

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 28, 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 28, 2004 Aastrom Biosciences, Inc. announced the signing of a clinical trial agreement with the Heart and Diabetes Center North Rhine-Westphalia for evaluation of the safety and effect of Aastrom's Tissue Repair Cells in the regeneration of peripheral vascular tissue to treat lower limb ischemia in diabetic patients. The press release announcing this development is attached hereto as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(c) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
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 28, 2004

AASTROM BIOSCIENCES, INC.

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

AASTROM BIOSCIENCES ANNOUNCES DIABETIC LIMB ISCHEMIA

CLINICAL TRIAL AGREEMENT

-- Aastrom's Proprietary TRCs to be Used in Treatment of Limb Ischemia at the
Bad Oeynhausen Heart and Diabetes Center in Germany --

ANN ARBOR, MICHIGAN, OCTOBER 28, 2004 -- Aastrom Biosciences, Inc. (NasdaqSC:ASTM) announced today that it has signed a clinical trial agreement with the Heart and Diabetes Center North Rhine-Westphalia (Center), located in Bad Oeynhausen, Germany. The clinical trial, which has also now received local Ethical Committee approval, will evaluate the safety and effect of Aastrom's Tissue Repair Cells (TRCs) in the regeneration of peripheral vascular tissue to treat lower limb ischemia in diabetic patients. The Principal Investigator for the study is Prof. Dr. Diethelm Tschoepe, Clinic Director at the Center.

This multi-arm feasibility trial will evaluate patients treated with TRCs produced from a sample of their own bone marrow, in comparison to patients treated with an equivalent sample of only their own bone marrow, and to patients receiving the standard of care treatment. For the Aastrom TRC and bone marrow treatments, two different routes of administration will be evaluated. The study can accrue up to 50 patients, who will be randomly divided among the different arms of the trial. Endpoints to be studied include improvements in vascularization and the healing of skin ulcers, as well as recovery of the ability to walk, limb salvage and reduced mortality. Aastrom expects the clinical trial to begin accruing patients by mid-calendar year 2005.

"This new trial is exciting and important for our Company in several ways. Limb ischemia is a major medical problem facing diabetics, for which the medical community is continually seeking more effective therapy. Aastrom's bone marrow adult stem cell TRC product may offer an innovative, alternative approach to the care of these patients," said R. Douglas Armstrong, Ph.D., Chairman and Chief Executive Officer of Aastrom. "Aastrom's TRCs are currently being studied in feasibility clinical trials for their ability to promote the regeneration of bone in fracture healing and sinus lift procedures. This new limb ischemia study represents another milestone in our strategic plan to develop multiple applications within regenerative medicine, from the same core technology and operational infrastructure. We are very pleased to be working with Prof. Dr. Tschoepe and his excellent clinical staff at the Bad Oeynhausen Heart and Diabetes Center."

ABOUT LIMB ISCHEMIA

Ischemia is a blood circulation deficiency in an organ or tissue caused by constriction or obstruction of its blood vessels, and is commonly associated with diabetes and Buerger's disease, as well as other diseases. Small artery obstruction is a major contributor to stroke, heart disease, deep ulcers of the feet, loss of limb function and limb amputation. For certain severe limb ischemic situations, current surgical intervention methodologies have been proven ineffective in the long-term management

of the problem. As a result, the medical and research communities have recently turned to the development of cell-based and other therapies as alternative treatments.

ABOUT HEART AND DIABETES CENTER NORTH RHINE-WESTPHALIA

The Heart and Diabetes Center North Rhine-Westphalia is a world-leading institution in the fields of cardiac, circulatory and metabolic diseases located in Bad Oeynhausen, Germany, offering both comprehensive diagnostics and treatment under one roof. It is one of several hospitals associated with the University Hospital of Ruhr-University located in Bochum, Germany.

ABOUT TISSUE REPAIR CELLS

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 bone marrow tissues.

ABOUT AASTROM BIOSCIENCES, INC.

Aastrom Biosciences, Inc. (NasdaqSC: ASTM) is a regenerative medicine company developing proprietary adult stem cell-based products for the repair of damaged human tissues and other medical disorders, or the generation of normal human tissues. 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), which are 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 AND THEIR EXPECTED RESULTS, 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 "EXPECTS," "MAY," "PLAN," "CAN," "SEEKING," 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 THE UNCERTAINTIES OF 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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