

AASTROM BIOSCIENCES INC

FORM 8-K

(Current report filing)

Filed 07/06/10 for the Period Ending 07/06/10

| | |
|-------------|--|
| Address | 24 FRANKL LLOYD WRIGHT DR PO BOX 376 ANN ARBOR, MI 48106 |
| Telephone | 7349305555 |
| CIK | 0000887359 |
| Symbol | ASTM |
| SIC Code | 2836 - Biological Products, Except Diagnostic Substances |
| Industry | Biotechnology & Drugs |
| Sector | Healthcare |
| Fiscal Year | 06/30 |

**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) **July 6, 2010**

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 July 6, 2010 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.

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)

July 6, 2010

(Date)

/s/ TIMOTHY M. MAYLEBEN

Timothy M. Mayleben
Chief Executive Officer and President

Exhibit Index

99.1 Press release dated July 6, 2010

Aastrom to Pursue Phase 3 Clinical Program in CLI

ANN ARBOR, Mich., July 6, 2010 (GLOBE NEWSWIRE) -- Aastrom Biosciences, Inc. (Nasdaq:ASTM), the leading developer of autologous cellular therapies for the treatment of severe cardiovascular diseases, today announced that the company will pursue a Phase 3 clinical program for its autologous cell therapy for the treatment of critical limb ischemia (CLI) through the U.S. Food and Drug Administration's special protocol assessment (SPA) process. Aastrom is currently completing a Phase 2b clinical trial of its cell therapy in patients with CLI and recently met with FDA officials to discuss plans for the Phase 3 program.

"Our recent discussion with the FDA was very productive and identified a path for pursuing Phase 3 testing of our autologous cell technology in patients with critical limb ischemia," said Tim Mayleben, president and CEO of Aastrom. "We now plan to proceed through the agency's special protocol assessment process which will ensure that we and FDA agree on the Phase 3 clinical program. We appreciate the FDA's thoughtful responses to our questions and their invitation to begin planning for the Phase 3 clinical program through the SPA process."

In June 2010, results from a planned interim analysis of the ongoing Phase 2b RESTORE-CLI clinical trial were announced at the Society for Vascular Surgery annual meeting. Included in the results was the achievement of statistical significance on amputation-free survival (P=0.038), defined as time to major amputation or death.

Critical limb ischemia (CLI), the most severe form of peripheral vascular disease, leads to over 160,000 major limb amputations per year in the U.S. Data suggests that approximately twenty percent of patients will die within the first 6-12 months of CLI onset. Current therapeutic options are limited and often ineffective for the most severely affected patients.

About Special Protocol Assessments

An SPA is a written agreement between the FDA and a drug sponsor concerning clinical trial design, endpoints and other clinical trial issues that can be used to support regulatory approval of a therapeutic product candidate. The process is intended to increase the likelihood that if the specified clinical trial protocols are followed, the clinical trial endpoints are achieved and there is a favorable risk-benefit profile, trial data may serve as the primary basis of an efficacy claim in support of a Biologic License Application (BLA). More information is available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm080571.pdf>.

About Aastrom Biosciences

Aastrom Biosciences is developing autologous cellular therapies for use in the treatment of severe cardiovascular diseases. The company's proprietary cell-processing technology enables the production of cellular therapies using a patient's own bone marrow that can be delivered directly to damaged tissues. Aastrom has advanced this technology into late-stage clinical development and is conducting two Phase 2 clinical trials to treat dilated cardiomyopathy and a Phase 2b clinical trial to treat critical limb ischemia. 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, objectives and expectations, clinical activity timing, intended product development, disease treatment and progression, patient symptoms and responses to treatment, treatment options 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: Berry & Company
Media Contact
Stephen Zoegall
212 253-8881
szoegall@berrypr.com

Aastrom Biosciences, Inc.
Investor Contact
Kimberli O'Meara
734 930-5777

ir@astrom.com