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# 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):
**February 1, 2005**

# Aastrom Biosciences, Inc.

(Exact name of registrant as specified in its charter)

| **Michigan** | **0-22025** | **94-3096597** |
|---|---|---|
| (State or other jurisdiction of incorporation) | (Commission File No.) | (I.R.S. Employer Identification No.) |

**24 Frank Lloyd Wright Drive**
**P.O. Box 376**
**Ann Arbor, Michigan 48106**
(Address of principal executive offices)

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

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:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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**Item 8.01 Other Events.**

On February 1, 2005 Aastrom Biosciences, Inc. announced that its US clinical trial for the treatment of long-bone, severe fractures had successfully achieved the first FDA-required clinical benchmark, meeting the clinical safety endpoint for this product when used in bone graft indications. Aastrom is now able to expand this trial to include a broader range of fracture indications. The press release announcing this milestone is attached hereto as Exhibit 99.1.

**Item 9.01 Financial Statements and Exhibits.**

(c) Exhibits.

| Exhibit No. | Description |
|---|---|
| 99.1 | Press release |

**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.

Date: February 1, 2005

**AASTROM BIOSCIENCES, INC.**

By: /s/ Alan M. Wright
Alan M. Wright
Senior Vice President, Administrative and
Financial Operations, CFO

Aastrom BIOSCIENCES INC
P.O. Box 376 • Ann Arbor, Michigan 48106 • Ph: 734-930-5555 • Fax: 734-665-0485
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FOR IMMEDIATE RELEASE

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**AASTROM BIOSCIENCES ACHIEVES**
**CLINICAL MILESTONE IN ITS PHASE I/II U.S. BONE GRAFTING TRIAL**

***— Safety Endpoint for TRC Product Reached; Trial Expanded —***

**Ann Arbor, Michigan, February 1, 2005 —** Aastrom Biosciences, Inc. (NasdaqSC: ASTM) today announced that its U.S. clinical trial of the Company's Tissue Repair Cell (TRC) product intended for the treatment of long-bone, severe fractures has successfully achieved the first FDA-required clinical benchmark, meeting the clinical safety endpoint for this product when used in bone graft indications. The Company is now able to expand this trial to include a broader range of fracture indications.

The first group of patients accrued into the trial suffered with long-term (at least 8 months), non-union tibial fractures. With the safety milestone achieved, the Company is permitted by the FDA-approved IND to now treat appendicular, or fresh, non-union fractures, which opens the trial to a larger patient population.

The sites engaged in this multi-center clinical trial are: Lutheran General Hospital in Park Ridge, IL, the University of Michigan Health System's Orthopedic Trauma Center, Ann Arbor, MI and the Department of Orthopedic Surgery at William Beaumont Hospital in Royal Oak, MI. The Company anticipates adding additional sites to this U.S. trial. The safety benchmark was achieved in the patient group accrued at Lutheran General Hospital, supplemented with the initial results from the Company's trial of this same product in Barcelona, Spain.

"We are progressively building the clinical foundation for the safety and usefulness of our Tissue Repair Cell technology for bone regeneration," said R. Douglas Armstrong, Ph.D., Chief Executive Officer and Chairman of Aastrom. "The expansion of this trial to include patients with fresh non-union fractures should accelerate accruals into our bone graft study."

Aastrom's bone graft TRC product is also in clinical trials in Barcelona, Spain and Bochum, Germany. In October 2004, the Company announced initial results of, and the decision to expand the Barcelona bone graft trial. In addition, the Company is currently engaged in a clinical trial in Barcelona for the use of TRCs in sinus lift procedures, and in 2005 the Company intends to initiate a clinical trial of its TRC product for the treatment of limb ischemia in diabetic patients in Germany. The Company is in the process of preparing an IND application to be filed with the FDA for its TRC product intended for use in spine fusions.

**About Aastrom's TRCs**

Tissue Repair Cells (TRCs) are Aastrom's proprietary mixture of adult bone marrow stem and progenitor cells produced using patented single-pass perfusion technology in the AastromReplicell® System. The clinical procedure begins with the collection of a small sample of bone marrow from the patient's hip in an outpatient setting. TRCs are then produced in the automated AastromReplicell System over a 12-day period. It has been demonstrated in the laboratory that TRCs are able to develop into different types of tissue lineages in response to

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inductive signals, including blood, bone, cartilage, adipose and vascular tubules. In previous clinical trials, TRCs have been shown to be safe and reliable in regenerating certain normal healthy bone marrow tissues.

**About Aastrom Biosciences, Inc.**

Aastrom Biosciences, Inc. (NasdaqSC: ASTM) is developing treatments for the repair of damaged human tissues and other medical disorders, or the generation of normal human tissues, utilizing the Company's proprietary adult stem cell-based products. Aastrom's strategic position in the tissue regeneration and cell therapy sectors is enabled by its proprietary Tissue Repair Cells (TRCs), a mix of bone marrow stem and progenitor cells, and the AastromReplicell® System, an industry-unique automated cell production platform used to produce cells for clinical use. Together TRCs and the AastromReplicell System provide a foundation that the Company is leveraging to produce multiple Prescription Cell Products (PCPs), several of which are now in the clinical stage in the U.S. and EU. TRCs are the core component of the PCPs Aastrom is developing for bone grafting, peripheral vascular disease, jaw bone reconstruction and spine fusion markets. The Company has also developed the AastromReplicell System for dendritic cell production for researchers and institutions developing vaccines to treat cancer and infectious diseases, under its Cell Production Products line.

For more information, visit Aastrom's website at www.aastrom.com.

***This document contains forward-looking statements, including without limitation, statements concerning planned clinical trials, product development objective, and potential product applications, which involve certain risks and uncertainties. The forward-looking statements are also identified through use of the words "intended," "should," "anticipates," and other words of similar meaning. Actual results may differ significantly from the expectations contained in the forward-looking statements. Among the factors that may result in differences are future clinical trial results, regulatory approval requirements, 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 and other filings with the Securities and Exchange Commission.***

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