results for the quarter ended September 30, 2015.

"During the third quarter, we continued to make significant progress with our clinical development of vepoloxamer," stated Brian M. Culley, Chief Executive Officer. "We recently surpassed the 80% enrollment mark in our Phase 3 'EPIC' study in sickle cell disease, we enrolled the first patient in our open-label, repeat-exposure EPIC-extension study, and we initiated a Phase 2 study of vepoloxamer in chronic heart failure with a new formulation."

"Additionally, the two Phase 2a studies of AIR001 in patients with heart failure with preserved ejection fraction (HFpEF) continue to enroll patients and we look forward to sharing interim and complete data from those clinical studies in coming months," continued Mr. Culley.

Third Quarter 2015 Operating Results

The Company's net loss for the third quarter of 2015 was \$9.9 million, or \$0.06 per share (basic and diluted), compared to a net loss of \$7.9 million, or \$0.06 per share (basic and diluted), for the same period in 2014.

Research and development (R&D) expenses for the third quarter of 2015 were \$7.3 million, an increase of \$1.9 million, or 36%, compared to \$5.4 million for the same period in 2014. The increase was due primarily to increases of \$1.8 million in external nonclinical study fees and expenses and a \$0.2 million in external clinical study fees and expenses, offset by a \$0.1 million decrease in personnel costs and share-based compensation expense. The \$1.8 million increase in external nonclinical study fees and expenses was due primarily to an increase in research-related manufacturing costs for vepoloxamer.

Selling, general and administrative (SG&A) expenses of \$2.5 million for the third quarter of 2015 were consistent with the same period in 2014.

Year-to-Date Financial Results

The Company's net loss for the nine months ended September 30, 2015 was \$29.7 million, or \$0.18 per share (basic and diluted), compared to a net loss of \$21.4 million, or \$0.19 per share (basic and diluted), for the same period in 2014.

R&D expenses for the nine months ended September 30, 2015 were \$21.1 million, an increase of \$6.6 million, or 46%, compared to \$14.5 million for the same period in 2014. The increase was due primarily to a \$4.1 million increase in external nonclinical study fees and expenses, a \$2.2 million increase in external clinical study fees and expenses and a \$0.2 million increase in personnel expenses.

The \$4.1 million increase in external nonclinical study fees and expenses was due primarily to a \$3.8 million increase in research-related manufacturing costs for vepoloxamer and a \$0.3 million increase in research-related manufacturing costs for AIR001. The \$2.2 million increase in external clinical study fees and expenses was due primarily to increases of \$2.7 million in EPIC study costs and \$0.4 million in costs for our Phase 2 study of vepoloxamer in heart failure, offset by decreases of \$0.5 million in AIR001 clinical study costs and \$0.5 million in costs for the discontinued Phase 2 study of vepoloxamer in acute limb ischemia.

SG&A expenses for the nine months ended September 30, 2015 were \$8.4 million, an increase of \$1.3 million, or 19%, compared to \$7.1 million for the same period in 2014. This increase was due primarily to a \$0.7 million increase in personnel costs and a \$0.5 million increase in professional and consulting fees.

The Company recognized a \$0.5 million bargain purchase gain during the nine months ended September 30, 2014 associated with its acquisition of Aires, which was included in other income.

Balance Sheet Highlights

As of September 30, 2015, the Company had cash, cash equivalents and investment securities totaling \$49.9 million. Stockholders' equity amounted to \$33.5 million as of September 30, 2015.

Investor Conference Call

The Company will hold a conference call today, November 12, 2015, at 4:30 p.m. ET / 1:30 p.m. PT to discuss its financial results for the third quarter of 2015 and provide a corporate update. Interested parties may access the conference call by dialing (855) 239-3120 from the U.S. and (412) 542-4127 from outside the U.S. and should request the Mast Therapeutics, Inc. Corporate Update Call. A live webcast of the conference call will be available online from the Investors section of Mast's website at <u>http://www.masttherapeutics.com/investors/events/</u>. Replays of the webcast will be available on the Company's website for 30 days and a telephone replay will be available through November 18, 2015 by dialing (877) 344-7529 from the U.S. and (412) 317-0088 from outside the U.S. and entering replay access code 10075708.

About Mast Therapeutics

Mast Therapeutics, Inc. is a publicly traded biopharmaceutical company headquartered in San Diego, California. The Company is leveraging its <u>MAST platform</u>, derived from over two decades of clinical, nonclinical and manufacturing experience with purified and non-purified poloxamers, to develop vepoloxamer (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 nebulizer, for the treatment of heart failure with preserved ejection fraction (HFpEF).

Vepoloxamer is an investigational new drug being tested 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 tested 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 and the Phase 2 study of vepoloxamer in chronic heart failure; 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 risk that, even if 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 potential for additional nonclinical or clinical studies to be required prior to initiation of a planned clinical study; 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 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

[Tables to Follow]

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

	Three months ended September 30, (Unaudited)				Nine months ended September 30, (Unaudited)			
		2015		2014		2015		2014
Total net revenue	\$		\$	—	\$	—	\$	—
Operating expenses:								
Research and development		7,330		5,402		21,106		14,503
Selling, general and administrative		2,460		2,455		8,448		7,091
Transaction-related expenses		_		2				271
Depreciation and amortization		38		25		105		60
Total operating expenses		9,828		7,884		29,659		21,925
Loss from operations		(9,828)		(7,884)		(29,659)		(21,925)
Interest and other (expense)/income, net		(84)		18		(20)		536
Net loss	\$	(9,912)	\$	(7,866)	\$	(29,679)	\$	(21,389)
Net loss per share – basic and diluted	\$	(0.06)	\$	(0.06)	\$	(0.18)	\$	(0.19)
Weighted average shares – basic and diluted		163,614		123,287	_	161,749		114,709

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

	Septe 2	December 31, 2014			
Cash, cash equivalents and investment securities	\$	49,913	\$	57,289	
Working capital		37,929		49,965	
Total assets		63,438		70,500	
		22.000		11.0.10	
Total liabilities		29,899		11,842	
		22 520			
Stockholders' equity		33,539		58,658	