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): May 7, 2007

# Aastrom Biosciences, Inc.

(Exact name of registrant as specified in its charter)

| Michigan | 000-22025 | 94-3096597 |
|---|---|---|
| (State or other jurisdiction of incorporation) | (Commission File Number) | (I.R.S. Employer Identification No.) |
| 24 Frank Lloyd Wright Drive, P.O. Box 376, Ann Arbor, Michigan | | 48106 |
| (Address of principal executive offices) | | (Zip Code) |

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

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 8.01 Other Events.**

On May 7, 2007, we issued a press release announcing approval from the FDA to initiate our U.S. Phase III clinical trial for the treatment of osteonecrosis of the femoral head. A copy of the press release is attached hereto as Exhibit 99.1.

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**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.

Aastrom Biosciences, Inc.

*May 7, 2007*

*By: /s/ Gerald D. Brennan, Jr.*

*Name: Gerald D. Brennan, Jr.*
*Title: Vice President, Administrative and Financial Operations, CFO*

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Exhibit Index

| Exhibit No. | Description |
| --- | --- |
| 99.1 | Press Release dated May 7, 2007 |

FOR IMMEDIATE RELEASE

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**FDA Approves Aastrom Phase III IND for Treatment of Osteonecrosis of the Femoral Head**

***— Patient-Specific Stem Cell Trial to Address Unmet Medical Need —***

**Ann Arbor, Michigan, May 7, 2007 —** Aastrom Biosciences, Inc. (Nasdaq: ASTM), a regenerative medicine company, today announced that the U.S. Food & Drug Administration (FDA) approved the Company's Investigational New Drug (IND) application to initiate a 120 patient Phase III clinical trial for the treatment of osteonecrosis (also known as avascular necrosis) of the femoral head. Aastrom intends this to be a pivotal trial with the goal of demonstrating clinical safety and efficacy for the submission of a Biologics License Application (BLA). In addition, the Company may have to generate further patient data in this indication, such as data from the ongoing pivotal trial in Spain, to support a U.S. BLA submission. Osteonecrosis is a progressive disease, with no established effective treatments, that often leads to a total hip replacement. Aastrom will use its Bone Repair Cell (BRC) product, based on Tissue Repair Cell (TRC) Technology, to evaluate this approach for treating patients suffering from osteonecrosis.

"This is our first Phase III clinical trial focused on tissue regeneration, and it represents a significant step forward for both the Company and the field of regenerative medicine. We are thrilled to report the achievement of this clinical milestone," said George Dunbar, President and Chief Executive Officer of Aastrom. "Should the clinical trial results meet our expectations, we intend to seek licensure and take the BRC product to market under our existing Orphan Drug Designation."

Initiation of this clinical trial complements the receipt of an Orphan Drug Designation from the FDA. Orphan drug status is granted to development-stage products that offer potential therapeutic value in the treatment of rare diseases and conditions. The Company may be entitled to several benefits prior to approval, including an expedited FDA review, the reduction or even elimination of filing fees, and the availability of possible tax credits, and will be entitled to seven years of marketing exclusivity once the product receives FDA approval.

This trial will seek to enroll 120 patients, randomized into two patient groups, at up to 20 clinical sites. The planned treatment approach for all patients will include a core decompression surgery where a core track (hole) is drilled into the head of the femur to relieve internal pressure. Patients randomized into the treatment group will have BRCs mixed with a bone matrix carrier placed into the core track, while control patients will receive bone matrix carrier without cells. If healthy bone can be successfully regenerated in the femoral head, we expect the need for a hip replacement could be delayed or eliminated in osteonecrosis patients. The primary efficacy endpoint of this trial is to prevent or delay the progression of osteonecrosis to fracture, and potentially collapse of the femur head, which will be measured by a blinded third-party reviewer through MRI and CT imaging. Patients will be followed for a total of 24 months, post-treatment.

"Osteonecrosis is a pressing medical problem in orthopedic medicine. This disease generally afflicts younger people, and often has a poor prognosis. More than half of the patients progress to debilitating fractures of the femoral head which require a total hip replacement without appropriate treatment, within two years of initial diagnosis," said Marc W. Hungerford, M.D., Assistant Professor of Orthopedics at the Johns Hopkins University School of Medicine. "This trial represents a novel and promising approach aimed at preserving the functional integrity of the hip joint. It could potentially eliminate the need to subject the patient to major surgery."

The tissues involved in osteonecrosis of the femoral head include bone, bone marrow and blood vessels (vascular), complicating the development of effective treatments in the past. Aastrom's TRC-based products, which include a proprietary mixture of stem and progenitor cells derived from a small sample of the patient's own bone marrow, have been used in other clinical trials involving different indications to evaluate regeneration in all three of these tissues. With this capability, the application of TRC Technology may offer a novel means to regenerate the tissues lost due to osteonecrosis.

This study initiation is Aastrom's second clinical trial evaluating the Company's TRC Technology in patients with osteonecrosis of the femoral head. In January, the Company announced it had treated the first two patients in a pivotal clinical trial for osteonecrosis in Spain.

**About Osteonecrosis**

The National Osteonecrosis Foundation indicates that in the U.S. alone, there are up to 20,000 people initially diagnosed with this debilitating disease each year, and current therapies are of limited effectiveness. Osteonecrosis is a painful medical condition where the tissue inside a bone is dying and unable to regenerate itself through natural processes. Ninety percent of the patients afflicted by this disease have osteonecrosis at the femoral head – the ball at the top of the femur bone that rotates inside the hip socket. Left untreated the femoral head eventually collapses, leading to a total hip joint replacement. In the U.S., it is estimated that up to 10% of all hip replacements are performed due to osteonecrosis. There are no established pharmaceuticals for the prevention or treatment of osteonecrosis. For more information, visit the National Osteonecrosis Foundation's website at www.nonf.org.

**About Aastrom Biosciences, Inc.**

Aastrom is a regenerative medicine company developing autologous cell products for the repair or regeneration of multiple human tissues, based on its proprietary Tissue Repair Cell (TRC) Technology. Aastrom's TRC-based products are a unique cell mixture of stem and progenitor cells, produced from a small amount of bone marrow taken from the patient. TRC-based products have been used in over 250 patients, and are currently in clinical trials for bone regeneration (osteonecrosis of the femoral head, long bone fractures and spine fusion applications) and vascular regeneration (critical limb ischemia applications). The Company is also developing programs to address cardiac and neural regeneration indications. TRC-based products have received Orphan Drug Designation from the FDA for use in the treatment of osteonecrosis of the femoral head and the treatment of dilated cardiomyopathy, a severe chronic disease of the heart.

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

***This document contains forward-looking statements, including without limitation, statements concerning clinical trials and anticipated results, product development objectives, regulatory approval matters, potential advantages of TRC-based products, and potential product applications, which involve certain risks and uncertainties. The forward-looking statements are also identified through use of the words "expect," "should," "could," "seek," "can," "intends," "expectations," "may," "planned," "possible," "potential," 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 potential patient accrual difficulties, clinical trial results, potential product development difficulties, the effects of competitive therapies, regulatory approval requirements and interpretations, the availability of financial and other 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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