
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):

March 19, 2013

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))
-

[Top of the Form](#)

Item 2.02 Results of Operations and Financial Condition.

On March 19, 2013, Mast Therapeutics, Inc. issued a press release announcing its financial results for the three months and year ended December 31, 2012. 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 filed with 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.

[Top of the Form](#)

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.

March 19, 2013

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 March 19, 2013 |



MAST THERAPEUTICS REPORTS FOURTH QUARTER AND FULL YEAR 2012 FINANCIAL RESULTS

SAN DIEGO – March 19, 2013 – Mast Therapeutics, Inc. (NYSE MKT: MSTX) today reported financial results for the fourth quarter and year ended December 31, 2012.

Brian M. Culley, Chief Executive Officer, said: “2013 will be an exciting year for Mast Therapeutics. We already have accomplished several key objectives, including initiating a pivotal phase 3 clinical study in sickle cell disease, initiating a thorough QT study of MST-188, identifying multiple new development opportunities with MST-188 and announcing our plans to develop it in complications of arterial disease.”

Key objectives for the remainder of 2013 include:

- Announcing results from the thorough QT/QTc study of MST-188, expected mid-year;
- Soliciting FDA input on our planned phase 2 study in acute limb ischemia, expected in the third quarter;
- Announcing results of nonclinical studies evaluating the physiologic significance of TEG results observed in prior nonclinical studies funded by the Defense Advanced Research Projects Agency (DARPA) Surviving Blood Loss (SBL) program, expected in the second half of the year;
- Initiating a microvascular blood flow sub-study in EPIC, expected in the fourth quarter;
- Initiating a phase 2 clinical proof-of-concept study of MST-188 in acute limb ischemia, expected in late 2013/early 2014;
- Obtaining orphan drug designation for MST-188 for acute limb ischemia;
- Submitting application(s) to request funding from the U.S. government to conduct a phase 2 clinical proof-of-concept study with MST-188 for resuscitation of shock following major trauma; and
- Filing patent applications claiming key aspects of our proprietary manufacturing process.

Mr. Culley continued: “Our strategy in arterial disease is to first demonstrate the utility of MST-188 in patients with acute limb ischemia, an advanced form of atherosclerosis, where we believe the potential to demonstrate a treatment effect is greatest. Based on the similar pathophysiology of atherosclerotic arterial disease, we believe that clinical proof-of-concept data in acute limb ischemia will increase development and partnering opportunities in other forms of occlusive arterial disease. We expect to generate clinical proof-of-concept data in a relatively short period of time and with relatively modest investment, which we plan to leverage to find a partner to develop MST-188 in larger market indications within arterial disease, such as stroke.”

Fourth Quarter 2012 Operating Results

The Company’s net loss for the fourth quarter of 2012 was \$4.0 million, or \$0.08 per share (basic and diluted), compared to a net loss of \$2.4 million, or \$0.06 per share (basic and diluted), for the same period in 2011.

Research and development (R&D) expenses for the fourth quarter of 2012 were \$2.1 million, an increase of \$0.3 million, or 20%, compared to \$1.8 million for the same period in 2011. The net increase was due to increases of \$0.3 million in external clinical study fees and expenses and \$0.2 million in personnel costs, offset by a \$0.2 million decrease in external nonclinical study fees and expenses. The increase in external clinical study fees and expenses was primarily related to an increase in clinical consulting and phase 3 study planning expenses for MST-188. The increase in personnel costs was primarily related to additional clinical and research-related manufacturing staff hired in 2012. The decrease in external nonclinical study fees and expenses was primarily related to a decrease in research-related manufacturing activities for ANX-514.

Selling, general and administrative (SG&A) expenses for the fourth quarter of 2012 were \$1.8 million, consistent with the same period in 2011.

Year-to-Date Operating Results

The Company’s net loss for the year ended December 31, 2012 was \$15.6 million, or \$0.33 per share (basic and diluted), compared to a net loss of \$13.3 million, or \$0.47 per share (basic and diluted), for the same period in 2011.

R&D expenses for the year ended December 31, 2012 were \$8.1 million, an increase of \$2.3 million, or 41%, compared to \$5.8 million

for the same period in 2011. The increase was due to a \$1.2 million increase in personnel costs, a \$0.6 million increase in external clinical study fees and expenses and a \$0.5 million increase in external nonclinical study fees. The increase in personnel costs was primarily related to additional clinical and research-related manufacturing staff hired in 2012, including relocation and recruitment costs for our new Chief Medical Officer. The increase in external clinical study fees and expenses was related primarily to a \$0.8 million increase in clinical consulting and phase 3 study planning expenses for MST-188, offset by a \$0.2 million decrease in clinical consulting expenses for ANX-514 and Exelbine™. The increase in external nonclinical study fees and expenses was related primarily to a \$2.0 million increase in research-related manufacturing activities and regulatory affairs-related consulting expenses for MST-188 and a \$0.7 million increase in research-related manufacturing activities for ANX-514, offset by a \$2.2 million decrease in commercial-readiness manufacturing activities for Exelbine. Due to its focus on MST-188, the Company elected to discontinue independent development of its ANX-514 and Exelbine programs in 2012 and 2011, respectively.

SG&A expenses for the year ended December 31, 2012 were \$7.5 million, an increase of \$0.3 million, or 5%, compared to \$7.2 million for the same period in 2011. The net increase resulted from a \$0.7 million increase in personnel costs, mainly due to additional staff hired in 2012, and a \$0.5 million increase in share-based compensation expense, offset by a \$0.9 million decrease in consulting fees and legal expenses.

Balance Sheet Highlights

As of December 31, 2012, the Company had cash, cash equivalents and short-term investments totaling \$36.5 million. Stockholders' equity amounted to \$41.8 million as of December 31, 2012. The Company's contingent asset related to the consideration for the acquisition of SynthRx in April 2011 was settled in December 2012. The Company recorded the fair value of the contingent asset as of the settlement date as an adjustment to equity and recognized as a transaction-related expense the increase in its fair value as of its settlement date relative to December 31, 2011.

About Mast Therapeutics

Mast Therapeutics, Inc. is a publicly traded biopharmaceutical company headquartered in San Diego, CA. 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 with significant unmet needs. MST-188 is a cytoprotective, hemorheologic, anti-inflammatory and anti-thrombotic agent that has potential utility in diseases or conditions characterized by microcirculatory insufficiency (endothelial dysfunction and/or impaired blood flow).

The Company is recruiting subjects in EPIC, a pivotal phase 3 study of MST-188 in sickle cell disease. The Company plans to initiate a phase 2 clinical study of MST-188 in acute limb ischemia, a complication of peripheral arterial disease, in late 2013 or early 2014. More information can be found on the Company's web site at www.masttherapeutics.com.

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 regarding the Company's development plans for MST-188, including in sickle cell disease, acute limb ischemia, and other indications, and plans for protecting its intellectual property related to MST-188, as well as the 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 for 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 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 prior to initiation of planned phase 2 clinical studies of MST-188 in any particular indication in which the Company determines to develop MST-188, including acute limb ischemia, which likely would increase the total time and cost of development in the indication; the risk that clinical studies of MST-188 are not successfully executed and/or do not successfully demonstrate its safety or efficacy; 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 MST-188 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 MST-188, including clinical studies, and regulatory activities for MST-188 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 MST-188 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 acceptable partnering opportunities for MST-188 may not be available in particular jurisdictions or indications and, consequently, the Company may not be able to pursue development of MST-188 in certain jurisdictions and indications; the risk that the FDA does not grant marketing approval of MST-188, on a timely basis, or at all; the risk that the Company is not able to adequately protect its intellectual property rights relating to the MAST platform and MST-188 and prevent competitors from duplicating or developing equivalent versions of its product candidates, including MST-188; 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.
(A Development Stage Enterprise)
Condensed Consolidated Statements of Operations
(In thousands except per share data)

| | <u>Three months ended</u> | | <u>Year ended</u> | |
|---|---------------------------|-----------------------------------|------------------------------------|--------------------|
| | <u>December 31,</u> | | <u>December 31, ⁽¹⁾</u> | |
| | <u>2012</u> | <u>(Unaudited)</u> <u>2011</u> | <u>2012</u> | <u>2011</u> |
| Total net revenue | \$ — | \$ — | \$ — | \$ — |
| Operating expenses: | | | | |
| Research and development | 2,112 | 1,754 | 8,088 | 5,758 |
| Selling, general and administrative | 1,787 | 1,810 | 7,519 | 7,190 |
| Transaction-related expenses | 105 | (1,130) | (69) | 411 |
| Depreciation and amortization | 12 | 9 | 90 | 38 |
| Total operating expenses | <u>4,016</u> | <u>2,443</u> | <u>15,628</u> | <u>13,397</u> |
| Loss from operations | (4,016) | (2,443) | (15,628) | (13,397) |
| Interest and other income, net | 19 | 71 | 69 | 137 |
| Net loss | <u>\$ (3,997)</u> | <u>\$ (2,372)</u> | <u>\$ (15,559)</u> | <u>\$ (13,260)</u> |
| Net loss per share – basic and diluted | <u>\$ (0.08)</u> | <u>\$ (0.06)</u> | <u>\$ (0.33)</u> | <u>\$ (0.47)</u> |
| Weighted average shares – basic and diluted | <u>47,419</u> | <u>37,091</u> | <u>47,641</u> | <u>28,175</u> |

(1) The condensed consolidated statements of operations for the years ended December 31, 2012 and 2011 have been derived from the audited financial statements but do not include all of the information and footnotes required by accounting principles generally accepted in the United States for the complete financial statements.

Mast Therapeutics, Inc.
(A Development Stage Enterprise)
Balance Sheet Data
(In thousands)

| | <u>December 31,</u> <u>2012</u> | <u>December 31,</u> <u>2011</u> |
|---|------------------------------------|------------------------------------|
| Cash, cash equivalents and short-term investments | \$ 36,511 | \$ 50,704 |
| Working capital | 34,603 | 49,323 |
| Total assets | 46,972 | 61,856 |
| Total liabilities | 5,179 | 5,078 |
| Stockholders' equity | 41,792 | 56,779 |