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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) January 14, 2004

# Aastrom Biosciences, Inc.

(Exact name of registrant as specified in charter)

| Michigan | 0-22025 | 94-3096597 |
|---|---|---|
| (State or other jurisdiction of incorporation) | (Commission File Number) | (IRS 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)

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**Item 5. Other Events.**

On January 14, 2004, Aastrom Biosciences issued a press release relating to the initiation of a clinical trial, in collaboration with investigators at the Illinois Bone and Joint Foundation, to evaluate the Company's bone generation Tissue Repair Cell stem cell product for the treatment of tibial non-union fractures. The press release is attached as Exhibit 99.1.

**Item 7. Financial Statements and Exhibits.**

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release of January 14, 2004 relating to the initiation of a clinical trial, in collaboration with investigators at the Illinois Bone and Joint Foundation, to evaluate the Company's bone generation Tissue Repair Cell stem cell product for the treatment of tibial non-union fractures. |

**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.**

Date: January 14, 2004

By: /s/ Alan M. Wright

Senior Vice President,
Administrative and Financial Operations, CFO

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EXHIBIT INDEX

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release of January 14, 2004 relating to the initiation of a clinical trial, in collaboration with investigators at the Illinois Bone and Joint Foundation, to evaluate the Company's bone generation Tissue Repair Cell stem cell product for the treatment of tibial non-union fractures. |

EXHIBIT 99.1

Aastrom Biosciences Inc.
Located at: Domino's Farms, Lobby L
P.O. Box 376
Ann Arbor, Michigan 48106
Ph: 734-930-5555
Fax: 734-665-0485

FOR IMMEDIATE RELEASE

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Becky Anderson
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Phone: (734) 930-5777

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

# AASTROM BIOSCIENCES INITIATES BONE GRAFT CLINICAL TRIAL AT LEAD U.S. SITE

## EVALUATION OF STEM CELL PRODUCT FOR LEG FRACTURE HEALING BEGINS IN CHICAGO

ANN ARBOR, MICHIGAN, JANUARY 14, 2004 -- Aastrom Biosciences, Inc. (NasdaqSC: ASTM) today announced that its U.S. clinical trial of the Company's bone generation Tissue Repair Cell (TRC) stem cell product has been initiated at its lead clinical trial site in Chicago, IL. This study follows the previously announced FDA approval of the Company's Investigational New Drug (IND) application which allows Aastrom's TRCs to be used at up to three centers for the treatment of tibial non-union fractures. The Principal Investigator in the trial is Matthew L. Jimenez, M.D., of the Illinois Bone & Joint Institute. The clinical trial will be conducted at Lutheran General Hospital in Park Ridge, IL.

This bone graft trial represents a key milestone that supports Aastrom's focus on the use of its stem cell-based TRCs for tissue generation. Laboratory evaluations of Aastrom's TRCs indicate that they contain a large number of bone-forming cells. In addition, these cells have been proven safe when administered to patients in previous clinical trials. Aastrom's new clinical trial will evaluate the use of these cells when applied at the fracture site to generate bone in patients with severe types of leg fractures. Pending the successful completion of the trial, TRCs could lead to a viable alternative to the current, highly invasive standard of treatment, for use in the multi-million dollar bone graft market.

"The launch of this bone generation trial brings Aastrom into the active clinical trial stage for our TRC stem cell product - clearly an important accomplishment for the Company that points to the leading strategic position we have attained in the cell therapeutics industry," said R. Douglas Armstrong, Ph.D., President, Chief Executive Officer and Chairman of Aastrom. "Progress is achieved one step at a time, and we intend to pursue additional clinical studies both here and in Europe, to determine the ability of TRCs to safely generate bone in patients and thus provide a valuable new tool in orthopedic medicine."

Up to three centers will be included in the current trial, and as many as 20 patients will be recruited who have either long-term (a minimum of 8 months) non-healing tibial leg fractures, or tibial non-union fractures that are severe enough to require a bone graft to aid repair. Aastrom expects to initiate the further evaluation of its TRCs at other centers in both the U.S. and Europe.

## ABOUT AASTROM'S TRCS

TRCs are Aastrom's proprietary stem and progenitor cells, produced from small samples of a patient's own bone marrow (autologous cells). TRCs are enriched for early stage stem and progenitor cells that can form bone and other tissues, and have been safely used in over 150 patients to generate normal bone marrow, as well as immune system cells. In addition, TRCs were successfully used in a compassionate use case to generate systemic bone in a patient with the genetic bone disease, infantile hypophosphatasia.

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ABOUT BONE GRAFTING

Bone grafting is used to treat over 1 million patients annually in the U.S. and Europe, in procedures including the repair of major fractures such as tibial non-union fractures, and various types of vertebral fusion. The current standard approach to obtain bone graft material involves chiseling out bone and marrow from a patient's hip. This invasive "autograft" process can result in substantial acute and chronic pain, discomfort, and mobility problems.

Current bone graft substitute products lack the cells needed to promote effective bone growth, and are therefore a less effective alternative. TRCs have substantially more bone-forming cells compared to native bone marrow, as has been demonstrated by lab and animal models testing bone generation. TRCs mixed with a matrix (allograft) should provide the components to form bone, and may provide an effective alternative to autograft. In the U.S. trial for tibial non-union fractures, Aastrom's TRCs will be mixed with commercial allograft matrix provided by the Musculoskeletal Transplant Foundation (MTF), Aastrom's collaboration partner for this trial.

ABOUT AASTROM BIOSCIENCES, INC.

Aastrom Biosciences, Inc. (NasdaqSC: ASTM) is a late-stage development company focused on human cell-based therapies. The AastromReplicell(TM) System - a patented, integrated system of instrumentation and single-use consumable kits for the production of patient-specific cells - is the Company's core technology for its Prescription Cell Products (PCP) business and its Cell Production Products (CPP) business. The principal focus of the PCP business is the repair or regeneration of tissue intended for large markets such as bone grafting, vascular systems and severe osteoporosis. The CPP business markets the AastromReplicell(TM) System to researchers and companies for their production of cells for clinical trials. These two businesses are intended to enable Aastrom to generate multiple paths to revenue. The initial commercial phase of the CPP business for dendritic cell production products is underway in Europe and the United States. 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(TM) SYSTEM AND RELATED CELLS, WHICH INVOLVE CERTAIN RISKS AND UNCERTAINTIES. THE FORWARD-LOOKING STATEMENTS ARE ALSO IDENTIFIED THROUGH USE OF THE WORDS "INTENDED," "EXPECTS," "MAY," "SHOULD," "COULD," "CAN," 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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