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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) September 2, 2003

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 September 2, 2003, Aastrom Biosciences issued a press release relating to FDA approval of Aastrom's application for a multi-center Phase I/II clinical trial for Aastrom's bone generation tissue repair cell product. The press release is attached as Exhibit 99.1.

Item 7. Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press Release of September 2, 2003 relating to FDA approval of Aastrom's application for a multi-center Phase I/II clinical trial for Aastrom's bone generation tissue repair cell product.

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: September 2, 2003

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 September 2, 2003 relating to FDA approval of Aastrom's application for a multi-center Phase I/II clinical trial for Aastrom's bone generation tissue repair cell product.

Exhibit 99.1

[AASTROM BIOSCIENCES INC. LETTERHEAD]

FOR IMMEDIATE RELEASE

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

AASTROM BIOSCIENCES RECEIVES FDA APPROVAL TO INITIATE MULTI-CENTER CLINICAL TRIAL FOR BONE GRAFT PRODUCT

-- IND APPROVAL KEY MILESTONE FOR AASTROM'S STEM CELL PRODUCT PROGRAM FOR TISSUE GENERATION --

ANN ARBOR, MICHIGAN, SEPTEMBER 2, 2003 -- Aastrom Biosciences, Inc. (NasdaqSC: ASTM) today announced that the U.S. Food and Drug Administration (FDA) has approved its Investigational New Drug (IND) application for a multi-center Phase I/II clinical trial for the Company's bone generation Tissue Repair Cell (TRC) stem cell product. The study allows Aastrom's TRCs to be used at up to three centers for the treatment of tibial non-union fractures, and could lead to a viable alternative to the current, highly morbid standard of treatment for use in the multi-million dollar bone graft market. The approval of the IND represents a key milestone that supports Aastrom's focus on the use of its stem cell-based TRCs for tissue generation.

The FDA's approval was based on its review of Aastrom's TRC product and data supporting the safety and bone forming capability of these cells. Although a start date for the trials has yet to be determined, Aastrom is currently finalizing documents, and participation agreements with leading orthopedic centers. Up to three such centers will be included in the trials, 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 non-union fractures that are severe enough to require a bone graft to aid repair.

The bone graft trial protocol combines Aastrom's TRCs with a standard orthopedic matrix, to be provided by the Musculoskeletal Transplant Foundation (MTF). This trial is the first conducted by Aastrom in affiliation with its new strategic partner, MTF, an industry leader in providing bone graft matrices for orthopedic surgery. The Company anticipates that this trial will be conducted concurrently with other planned trials in Europe that are intended to demonstrate the safety and efficacy of TRCs for bone graft indications.

"We are in the final stages of preparation for this trial of our stem cell product for the repair of major leg fractures, which represents a significant achievement in bringing our novel, cell-based procedure to the multi-million dollar bone graft market," said R. Douglas Armstrong, Ph.D., President, Chief Executive Officer and Chairman of Aastrom. "FDA approval of our IND is an important benchmark that supports the research and development resources we have devoted to our TRC products, and allows the Company to move forward with this initial U.S. bone generation clinical trial."

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 in over 1 million patients annually in the U.S. and Europe, including repair of major fractures such as tibial non-union fractures, and various types of vertebral fusion. A 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. TRCs mixed with a matrix (allograft) should provide the components to form bone, and may provide an effective alternative to autograft.

ABOUT THE AASTROM/MTF STRATEGIC ALLIANCE

Aastrom and the Musculoskeletal Transplant Foundation (MTF) have formed a strategic alliance to jointly develop and commercialize innovative treatments for the regeneration of tissues such as bone and cartilage. Aastrom's collaboration with MTF, the leading provider (annual revenue over $200 million) of allograft matrices, or donor-derived tissue, will focus on forming a coordinated business and clinical approach for new products and treatments needed in orthopedic medicine. Under the terms of the alliance, Aastrom and MTF will coordinate and fund the development of products that are based on combinations of MTF's matrices and Aastrom's Tissue Repair Cells (TRCs). The companies will share in the development and clinical trial expense of these treatment approaches and products, and will adopt a coordinated promotion and marketing strategy for future products. In addition to the initial focus on jointly developed bone graft treatments, the companies will explore new approaches for the regeneration of joint cartilage, as well as effective combinations of TRCs with MTF's new ceramic technology.

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," "MAY," "SHOULD," "COULD," "CAN," "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, ACTIONS TAKEN BY COLLABORATORS AND COMPETITORS, 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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