



**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) February 4, 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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EXHIBIT INDEX

| Exhibit<br>No. | Description                          |
|----------------|--------------------------------------|
| 99.1           | Press Release dated February 4, 2004 |

[Aastrom Logo]

FOR IMMEDIATE RELEASE

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AASTROM BIOSCIENCES, INC. REPORTS  
 SECOND QUARTER FISCAL YEAR 2004 FINANCIAL RESULTS

ANN ARBOR, MICHIGAN, FEBRUARY 4, 2004 -- Aastrom Biosciences, Inc. (NasdaqSC: ASTM), today reported financial results for the second quarter of fiscal year 2004 ended December 31, 2003. The Company also summarized recent key operational and clinical achievements that continue to drive its cell-based therapeutic products toward standard medical use.

## HIGHLIGHTS

- - In early January 2004, Aastrom announced that its U.S. clinical trial of the Company's bone generation Tissue Repair Cell (TRC) stem cell product has been initiated at its lead clinical trial site in Chicago, IL. This study follows the previously announced U.S. Food and Drug Administration (FDA) approval of the Company's Investigational New Drug (IND) application which allows Aastrom's TRCs to be used at up to three centers for the treatment of tibial non-union fractures. The Principal Investigator in the trial is Matthew L. Jimenez, M.D., of the Illinois Bone & Joint Institute. The clinical trial will be conducted at Lutheran General Hospital in Park Ridge, IL. This bone graft trial represents a key milestone that supports Aastrom's focus on the use of its stem cell-based TRCs for tissue generation.
- - Aastrom announced 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 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(TM) System ("System"). This trial is funded by a National Institutes of Health (NIH) grant awarded to Aastrom and is being conducted under an IND application that was submitted to the FDA 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.
- - The NIH awarded a \$100,000 Phase I Small Business Innovation Research grant to Aastrom in October 2003 for the development of a bone marrow stem cell-based treatment of circulation ischemia caused by vascular diseases and diabetes. This six-month study, undertaken in collaboration with Case Western Reserve University, will utilize Aastrom's patented single-pass perfusion stem cell technology to try to create a clinically suitable cell therapy for regeneration of vascular tissue (veins and arteries). The Company's proprietary System will be used to produce the expanded bone marrow stem and endothelial progenitor cell product that will be tested in an in vivo animal model for hind limb ischemia. The Company anticipates that successful completion of this study could lead to further grant applications as well as clinical trials for the treatment of vascular diseases. Kristin Goltry, Ph.D., Stem Cell Program Leader at Aastrom Biosciences, is lead investigator on the study.
- - The Company announced the appointment of Herbert S. Schwartz, M.D. to its Technology Review Board. Dr. Schwartz is Professor of Orthopedics and Rehabilitation, Professor of

- more -

Pathology and Vice Chair for Research at Vanderbilt University Medical Center (Vanderbilt), where he heads a major U.S. center for orthopedic oncology. Dr. Schwartz has been at Vanderbilt since 1987, and is currently one of the most senior and experienced full-time academic orthopedic oncologists in the country, one of only 50 such specialists.

"We are pleased to report a very productive and active first six months of our fiscal year. Among our many major accomplishments was the approval by the FDA of our IND application for a multi-center Phase I/II clinical trial for the Company's bone generation TRC stem cell product for the repair of major leg fractures, and the subsequent commencement of our U.S. clinical trial which has been initiated at our lead clinical trial site in Chicago, IL," said R. Douglas Armstrong, Ph.D., President, Chief Executive Officer and Chairman of Aastrom. "Last week we announced that enrollment had begun for a similar clinical study at a site in Bochum, Germany, and we anticipate the initiation of additional bone graft clinical trial studies, both in the U.S. and Europe, in the near term. We are pleased with the ongoing momentum of our business and are focused on capitalizing on our strong position in human cell-based therapies to bring new products to patients and generate value for shareholders. I want to thank all of our staff at Aastrom for their hard work as we continue to successfully execute our business plan."

#### SECOND QUARTER AND SIX-MONTHS ENDED DECEMBER 31, 2003 RESULTS

Total revenue, consisting of product sales and rentals, as well as grant and other revenue, increased for the quarter and six month periods ended December 31, 2003 to \$0.4 million and \$0.7 million, respectively, compared to \$0.3 million and \$0.4 million for the same periods in 2002. An increase in grant revenue for the quarter and six-month periods ended December 31, 2003 was the primary reason for the increase in revenues relative to the comparable periods of fiscal year 2003. Aastrom reported a net loss of \$2.4 million for the quarter, or \$.03 per common share, compared to a net loss of \$2.3 million, or \$.05 per common share for the same period in fiscal year 2003. For the six months ended December 31, 2003, the Company reported a net loss of \$5.2 million, or \$.07 per common share, in fiscal 2004 compared to a net loss of \$4.7 million, or \$.10 per common share, for the same period in fiscal 2003.

Costs and expenses for the quarter and six months ended December 31, 2003 increased to \$2.8 million and \$6.0 million, respectively, compared to \$2.6 million and \$ 5.2 million for the same periods in fiscal year 2003. Expenses reflect decreases in cost of sales and rentals to \$5,000 and \$17,000 for the quarter and six months ended December 31, 2003, from \$111,000, for the three and six month periods ended December 31, 2002. The non-cash provision for obsolete and excess inventory decreased to \$0 for the quarter ended December 31, 2003, compared to \$0.3 million for the same period in fiscal year 2003, and was \$0.3 million for the six-month periods ended December 31, 2003 and 2002. Research and development expenses increased slightly to \$1.5 million for the quarter ended December 31, 2003, from \$1.4 million in the comparable quarter of fiscal year 2003. Research and development expenses were \$2.8 million for the six-month periods ended December 31, 2003 and 2002. Selling, general and administrative expenses increased to \$1.3 million and \$2.9 million for the quarter and six months ended December 31, 2003, compared to \$0.9 million and \$2.0 for the same periods in fiscal year 2003.

Aastrom's Prescription Cell Products business is led by the use of its Tissue Repair Cells (TRCs) for bone grafting applications. Bone grafting clinical trials have recently been initiated in the U.S. and Europe for the treatment of tibial non-union fractures, and the Company expects to announce additional clinical sites for this application. The initiation of European clinical trials for dental implants has been delayed pending the finalization of the European Union cell production licensing requirements.

## AASTROM CONFERENCE CALL INFORMATION

R. Douglas Armstrong, Ph.D., President, Chief Executive Officer and Chairman, and Alan M. Wright, Senior Vice President Administrative & Financial Operations and Chief Financial Officer of Aastrom Biosciences, Inc., will review and discuss the second quarter fiscal year 2004 financial results and the Company's recent progress and future goals on February 4, 2004, at 11:00 a.m. (EST) when they will host a conference call. Interested parties should call 785-832-2422, or toll-free 800-540-0559, fifteen minutes before the start of the call to register and identify themselves as registrants of the 'Aastrom Conference Call'. The call will be simulcast on the web at <http://www.firstcallevents.com/service/ajwz398543957gf12.html>, and the entire call will be archived for replay at the same site for 90 days.

## 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 clinical trial goals and expectations, intended product development and commercialization objectives, potential product applications, and potential advantages of the AastromReplicell(TM) System and related cell therapy products, which involve certain risks and uncertainties. The forward-looking statements are also identified through use of the words "plan," "intend," "potential," "expected," "could," "proposes," "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 the inherent uncertainties associated with clinical trial and development activities, regulatory approval requirements, 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.

- Financial Table Follows -

- more -

AASTROM BIOSCIENCES, INC.  
(Unaudited)

CONSOLIDATED STATEMENT OF OPERATIONS DATA:

|   | Quarter ended December 31, |                | Six months ended December 31, |                |
|---|----------------------------|----------------|-------------------------------|----------------|
|   | 2002                       | 2003           | 2002                          | 2003           |
|   | ----                       | ----           | ----                          | ----           |
| <b>REVENUES:</b>  |                            |                |                               |                |
| Product sales and rentals   | \$ 161,000                 | \$ 10,000      | \$ 168,000                    | \$ 35,000      |
| Grants and other  | 135,000                    | 366,000        | 221,000                       | 641,000        |
|   | -----                      | -----          | -----                         | -----          |
| Total revenues  | 296,000                    | 376,000        | 389,000                       | 676,000        |
|   | -----                      | -----          | -----                         | -----          |
| <b>COSTS AND EXPENSES:</b>  |                            |                |                               |                |
| Cost of product sales and rentals   | 111,000                    | 5,000          | 111,000                       | 17,000         |
| Cost of product sales and rentals - provision for obsolete and excess inventory | 171,000                    | --             | 259,000                       | 253,000        |
| Research and development  | 1,432,000                  | 1,455,000      | 2,817,000                     | 2,811,000      |
| Selling, general and administrative   | 902,000                    | 1,356,000      | 2,015,000                     | 2,921,000      |
|   | -----                      | -----          | -----                         | -----          |
| Total costs and expenses  | 2,616,000                  | 2,816,000      | 5,202,000                     | 6,002,000      |
|   | -----                      | -----          | -----                         | -----          |
| OTHER INCOME  | 33,000                     | 37,000         | 74,000                        | 85,000         |
|   | -----                      | -----          | -----                         | -----          |
| NET LOSS  | \$ (2,287,000)             | \$ (2,403,000) | \$ (4,739,000)                | \$ (5,241,000) |
|   | =====                      | =====          | =====                         | =====          |
| NET LOSS PER COMMON SHARE<br>(Basic and Diluted)                                | \$ (.05)                   | \$ (.03)       | \$ (.10)                      | \$ (.07)       |
|   | =====                      | =====          | =====                         | =====          |
| Weighted average number of common shares outstanding                            | 48,550,000                 | 71,294,000     | 46,718,000                    | 70,978,000     |
|   | =====                      | =====          | =====                         | =====          |

CONSOLIDATED BALANCE SHEET DATA:

|   | June 30,<br>2003 | December 31,<br>2003 |
|---|------------------|----------------------|
|   | ----             | ----                 |
| <b>ASSETS</b>                               |                  |                      |
| Cash and investments                        | \$10,512,000     | \$10,784,000         |
| Other current assets                        | 1,341,000        | 1,427,000            |
| Property, net                               | 302,000          | 291,000              |
|   | -----            | -----                |
| Total assets                                | \$12,155,000     | \$12,502,000         |
|   | =====            | =====                |
| <b>LIABILITIES AND SHAREHOLDERS' EQUITY</b> |                  |                      |
| Current liabilities                         | \$ 580,000       | \$ 557,000           |
| Shareholders' equity                        | 11,575,000       | 11,945,000           |
|   | -----            | -----                |
| Total liabilities and shareholders' equity  | \$12,155,000     | \$12,502,000         |
|   | =====            | =====                |

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