
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):

August 11, 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 2.02 Results of Operations and Financial Condition.

On August 11, 2014, Mast Therapeutics, Inc. issued a press release announcing its financial results for the three and six months ended June 30, 2014. 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.

August 11, 2014

By: /s/ Patrick L. Keran

Name: Patrick L. Keran

Title: President and Chief Operating Officer

Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release, dated August 11, 2014



MAST THERAPEUTICS PROVIDES CORPORATE UPDATE AND REPORTS SECOND QUARTER 2014 FINANCIAL RESULTS

- Update on Company's clinical and preclinical programs
- 4 clinical study read-outs anticipated over the next 12 to 18 months
- Targeting pathologies characterized by membrane dysfunction with substantial commercial opportunity

SAN DIEGO – August 11, 2014 – Mast Therapeutics, Inc. (NYSE MKT: MSTX) today provided a corporate update and reported financial results for the quarter ended June 30, 2014.

Brian M. Culley, Chief Executive Officer, said: "This is an important time for Mast. We have an ongoing Phase 3 study in a rare disease with more than an 18-month head start on our nearest competitor. We have an ongoing Phase 2 study that will demonstrate whether MST-188 improves the effectiveness of a thrombolytic agent that's used everywhere from acute limb ischemia to pulmonary embolism to heart attack and stroke. We have another Phase 2 study planned in heart failure, the leading cause of hospitalization in patients over 65. And, we have cash to move these and our other programs towards major value inflection points."

Upcoming News and Events

- Phase 2 Study (pulmonary arterial hypertension): preliminary data Q3 2014
- Phase 2 Study (heart failure): agreement with FDA on protocol Q4 2014
- Nonclinical Study (heart failure): data Q1 2015
- Nonclinical Study (embolic stroke): data Q2 2015
- Phase 2 Study (heart failure): initiate enrollment 1H 2015
- Phase 2 Study (acute limb ischemia): complete enrollment Q4 2015
- EPIC Study (sickle cell disease): complete enrollment Q4 2015
- Phase 2 Study (WHO Group 2 pulmonary hypertension): data 2H 2015
- Phase 2 Study (heart failure): data (interim analysis) 2H 2015

More information regarding these events and each of the Company's programs is provided in the "Corporate Update" section, below.

Corporate Update

MST-188 – Sickle Cell Disease (SCD)

The Company continues to enroll patients in EPIC, its pivotal Phase 3 study of MST-188 in SCD, and reiterates its prior guidance that enrollment will complete at the end of 2015. MST-188 has orphan drug status for SCD in both the U.S. and EU, as well as fast track status with the FDA.

The Company recently announced or completed several of numerous initiatives underway to support MST-188, the most clinically advanced new drug in development to treat an on-going crisis in SCD, including:

- Announced data from an *ex vivo* study, conducted at Loyola University Medical Center, where MST-188 reduced mean erythrocyte sedimentation rate, a measure of inflammation, by 50% relative to control in blood collected from individuals with sickle cell disease, which adds to the body of data supporting MST-188's potential to shorten the duration of sickle cell crisis;
- Initiated patient enrollment in a sub-study within EPIC to quantify the effect of MST-188 on tissue oxygenation, which will provide insight into the potential for MST-188 to reduce end-organ failure and associated premature death in individuals with sickle cell disease; and
- Reported that, following a review of clinical data from enrolled subjects, the EPIC independent data safety monitoring board recommended the EPIC study continue without modification.

MST-188 – Occlusive Arterial Disease

In 2014, the Company achieved several milestones related to its clinical-stage program in occlusive arterial disease, including:

- Initiated a Phase 2 study that will demonstrate whether MST-188 improves the effectiveness of recombinant tissue plasminogen activator (rt-PA) in patients with acute limb ischemia, a complication of occlusive arterial disease;

- Initiated a nonclinical study in a well-validated model of embolic stroke that will demonstrate whether and to what degree MST-188 extends the therapeutic window of rt-PA, the potential for which is based on studies showing that MST-188 salvages tissue in the “ischemic penumbra,” protects the blood-brain barrier, improves thrombolysis, and improves blood-flow in collateral (non-occluded) vessels; and
- Obtained from the FDA orphan drug designation for MST-188 for the treatment of acute limb ischemia (Nov 2013) and submitted an application for orphan drug designation in the EU.

An estimated 800,000 people suffer a stroke each year in the U.S. (15 million worldwide), over 85% of which are ischemic strokes, yet the American Heart Association estimates that only 7% of all hospital admissions for acute ischemic stroke receive rt-PA, the only FDA-approved drug. A major reason for the limited use of rt-PA is its narrow therapeutic window (within 3 hours of onset of stroke symptoms), as well as the risk of intracerebral hemorrhage. An agent that improves the effectiveness of rt-PA (which the Company is evaluating in its ongoing Phase 2 study) and/or expands its therapeutic window (which the Company is evaluating in its ongoing nonclinical study) has the potential to improve outcomes and make rt-PA an option in the estimated 93% of hospital admissions where it is not used.

MST-188 – Heart Failure

Earlier this year, the Company reported positive results from a nonclinical study in a well-validated model of chronic heart failure, in which a single, 2-hour infusion of MST-188 demonstrated statistically significant, progressive and lasting (up to 2 weeks) improvements in key hemodynamic parameters and markers of cardiac injury and stress. Based on feedback from cardiovascular thought leaders, the Company plans to develop MST-188 in heart failure. Near-term activities include:

- Initiating additional nonclinical study(ies) to evaluate how long (beyond 2 weeks) previously observed improvements persist and the effect of repeat administration of MST-188, as well as to characterize the mechanism underlying observed improvements;
- Reaching agreement with FDA on requirements to initiate a Phase 2 study of MST-188 in patients with heart failure; and
- Initiating the Phase 2 study in heart failure, which may demonstrate that MST-188 reduces biomarkers associated with increased 180-day all-cause mortality in heart failure patients.

Over 25% of Medicare patients discharged following hospitalization for heart failure will be re-admitted within 30 days. This high rate may reflect the limitations of existing treatment options (e.g., vaso-dilators, diuretics), which are effective at resolving the symptoms of heart failure (e.g., edema) but may not directly improve heart function. In contrast, the Company believes the membrane-sealing activity of MST-188 directly improve heart contractility and function. Further, the Company’s ongoing nonclinical study will determine whether a second dose of MST-188 duplicates the benefits observed after the first dose and extends improvements to 4 weeks (or beyond), which may translate into a positive impact on rehospitalization rates, such as 30-day readmission.

MST-188 – Trauma

Recently, the Company signed a Cooperative Research and Development Agreement with a branch of the U.S. military to evaluate the utility of MST-188 in specific models of trauma of interest to the U.S. government. Pilot studies are expected to begin in 2014. If results are positive, the Company expects the U.S. government will be interested in further exploring the potential of MST-188 as a treatment following major trauma.

AIR001 – Pulmonary Hypertension

In February 2014, the Company completed its acquisition of Aires Pharmaceuticals, a clinical-stage biopharmaceutical company, and its lead product candidate, AIR001. Near-term news and events related to AIR001 include:

- Reporting data from the 29 patients enrolled in a Phase 2 study in pulmonary arterial hypertension;
- Initiating enrollment of patients with pulmonary hypertension with left heart disease (WHO Group 2 PH) in an on-going university-sponsored Phase 2 study of AIR001; and
- Announcing the Company’s overall development strategy with AIR001.

Board of Directors

In June, the Company expanded its expertise and depth by welcoming Dr. Howard Dittrich to its Board of Directors. Dr. Dittrich brings a proven track record of success in cardiovascular disease, evidenced in part by the sale of NovaCardia to Merck & Co. in 2007 for \$350 million.

Second Quarter 2014 Financial Results

The Company’s net loss for the second quarter of 2014 was \$7.2 million, or \$0.06 per share (basic and diluted), compared to a net loss of \$4.9 million, or \$0.09 per share (basic and diluted), for the same period in 2013.

Research and development expenses for the second quarter of 2014 were \$4.8 million, an increase of \$2.0 million, or 70%, compared to \$2.8 million for the same period in 2013. The increase was primarily due to a \$1.1 million increase in external clinical study fees and expenses, a \$0.6 million increase in external nonclinical study fees and expenses and a \$0.3 million increase in personnel costs. The increase in external clinical study fees and expenses was largely related to the Company’s ongoing pivotal Phase 3 study in sickle cell disease (the EPIC study) and Phase 2 study in ALL. The increase in external nonclinical study fees and expenses was primarily related to manufacturing additional MST-188 clinical trial material.

Selling, general and administrative expenses for the second quarter of 2014 were \$2.4 million, an increase of \$0.3 million, or 13%, compared to \$2.1 million for the same period in 2013. The increase resulted primarily from an increase in personnel costs.

Year-to-Date Financial Results

The Company's net loss for the six months ended June 30, 2014 was \$13.5 million, or \$0.12 per share (basic and diluted), compared to a net loss of \$10.5 million, or \$0.21 per share (basic and diluted), for the same period in 2013.

Research and development expenses for the six months ended June 30, 2014 were \$9.1 million, an increase of \$2.8 million, or 45%, compared to \$6.3 million for the same period in 2013. The increase was primarily due to a \$1.1 million increase in external clinical study fees and expenses, a \$1.1 million increase in external nonclinical study fees and expenses and a \$0.6 million increase in personnel costs. The increase in external clinical study fees and expenses was related primarily to the ongoing EPIC study and Phase 2 study in ALI, as well as the wind-down of the AIR001 studies in PAH, which increased costs were offset by the absence of any material fees and expenses related to its thorough QT/QTc clinical study of MST-188 that was completed in 2013. The increase in external nonclinical study fees and expenses was primarily related to manufacturing additional MST-188 clinical trial material. The increase in personnel costs was primarily related to additional clinical and research-related manufacturing staff hired after the first half of 2013.

Selling, general and administrative expenses for the six months ended June 30, 2014 were \$4.6 million, an increase of \$0.4 million, or 10%, compared to \$4.2 million for the same period in 2013. The increase resulted primarily from an increase in personnel costs.

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

Balance Sheet Highlights

As of June 30, 2014, the Company had cash, cash equivalents and investment securities totaling \$46.4 million. Stockholders' equity amounted to \$50.2 million as of June 30, 2014.

About Mast Therapeutics

Mast Therapeutics, Inc. is a publicly traded biopharmaceutical company headquartered in San Diego, California. The Company is leveraging the MAST (Molecular Adhesion and Sealant Technology) platform, derived from over two decades of clinical, nonclinical and manufacturing experience with purified and non-purified poloxamers, to develop 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 enrolling subjects in EPIC, a pivotal Phase 3 study of MST-188 in sickle cell disease, and in a Phase 2 study to evaluate whether MST-188 improves the effectiveness of recombinant tissue plasminogen activator therapy in patients with acute limb ischemia. The Company also is planning to initiate a Phase 2 clinical study of MST-188 in patients with acute decompensated heart failure in the first half of 2015 and to announce details of the study's design later this year. More information can be found on the Company's web site at www.masttherapeutics.com. (Twitter: [@MastThera](https://twitter.com/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 that are based on the Company's current expectations and assumptions. Such forward-looking statements include, but are not limited to, statements relating to prospects for successful development of MST-188 in sickle cell disease, occlusive arterial disease, including ALI, heart failure, and trauma, and the anticipated timing of achievement of development milestones for its product candidates, 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 the Company's product candidates and the risk that its product candidates, including MST-188, 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; the potential for institutional review boards or the FDA or other regulatory agencies to require additional nonclinical or clinical studies prior to initiation of a planned clinical study of a product candidate; the risk that, even if 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 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 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 relating to the MAST platform and MST-188 or AIR001 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 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 June 30, (Unaudited)		Six months ended June 30, (Unaudited)	
	2014	2013	2014	2013
Total net revenue	\$ —	\$ —	\$ —	\$ —
Operating expenses:				
Research and development	4,820	2,837	9,101	6,280
Selling, general and administrative	2,370	2,100	4,636	4,213
Transaction-related expenses	(11)	7	269	35
Depreciation and amortization	23	9	35	18
Total operating expenses	<u>7,202</u>	<u>4,953</u>	<u>14,041</u>	<u>10,546</u>
Loss from operations	(7,202)	(4,953)	(14,041)	(10,546)
Interest and other income, net	50	12	518	24
Net loss	<u>\$ (7,152)</u>	<u>\$ (4,941)</u>	<u>\$ (13,523)</u>	<u>\$ (10,522)</u>
Net loss per share – basic and diluted	<u>\$ (0.06)</u>	<u>\$ (0.09)</u>	<u>\$ (0.12)</u>	<u>\$ (0.21)</u>
Weighted average shares – basic and diluted	<u>115,587</u>	<u>53,750</u>	<u>110,350</u>	<u>50,028</u>

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

	June 30, 2014 (Unaudited)	December 31, 2013
Cash, cash equivalents and investment securities	\$46,438	\$44,393
Working capital	41,819	40,695
Total assets	59,370	55,250
Total liabilities	9,149	7,442
Stockholders' equity	50,221	47,808