

**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) **June 1, 2011**

Aastrom Biosciences, Inc.

(Exact name of registrant as specified in its charter)

Michigan
(State or other jurisdiction
of incorporation)

0-22025
(Commission File Number)

943096597
(IRS Employer Identification No.)

24 Frank Lloyd Wright Drive
P.O. Box 376
Ann Arbor, Michigan
(Address of principal executive offices)

48106
(Zip Code)

Registrant's telephone number, including area code: **(734) 930-5555**

(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))

Item 8.01. Other Events.

On June 1, 2011 the Registrant issued a press release, a copy of which is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

Exhibit 99.1. Press release dated June 1, 2011

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Aastrom Biosciences, Inc.

(Registrant)

June 1, 2011

/s/ **TIMOTHY M. MAYLEBEN**

(Date)

Exhibit Index

99.1 Press release dated June 1, 2011

Aastrom Demonstrates Statistically Significant Improvement in Time to First Occurrence of Treatment Failure at 12 Months in RESTORE-CLI Clinical Trial

RESTORE-CLI Results Meet Primary Safety and Efficacy Endpoints

ANN ARBOR, Mich., June 1, 2011 (GLOBE NEWSWIRE) -- Aastrom Biosciences, Inc. (Nasdaq:ASTM), the leading developer of patient-specific, expanded multicellular therapies for the treatment of severe, chronic, cardiovascular diseases, today announced that the final analysis of data from all 86 randomized patients in the RESTORE-CLI trial showed that the trial met its primary safety and efficacy endpoints, demonstrating a statistically significant improvement in the time to first occurrence of treatment failure (TTF) at 12 months. The RESTORE-CLI clinical trial assessed the safety and ability of ixmyelocel-T, Aastrom's expanded, bone marrow-derived cellular therapy, to restore damaged tissue in a lower extremity affected by critical limb ischemia (CLI).

In the clinical trial, the assessment of TTF included four components: major amputation of the treated leg, all-cause mortality, doubling of wound size from baseline, and *de novo* gangrene. All of these components together comprised the primary composite endpoint for this trial. CLI patients with tissue loss (i.e., *de novo* gangrene and increasing wound size) are five times more likely to experience amputation. As a result, tissue loss represents a widely accepted predictor of amputation risk in CLI patients. Aastrom plans to present the full data from the RESTORE-CLI trial at an appropriate medical meeting in the fourth quarter of 2011. The RESTORE-CLI trial is the largest, fully controlled cellular therapy clinical trial ever conducted in CLI.

"We are extremely pleased to report that the RESTORE-CLI trial met its primary safety and efficacy endpoints, providing substantial confirmation that ixmyelocel-T could represent an historic advance in the treatment of CLI for hundreds of thousands of patients who currently have no good treatment options available. I believe Aastrom is well positioned to advance this promising therapy through Phase 3 clinical testing and on to regulatory review," said Tim Mayleben, president and CEO of Aastrom.

Critical limb ischemia is considered the end-stage form of peripheral artery disease. It is the result of a chronic lack of blood flow to the lower extremities resulting in a variety of debilitating conditions, including severe rest pain, non-healing wounds, and gangrene. The double-blind, placebo-controlled RESTORE-CLI clinical trial randomized 86 men and women between the ages of 18 and 90 with a diagnosis of CLI and no previous major amputations. CLI was defined as persistent, recurring ischemic pain for at least two weeks, or ulcerations (grade 4 or 5 on the Wagner scale) or gangrene of the foot or toe. Participants in the clinical trial were randomized 2:1 to receive intramuscular injections of ixmyelocel-T or an electrolyte solution into the affected limb. Patients were followed for 12 months after treatment and otherwise received normal standard of care. The clinical trial was conducted at 20 medical centers throughout the U.S.

"Given the limited treatment options available in CLI, the results of this important Phase 2b study are encouraging for both patients and vascular physicians," said William R. Hiatt, MD, Novartis Foundation endowed professor for cardiovascular research at the University of Colorado School of Medicine and president of CPC Clinical Research, which has been chosen to collaborate with Aastrom on the upcoming Phase 3 clinical studies for ixmyelocel-T. "I look forward to working with Aastrom on what I believe is a very well-designed Phase 3 clinical development program for ixmyelocel-T in CLI, which also represents a translational step in the development of cellular therapies to treat human disease," Dr. Hiatt added.

Based on interim analyses from the RESTORE-CLI clinical trial, in October 2010 Aastrom announced plans to initiate a Phase 3 CLI clinical development program for ixmyelocel-T under special protocol assessments (SPA) and Fast Track designation by the FDA. Aastrom has been actively working with the FDA to finalize the special protocol assessment for the no option SPA and expects to conclude those discussions in the next several weeks.

About Aastrom Biosciences

Aastrom Biosciences is developing patient-specific, expanded multicellular therapies for use in the treatment of severe, chronic cardiovascular diseases. The company's proprietary cell-processing technology enables the manufacture of ixmyelocel-T, a patient-specific multicellular therapy expanded from a patient's own bone marrow and delivered directly to damaged tissues. Aastrom has advanced ixmyelocel-T into late-stage clinical development, including a planned Phase 3 clinical program to study patients with critical limb ischemia and two ongoing Phase 2 clinical trials in patients with dilated cardiomyopathy. For more information, please visit Aastrom's website at www.aastrom.com.

The Aastrom Biosciences, Inc. logo is available at <http://www.globenewswire.com/newsroom/prs/?pkgid=3663>

This document contains forward-looking statements, including, without limitation, statements concerning clinical trial plans and progress, objectives and expectations, clinical activity timing, intended product development, the performance and contribution of certain individuals and expected timing of collecting and analyzing treatment data, all of which involve certain risks and uncertainties. These statements are often, but are not always, made through the use of words or phrases such as "anticipates," "intends," "estimates," "plans," "expects," "we believe," "we intend," and similar words or phrases, or future or conditional verbs such as "will," "would," "should," "potential," "could," "may," or similar expressions. Actual results may differ significantly from the expectations contained in the forward-looking statements. Among the factors that may result in differences are the inherent uncertainties associated with clinical trial and product development activities, regulatory approval requirements, competitive developments, and the availability of resources and the allocation of resources among different potential uses. These and other significant factors are discussed in greater detail in Aastrom's Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and

other filings with the Securities and Exchange Commission. These forward-looking statements reflect management's current views and Aastrom does not undertake to update any of these forward-looking statements to reflect a change in its views or events or circumstances that occur after the date of this release except as required by law.

CONTACT: Media contact
Bill Berry
Berry & Company
bberry@berrypr.com
(212) 253-8881

Investor contact
Danielle Spangler
The Trout Group
dspangler@troutgroup.com
(646) 378-2924