
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):
October 18, 2004

Aastrom Biosciences, Inc.

(Exact name of registrant as specified in its charter)

Michigan
(State or other jurisdiction of
incorporation)

0-22025
(Commission File No.)

94-3096597
(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:

- 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 October 18, 2004 Aastrom Biosciences, Inc. announced that its clinical trial in Barcelona, Spain would be expanded based on the initial results from the first phase of patient treatment. 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: October 18, 2004

AASTROM BIOSCIENCES, INC.

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

(AASTROM BIOSCIENCES LOGO)

P.O. Box 375 - Ann Arbor, Michigan 48106 - Ph: 734-930-5555 - Fax: 734-665-0485
 Located at: Domino's Farms, Lobby L

FOR IMMEDIATE RELEASE

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CONTACTS: Kris M. Maly or
 Becky Anderson
 Investor Relations Department
 Aastrom Biosciences, Inc.
 Phone: (734) 930-5777

Kevin McGrath
 Cameron Associates
 Phone: (212) 245-4577

AASTROM BIOSCIENCES ANNOUNCES PLANS TO EXPAND BONE GRAFT STUDY
 BASED ON RESULTS OF SEVERE FRACTURE TREATMENTS

ANN ARBOR, MICHIGAN, OCTOBER 18, 2004 -- Aastrom Biosciences, Inc. (NasdaqSC: ASTM) and the Institut de Terapia Regenerativa Tissular (IIRT) announced today that their clinical trial in Barcelona, Spain will be expanded based on initial results from the first phase of patient treatments. The trial involved 5 patient treatments using Aastrom's Tissue Repair Cells (TRCs) for the bone graft repair of severe long bone non-union fractures, and was completed at the Hospital General de l'Hospitalet, Centro Medico Teknon and Hospital de Barcelona-SCIAS. The results to date show that Aastrom's TRCs were safe, with no adverse events reported, and that patients are exhibiting various early stages of healing. Aastrom will continue monitoring the progressive bone regeneration in these patients, while expanding the trial to include additional patients and formalizing a plan for the registration of its TRC product for use in bone graft surgery in the EU.

This trial, one of three clinical studies of Aastrom's bone graft TRC product currently underway, was initiated in March 2004 in cooperation with IIRT (Barcelona, SP), who coordinated the trial implementation. This proof of concept feasibility clinical trial was designed to evaluate the safety and effectiveness of the Company's TRCs to regenerate new, healthy bone in the repair of long bone non-union fractures. All of the patients who received TRC treatment had previously failed to repair their non-union fractures using standard of care procedures, during the preceding 6 to 16 months. The results to date are interim, as complete bone fusion typically takes many months.

The trial was completed under the direction of Principal Investigators, Dr. Carlos Solano-Puerta and Dr. Lluís Orozco. These physicians reported that each patient is exhibiting increased mobility and freedom from pain as a result of the healing process at the fracture site. Non-union fractures often present problems related to their repair due to the severity of the fracture in which the bone pieces are completely separated. This type of fracture usually requires various mechanical fixations and bone graft processes for repair. However, standard procedures may fail, requiring the patients to undergo additional surgery and bone grafting approaches. This was the situation for all of the patients in the Barcelona trial, who having failed to heal their fractures after standard of care treatments, received TRCs mixed with a synthetic commercial matrix, directly at the fracture site.

Dr. Lluís Orozco, Scientific Director of IIRT, commented on the study, "We are very satisfied with the results that we have seen in these first five patient treatments, and with the process, utilizing Aastrom's Tissue Repair Cell technology. We are motivated to now expand the trial to treat additional patients with this new adult stem cell-based approach. We believe the potential ability of TRCs to eliminate the standard surgical process of autograft bone chip collection would offer a better procedure for our patients."

"Completing these first 5 patient treatments, and observing positive safety and patient progress are very important milestones for the Company, and we believe represent the first such results in the clinic using an ex vivo-produced bone marrow stem cell product," said R. Douglas Armstrong, Ph.D., Chairman and Chief Executive Officer of Aastrom. "While additional clinical data must be collected in continued trials of our TRC product to provide conclusive evidence, we are confident that this data is sufficient proof of concept for the Company to aggressively pursue the clinical trials and activities needed for EU product registration."

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Typical bone grafting procedures are used to repair major fractures of legs and arms, as well as to reconstruct bone in the jaw and to fuse spine vertebrae. The long-time standard treatment procedure, called autograft, involves surgically chiseling out bone chips and marrow from the patient's hip to obtain the necessary quantities of bone graft material. This process generally results in substantial acute and chronic pain and complications at the hip collection site. In an attempt to eliminate this clinical problem, various bone matrix substitutes have been developed and are sometimes used as an alternative to autograft procedures. These alternatives are not as effective because bone matrix substitutes lack the cellular components needed to generate bone. In this study, Aastrom's TRCs, which have been shown to contain large numbers of adult stem and other cells needed to generate bone, are combined with a synthetic matrix product, and applied directly at the fracture site. The application of TRCs is intended to form an optimized bone graft, without the after effects of the autograft procedure.

ABOUT TISSUE REPAIR CELLS

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Tissue Repair Cells (TRCs) are Aastrom's proprietary mixture of bone marrow stem and progenitor cells produced using patented single-pass perfusion technology in the AastromReplicell(R) 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 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.

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Aastrom Biosciences, Inc. (NasdaqSC: ASTM) is a regenerative medicine company developing proprietary adult stem cell-based products for the repair or generation of damaged human tissues and other medical disorders. 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(R) 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), the first of which is 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 OBJECTIVES, POTENTIAL PRODUCT APPLICATIONS, AND POTENTIAL ADVANTAGES OF THE AASTROMREPLICELL(R) SYSTEM, WHICH INVOLVE CERTAIN RISKS AND UNCERTAINTIES. THE FORWARD-LOOKING STATEMENTS ARE ALSO IDENTIFIED THROUGH USE OF THE WORDS "INTENDED," "PLAN," "POTENTIAL," "BELIEVE," 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 CLINICAL TRIAL RESULTS, POTENTIAL PRODUCT DEVELOPMENT DIFFICULTIES, THE EFFECTS OF COMPETITIVE THERAPIES, REGULATORY APPROVAL REQUIREMENTS, 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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