
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):

November 4, 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 2.02 Results of Operations and Financial Condition.

On November 4, 2004, we issued a press release announcing financial results and operational achievements for our first fiscal quarter ended September 30, 2004. A copy of the press release is attached hereto as Exhibit 99.1.

Pursuant to General Instruction B.2 of Form 8-K, this report and the exhibit are not deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, nor shall this report and the exhibit be incorporated by reference into our filings under the Securities Act of 1933 or the Securities Exchange Act of 1934, except as expressly set forth by specific reference in such future filing.

Item 9.01 Financial Statements and Exhibits.

(c) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated November 4, 2004

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: November 4, 2004

AASTROM BIOSCIENCES, INC.

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

(AASTROM BIOSCIENCES, INC. LETTERHEAD)

FOR IMMEDIATE RELEASE

CONTACTS:	Kris M. Maly or Becky Anderson Investor Relations Department Aastrom Biosciences, Inc. Phone: (734) 930-5777	Kevin McGrath Cameron Associates Phone: (212) 245-4577
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AASTROM BIOSCIENCES, INC. REPORTS FIRST QUARTER
FISCAL YEAR 2005 FINANCIAL RESULTS

ANN ARBOR, MICHIGAN, NOVEMBER 4, 2004 -- Aastrom Biosciences, Inc. (NasdaqSC: ASTM) today reported financial results for the first fiscal quarter ended September 30, 2004. The Company also reported several achievements during the last quarter, both clinically and operationally. For the quarter ended September 30, 2004, these achievements included:

- o New management appointment - Janet M. Hock, B.D.S., Ph.D. named Vice President Global Research, responsible for Aastrom's biological research and clinical development programs. This appointment follows the recent addition of James Cour as President and Chief Operating Officer
- o Research grant - award of a Phase I Small Business Innovation Research grant entitled "Dendritic Cell Subset for Enhanced Cancer Vaccine" from the National Institutes of Health National Cancer Institute. The eight-month study will determine the efficacy and ability of the Company's proprietary AastromReplicell(R) System to enhance the immunostimulatory potency of dendritic cell-based cancer vaccines through its patented single-pass perfusion technology
- o Clinical update - completion of patient accrual for first phase of clinical trial at Barcelona, Spain, for use of Aastrom's Tissue Repair Cells (TRCs) in the regenerative repair of severe long bone non-union fractures

"The progress of our lead adult stem cell TRC clinical program is driving our emergence as a leading company in regenerative medicine, and contributes greatly to our ability to attract high quality executive personnel, such as Dr. Hock and Mr. Cour. Their contributions will be invaluable in bringing our technology to the marketplace," commented R. Douglas Armstrong, Ph.D., Chief Executive Officer and Chairman of Aastrom.

Dr. Armstrong continued, "Looking forward, we expect continued progress in the clinic; for example the addition of clinical sites to our Phase I/II U.S. multi-center trial for non-union tibial fractures, the completion of patient enrollment into our recently announced clinical trial for the use of our TRCs in maxillary sinus lift bone graft procedures in Spain, and the commencement of our German clinical study evaluating the ability of TRCs to regenerate vascular tissue in patients with diabetic limb ischemia. Our strategy of accessing large, diverse therapeutic areas utilizing the same TRC technology is on track, and as our portfolio of product candidates moves forward, we will focus our efforts on developing the appropriate marketing partnerships for these products."

FIRST QUARTER FISCAL YEAR 2005 ENDED SEPTEMBER 30, 2004 RESULTS

Total revenue for the quarter ended September 30, 2004, consisting of product sales and rentals in the EU and grants, was \$187,000 compared to \$300,000 for the same period in fiscal year 2004.

Net loss for the quarter ended September 30, 2004 was \$2.65 million, or \$.03 per share, compared to a net loss of \$2.8 million, or \$.04 per share for the same period in fiscal year 2004.

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At September 30, 2004, the Company had \$15.0 million in cash, cash equivalents and marketable securities as compared to \$16.9 million in cash, cash equivalents and marketable securities at September 30, 2003. The cash balance at September 30, 2004 does not include proceeds from a \$10 million sale of the Company's common stock to institutional investors in a registered direct placement completed in late October 2004.

Total costs and expenses for the quarter ended September 30, 2004 were \$2.9 million compared to \$3.2 million for the same period in fiscal year 2004.

Research and development expenses for the quarter ended September 30, 2004 increased slightly to \$1.6 million, from \$1.4 million for the same period in fiscal year 2004. This increase reflects our continued research and product development activities in the area of tissue regeneration, including our ongoing and planned TRC clinical trials in the United States and the EU.

Selling, general and administrative expenses decreased slightly to \$1.3 million for the quarter ended September 30, 2004, compared to \$1.6 million for the same period in fiscal year 2003, primarily due to a non-recurring, non-cash compensation expense recorded during the quarter ended September 30, 2004.

"Our increased financial resources place us in a better position to respond operationally to any positive results from our ongoing clinical programs," said Alan M. Wright, Senior Vice President Administrative and Financial Operations and Chief Financial Officer of Aastrom.

MILESTONES EXPECTED DURING FISCAL YEAR 2005

Aastrom entered fiscal year 2005 with sufficient funding to support planned clinical and operational goals and objectives, including:

- o Continued accrual of patients in our current FDA multi-center bone graft trial in the U.S., and expansion to additional institutions as clinical sites
- o Expansion of clinical studies in Spain for bone grafting repair of severe non-union fractures; pending positive results, move toward commercialization in the EU
- o Completion of a recently initiated jaw bone reconstruction clinical trial in the EU for sinus lift procedures for dental implants; pending positive results, move toward commercialization in the EU
- o Initiation of an German clinical study to evaluate the ability of TRCs to regenerate vascular tissue in patients with diabetic limb ischemia
- o Pursuit of applicable opportunities for grants, to further define potential uses and applications for our proprietary technology and cell products

AASTROM CONFERENCE CALL INFORMATION

R. Douglas Armstrong, Ph.D., 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 first quarter fiscal year 2005 financial results and the Company's recent progress and future goals today, November 4, 2004, at 11:00 a.m. (EST) when they will host a conference call. Interested parties should call (785) 832-0201, or toll-free (800)

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223-9488, 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://phx.corporate-ir.net/playerlink.zhtml?c=85924&s=wm&e=959337>, 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 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 clinical trial plans and expectations, intended product development and commercialization objectives, the expected adequacy of capital resources to support planned activities, expected milestones and plans for the current fiscal year, potential product applications, and potential advantages of the AastromReplicell System and related cell therapy products, which involve certain risks and uncertainties. The forward-looking statements are also identified through use of the words "expect," "expected," "planned," "potential," "should," 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 product 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 --

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AASTROM BIOSCIENCES, INC.
(Unaudited)

CONSOLIDATED STATEMENT OF OPERATIONS DATA:

Quarter ended September 30, -----		
----- 2003 2004 -----		
----- REVENUES: Product sales and		
rentals	\$ 25,000	\$
15,000 Grants and other		
.....	275,000	
172,000 -----	Total	
revenues		
300,000 187,000 -----		
COSTS AND EXPENSES: Cost of product sales		
and rentals	12,000	15,000
Cost of product sales and rentals -		
provision for obsolete and excess inventory		
.....	253,000	-- Research and
development		
1,356,000 1,567,000 Selling, general and		
administrative	1,565,000	
1,314,000 -----	Total	
costs and expenses		
3,186,000 2,896,000 -----		
---- OTHER INCOME		
.....		
48,000 60,000 -----		
NET LOSS		
.....		
\$ (2,838,000) \$ (2,649,000) =====		
===== NET LOSS PER COMMON SHARE		
(Basic and Diluted)		
.....	\$ (.04)	\$
(.03) =====	Weighted	
average number of common shares outstanding		
.....		
70,662,000 82,738,000 =====		
=====		

CONSOLIDATED BALANCE SHEET DATA:

June 30, September 30, 2004 2004		

ASSETS Cash and investments		
.....	\$	
16,926,000 \$ 14,995,000 Other		
current assets		
.....		
906,000 1,690,000 Property and		
equipment, net		
.....	334,000	
386,000 -----	Total assets	

\$ 18,166,000 \$ 17,071,000		
=====		
LIABILITIES AND SHAREHOLDERS'		
EQUITY Current liabilities		
.....	\$	
558,000 \$ 779,000 Shareholders'		
equity		
.....		
17,608,000 16,292,000 -----	Total	
-----	liabilities and shareholders'	
equity ... \$ 18,166,000 \$		
17,071,000 =====		
=====		