
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 21, 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))
-
-

TABLE OF CONTENTS

[Item 8.01 Other Events.](#)

[Item 9.01 Financial Statements and Exhibits.](#)

[SIGNATURES](#)

[EXHIBIT 99.1](#)

[Table of Contents](#)

Item 8.01 Other Events.

On October 21, 2004 Aastrom Biosciences, Inc. announced the initiation of its clinical trial in Barcelona, Spain to determine the safety and efficiency of Aastrom's Tissue Repair Cells in maxillary sinus lift bone graft procedures necessary for dental implants. The press release announcing this trial 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 21, 2004

AASTROM BIOSCIENCES, INC.

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

[GRAPHIC OF AASTROM LOGO WITH LETTERHEAD]

FOR IMMEDIATE RELEASE

CONTACTS: Kris M. Maly or Kevin McGrath
Becky Anderson Cameron Associates
Investor Relations Department Phone: (212) 245-4577
Aastrom Biosciences, Inc.
Phone: (734) 930-5777

AASTROM BIOSCIENCES ANNOUNCES INITIATION OF
CLINICAL TRIAL FOR SINUS LIFT BONE GRAFT PROCEDURES IN SPAIN

-- AASTROM'S PROPRIETARY TRCS TO BE UTILIZED
TO BUILD NEW BONE TISSUE FOR DENTAL IMPLANTS --

ANN ARBOR, MICHIGAN, OCTOBER 21, 2004 -- Aastrom Biosciences, Inc. (NasdaqSC: ASTM), and the Institut de Terapia Regenerativa Tissular (ITRT) announced today that they have initiated patient enrollment in a clinical trial with Instituto de Cirugia Maxilofacial e Implantologia in Barcelona, Spain to determine the safety and efficacy of Aastrom's proprietary Tissue Repair Cells (TRCs) in maxillary sinus lift bone graft procedures necessary for dental implants. The study is being conducted at Centro Medico Teknon under the direction of Principal Investigator, Dr. Federico Hernandez-Alfaro.

The trial will target regions in the upper (maxillary) jaw where premature tooth loss has thinned the bone to such an extent that surgery for tooth replacement cannot be effectively completed. To address this clinical problem, this new study will evaluate the ability of TRCs to regenerate and thicken the maxillary sinus bone needed for a dental implant post. Dental implant surgery can improve function and dental aesthetics in patients suffering from tooth loss. In the initial phase of this trial, five patients will be accrued to compare the outcome of the innovative Aastrom TRC treatment procedure with that of a standard therapy.

This is the fourth clinical trial initiated by Aastrom to evaluate the safety and ability of the Company's TRC technology to generate local bone tissue. The three previously announced studies focus on the use of TRCs to regenerate bone in severe long bone non-union fractures that had previously failed to heal with conventional therapies. One of the development objectives intended for TRCs is to provide an effective way for surgeons to generate or repair local bone tissue for any bone type, including long bones, spine and facial bones. If this can be achieved, Aastrom's TRC products may serve as an alternative to autograft, the invasive and painful procedure of surgically carving out bone tissue from the hip.

"With four proof-of-concept feasibility clinical trials now underway, we are diligently working to demonstrate the full value that our TRC technology can bring to the generation of local bone tissue," said R. Douglas Armstrong, Ph.D., Chairman and Chief Executive Officer of Aastrom. "I am proud that our team here at Aastrom has been able to effectively implement these different studies, which should establish our strategic position in these major market areas. We are excited to work in collaboration with Dr. Hernandez-Alfaro and his clinical team on a highly innovative therapy that has the potential to represent a breakthrough in maxillofacial bone repair."

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,

-more-

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.

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 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 "INTENDED," "MAY," "POTENTIAL," "SHOULD," "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 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.

###