



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) December 11, 2003

**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 December 11, 2003, Aastrom Biosciences issued a press release relating to the initiation of a Phase I clinical trial, in collaboration with investigators at Duke University Medical Center, to evaluate a dendritic cell-based vaccine as a new treatment for an assortment of gastro-intestinal system cancers. 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 December 11, 2003 relating to the initiation of a Phase I clinical trial, in collaboration with investigators at Duke University Medical Center, to evaluate a dendritic cell-based vaccine as a new treatment for an assortment of gastro-intestinal system cancers.

**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: December 11, 2003

By: */s/ Alan M. Wright*

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Senior Vice President,  
Administrative and Financial Operations, CFO

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EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release of December 11, 2003 relating to the initiation of a Phase I clinical trial, in collaboration with investigators at Duke University Medical Center, to evaluate a dendritic cell-based vaccine as a new treatment for an assortment of gastro-intestinal system cancers.

[AASTROM LETTERHEAD]

FOR IMMEDIATE RELEASE

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AASTROM'S DENDRITIC CELL VACCINE TECHNOLOGY  
 TO BE UTILIZED IN DUKE UNIVERSITY'S CLINICAL TRIAL FOR  
 NEW CANCER TREATMENT

-- Duke Clinical Trial Seeks New Treatment for GI Tract Cancers --

ANN ARBOR, MICHIGAN, DECEMBER 11, 2003 -- Aastrom Biosciences, Inc. (NasdaqSC:ASTM) announced today the initiation of a Phase I clinical trial in collaboration with investigators at Duke University Medical Center (Duke). The clinical trial will evaluate a dendritic cell-based vaccine as a new treatment for an assortment of gastro-intestinal (GI) system cancers, including colorectal, stomach and pancreatic cancers. The trial protocol proposes to examine the safety, feasibility, immune outcome and clinical efficacy of a vaccination that is produced by loading tumor-associated peptide antigens onto a patient's blood-derived dendritic cells produced using Aastrom's DCV-II dendritic cell vaccine production kit and the AastromReplicell System(TM) ("System").

This trial is funded by a National Institutes of Health (NIH) grant awarded to Aastrom and is being conducted under a FDA Investigational New Drug application that was submitted by Duke. The protocol for the trial is approved for accrual of up to 12 patients, and is expected to take up to 24 months to complete. In addition to determining safety and certain immune system and tumor endpoints, the trial will evaluate the number of vaccinations needed to elicit potent immunity against CEA (carcinoembryonic antigen), a tumor-specific protein. Aastrom's System is expected to produce sufficient, clinical amounts of patient-derived dendritic cells to allow each patient to receive multiple vaccinations.

"It is our strategy to initiate important collaborations, such as this one with Duke, to provide access to Aastrom's unique dendritic cell vaccine production and cells, which is intended to lead to new therapeutic products for the Company. If a patient's immunity can be successfully induced, this approach to cancer vaccine treatment could offer tremendous benefits to a large number of cancer patients," said R. Douglas Armstrong, Ph.D., President, Chief Executive Officer and Chairman of Aastrom. "Furthermore, Aastrom's DCV-II product could provide a reliable vaccine production capability that will aid in meeting the regulatory requirements for vaccine manufacturing, and enables successful vaccines to be produced large-scale, a necessity for standard medical practice. Through the use of Aastrom's System, innovative scientific approaches like the one being developed by researchers at Duke, can be introduced into the clinical setting in a manner that can be extended into general patient care."

Dendritic cells are key components of the human immune system. When loaded with antigen and administered through vaccination, dendritic cells can stimulate specific immunities. CEA is frequently over-expressed on tumor cells. By developing immunity against components of a tumor (CEA), a patient's immune system could be activated to selectively destroy tumors. Cancer patients with tumors containing the protein CEA will be treated in this clinical trial.

Tumors expressing CEA include many tumors of the GI tract, such as colorectal, stomach and pancreatic; tumors of the lung and breast can also express CEA. If successful, this tumor vaccine

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could facilitate the treatment of a substantial number of cancer patients who, if they develop immunity, could gain control of their disease, which is currently incurable in late-stage patients.

In August 2000, Aastrom was awarded a Phase II, Small Business Innovation and Research (SBIR) grant from the NIH's National Cancer Institute to support the development of the AastromReplicell(TM) System for the clinical production of human dendritic cells. The grant research was led by Principal Investigator, Douglas M. Smith, Ph.D., Immunology Program Leader at Aastrom. The initiation of this clinical study at Duke, led by Co-Principal Investigators Michael Morse, M.D., MHS, Division of Medical Oncology and Transplantation, and H. Kim Lyerly, M.D., Director, Duke Comprehensive Cancer Center, is the culmination of the two-year research study conducted by Aastrom and Duke.

#### ABOUT THE AASTROMREPLICELL(TM) SYSTEM AND DCV-II KIT

Aastrom's proprietary AastromReplicell(TM) System ("System") is a fully-automated, closed-system platform that enables GMP compliance for producing large quantities of highly robust human cells outside the body, and is intended for use in a broad range of cell therapy treatments. In dendritic cell vaccine production, the platform eliminates many of the difficulties related to current methods of producing dendritic cells using standard laboratory manual culture methods, and produces clinical quantities of viable cells that can be harvested within 8 days. The System and three disposable dendritic cell production kits (DC-I, DCV-I and DCV-II) provide the foundation for Aastrom's Cell Production Products business, and are currently marketed and sold in Europe under CE Mark authorization. In the clinical trial being conducted at Duke, the System, along with the DCV-II dendritic cell production kit, will be used to produce peptide-loaded dendritic cell vaccines. The System's technology is also an integral component of the Company's Prescription Cell Products business, which develops adult stem cell-based products intended for the repair and regeneration of normal human tissue.

#### 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).

THIS DOCUMENT CONTAINS FORWARD-LOOKING STATEMENTS, INCLUDING WITHOUT LIMITATION, STATEMENTS CONCERNING EXPECTED SYSTEM PERFORMANCE, PRODUCT DEVELOPMENT OBJECTIVES, POTENTIAL PRODUCT APPLICATIONS, AND NEW THERAPEUTIC APPROACHES TO TREATMENT OF CERTAIN CANCERS, WHICH INVOLVE CERTAIN RISKS AND UNCERTAINTIES. THE FORWARD-LOOKING STATEMENTS ARE ALSO IDENTIFIED THROUGH USE OF THE WORDS "INTEND," "EXPECTED," "COULD," "SEEKS," 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 INHERENT IN EARLY STAGE CLINICAL TRIALS AND NEW APPROACHES TO TREATING DISEASES, ACTIONS TAKEN BY COLLABORATORS, 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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