



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 22, 2004

**Aastrom Biosciences, Inc.**

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(Exact name of registrant as specified in charter)

Michigan

0-22025

94-3096597

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(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

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(Address of principal executive offices)

(Zip Code)

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

Not Applicable

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(Former name or former address, if changed since last report)

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**Item 5. Other Events.**

On January 22, 2004, Aastrom Biosciences issued a press release relating to the initiation of a clinical trial, in collaboration with investigators at the BG-Kliniken "Bergmannsheil" Ruhr-University located in Bochum, Germany, to evaluate the Company's bone forming Tissue Repair Cell stem cell product for the treatment of serious leg (tibia) fractures that require a bone graft for recovery. The press release is attached as Exhibit 99.1.

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

<b>Exhibit No.</b>	<b>Description</b>
99.1	Press Release of January 22, 2004 relating to the initiation of a clinical trial, in collaboration with investigators at BG-Kliniken "Bergmannsheil" Ruhr-University located in Bochum, Germany.

**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.**

By: /s/ Alan M. Wright

Date: January 22, 2004

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Senior Vice President,  
Administrative and Financial Operations, CFO

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99.1	Press Release of January 22, 2004 relating to the initiation of a clinical trial, in collaboration with investigators at BG-Kliniken "Bergmannsheil" Ruhr-University located in Bochum, Germany.

[AASTROM BIOSCIENCES LETTERHEAD]

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

FOR IMMEDIATE RELEASE

EXHIBIT 99.1

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 INITIATION OF  
BONE GRAFT CLINICAL STUDY IN GERMANY

-- BERGMANNsheil UNIVERSITY BEGINS PATIENT ENROLLMENT FOR  
NEW STEM CELL TREATMENT OF SEVERE LEG FRACTURES --

ANN ARBOR, MICHIGAN, JANUARY 22, 2004 -- Aastrom Biosciences, Inc. (NasdaqSC: ASTM) and its wholly owned subsidiary, Zellera AG (Berlin, Germany), announced today that its clinical study in collaboration with BG-Kliniken `Bergmannsheil' Ruhr-University, located in Bochum, Germany, has been initiated. This bone graft clinical study will use Aastrom's proprietary bone-forming TRCs in combination with a commercial synthetic bone graft matrix (provided through collaboration with Mathys Medical, a division of Synthes located in Bettlach, Switzerland) to treat patients with serious leg (tibia) fractures that require a bone graft for recovery. The study, which expects to accrue up to ten patients, will be conducted at Bergmannsheil, a leading orthopedic trauma treatment center in Germany. The lead investigator for the trial is Thomas A. Schildhauer, M.D., Ph.D., Attending Physician of the Traumatology-Surgery Department.

The trial initiation follows a series of successful preclinical and clinical studies that have demonstrated the bone-forming potential of Aastrom's TRCs and their safety in patients, as well as FDA approval of the Company's Investigational New Drug (IND) application for a bone grafting trial in the U.S., and finally, successful validation experiments at the Bergmannsheil University Clinic. Aastrom's TRCs are produced from small samples of bone marrow (which contain adult stem cells) using the AastromReplicell(TM) System, the Company's pioneering automated cell production platform. The AastromReplicell(TM) System has already received approval to affix the CE Mark, a regulatory requirement for commercial use in Europe.

"The initiation of this trial in Bochum is a material step towards commercial use of Aastrom's TRCs in patients for bone regeneration. The clinical evaluation of TRCs is now active in both the U.S. and Europe, and we are gratified by the enthusiasm these studies are generating," said R. Douglas Armstrong, Ph.D., President, Chief Executive Officer and Chairman of Aastrom. "We are very impressed with our partners in this collaborative study, and believe that the data generated will provide a strong indication of the usefulness of TRCs in bone regeneration, a major medical market."

Typical bone grafting procedures include various types of spinal fusions and repair of major fractures such as non-union fractures of legs and arms. The long-time standard treatment procedure 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 the standard procedure. These alternatives are typically not as effective, however, because they lack the cellular components needed to generate bone. In this clinical study, Aastrom's bone-forming TRCs will be combined with Synthes' synthetic bone matrix product, and used by Dr. Schildhauer and his colleagues to augment the repair of serious non-union leg fractures.

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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](http://www.aastrom.com).

ABOUT ZELLERA AG

Zellera AG is a wholly owned subsidiary of Aastrom Biosciences, Inc., located in Berlin, Germany. Zellera serves as the sales and marketing operational base for Aastrom's products throughout Europe. For more information, visit Zellera's website at [www.zellera.de](http://www.zellera.de), or contact Zellera's Managing Director, Holger Beckmann, at 011-49-30-20659165.

THIS DOCUMENT CONTAINS FORWARD-LOOKING STATEMENTS, INCLUDING WITHOUT LIMITATION, STATEMENTS CONCERNING PLANNED CLINICAL TRIALS AND ANTICIPATED RESULTS, PRODUCT DEVELOPMENT OBJECTIVES, COMMERCIALIZATION GOALS, POTENTIAL PRODUCT APPLICATIONS, AND POTENTIAL ADVANTAGES OF THE AASTROMREPLICELL(TM) SYSTEM AND RELATED PRODUCTS, WHICH INVOLVE CERTAIN RISKS AND UNCERTAINTIES. THE FORWARD-LOOKING STATEMENTS ARE ALSO IDENTIFIED THROUGH USE OF THE WORDS "EXPECTS," "INTENDED," "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 INHERENT UNCERTAINTIES IN CLINICAL TRIAL RESULTS, POTENTIAL PRODUCT DEVELOPMENT DIFFICULTIES, REGULATORY 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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