
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):

September 8, 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 September 8, 2004, we issued a press release announcing financial results and operational achievements for our fourth fiscal quarter and fiscal year ended June 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 September 8, 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: September 8, 2004

AASTROM BIOSCIENCES, INC.

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



Located at: Domino's Farms, Lobby L

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FOR IMMEDIATE RELEASE

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AASTROM BIOSCIENCES, INC. REPORTS FOURTH QUARTER 2004 FINANCIAL RESULTS

Ann Arbor, Michigan, September 8, 2004 — Aastrom Biosciences, Inc. (NasdaqSC: ASTM) today reported financial results for the fourth quarter and fiscal year ended June 30, 2004. The Company also reported significant achievements during the last quarter and fiscal year, both clinically and operationally. For the quarter ended June 30, 2004, these achievements included:

- Expanding U.S. Phase I/II clinical trial for bone fractures to include a second site. We added The University of Michigan Health System's orthopedic trauma center for the trial of our bone generation Tissue Repair Cell (TRC) adult stem cell product. We expect a third clinical site to be included in this trial for patients with severe tibial leg fractures
- Appointing James A. Cour President and Chief Operating Officer on July 6th, strengthening senior management's operational expertise. Previously Mr. Cour held executive level management positions with Baxter International, Windsor VanGelder Limited and Cytomedix

"Aastrom achieved a significant number of milestones in fiscal year 2004, led by the expansion and advancement of our clinical trials for patient treatment and our product development pipeline," commented R. Douglas Armstrong, Ph.D., Chief Executive Officer and Chairman of Aastrom. "We are demonstrating material progress toward our goal of generating a focused portfolio of adult stem cell-based products for the regenerative repair of damaged human tissues that have substantial therapeutic and commercial potential. I believe fiscal year 2005 is going to be an important year in our evolution from the research and development phase into the commercialization phase as we expand the clinical evaluation of our adult stem cell-based TRCs for tissue regeneration, and begin to report on the results."

Other significant highlights during the 2004 fiscal year included the following:

- Received the Company's first TRC-related FDA approved Investigational New Drug (IND) application for a multi-center clinical trial for local bone repair, followed by the initiation of our lead clinical trial site in Chicago, IL
- Commenced European Union (EU) bone graft clinical studies with BG-Kliniken 'Bergmannsheil' Ruhr-University Hospital in Germany and the Hospital General de l'Hospitalet in Barcelona, Spain. These studies utilize our proprietary bone-forming TRCs in combination with commercial synthetic matrix products to treat non-union large bone fractures
- Issued a patent by the U.S. Patent and Trademark Office that covers a method of bone marrow transplantation, often referred to as stem cell transplants, using cells produced with our proprietary single-pass perfusion technology

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- Awarded a Phase I SBIR grant by the NIH for the development of a bone marrow stem cell-based treatment of circulation ischemia caused by vascular diseases and diabetes

Fourth Quarter and Twelve Months ended June 30, 2004 Results

Total revenue for the quarter ended June 30, 2004, consisting of product sales and rentals in the EU and grants, was \$0.2 million, unchanged from the same period in fiscal year 2003. Total revenue for the twelve months ended June 30, 2004 was \$1.3 million compared to \$0.8 million for the same period in fiscal year 2003.

Net loss for the quarter ended June 30, 2004 was \$2.7 million, or \$.03 per share, compared to a net loss of \$2.7 million, or \$.05 per share for the same period in fiscal year 2003. Net loss for the twelve months ended June 30, 2004, was \$10.5 million, or \$.14 per share, compared to \$9.6 million, or \$.19 per share for the same period in fiscal year 2003.

At June 30, 2004, the Company had \$16.9 million in cash, cash equivalents and marketable securities as compared to \$10.5 million in cash, cash equivalents and marketable securities at June 30, 2003.

“Our financial condition continues to be strong. The Company’s cash position and our controlled level of expenditures allow us to advance our ongoing bone grafting clinical trials, and move forward with the planned expansion of our clinical trials program,” said Alan M. Wright, Senior Vice President Administrative and Financial Operations and Chief Financial Officer of Aastrom.

Total costs and expenses for the quarter ended June 30, 2004 were \$3.0 million, compared to \$2.9 million for the same period in fiscal year 2003. Total costs and expenses for the twelve months ended June 30, 2004 increased to \$12.0 million, compared to \$10.6 million for the same period in fiscal year 2003.

Research and development expenses for the quarter ended June 30, 2004 increased slightly to \$1.8 million, from \$1.5 million for the same period in fiscal year 2003. Research and development expenses for the twelve months ended June 30, 2004 increased to \$6.3 million, compared to \$5.6 million for the same period in fiscal year 2003. These increases reflect our continued research and product development activities in the area of tissue regeneration, including our on-going and planned bone grafting clinical trials in the United States and the EU.

Selling, general and administrative expenses increased slightly to \$1.2 million for the quarter ended June 30, 2004, compared to \$1.1 million for the same period in fiscal year 2003. Selling, general and administrative expenses increased to \$5.4 million for the twelve months ended June 30, 2004, from \$4.0 million for the same period in fiscal year 2003. The increase in these expenses resulted from continued expansion of business and clinical trial activities in the EU, and additional capital raising expenses not related to specific transactions. Selling, general and administrative expenses for fiscal year ended June 30, 2004 also include a non-cash charge of \$53,000 relating to certain warrants issued in August 2003 for public and investor relations services and a \$372,000 non-cash charge related to an employee performance-based stock option that vested in September 2003.

Dr. Armstrong concluded, “After serving with distinction for the past 6 years we regretfully report that on August 5, 2004, Mary Lincoln Campbell resigned from our Board and as audit committee chairperson, due to the requirements of her other business commitments. We thank Mary for her many contributions and for her devotion to helping guide the Company through important issues over the years.”

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Outlook for the Coming Year

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

- Continue the accrual of patients in our current FDA multi-center bone graft trial in the U.S., and add a third institution as a clinical site
- Complete the first phase of clinical studies in the EU for bone grafting repair of severe non-union fractures; pending positive results, move toward commercialization
- Initiate and complete a jaw bone reconstruction clinical trial in the EU for sinus lift procedures for dental implants
- Prepare for and initiate an EU clinical study utilizing TRCs to regenerate vascular tissue in patients with diabetic limb ischemia
- Pursue 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, James A. Cour, President and Chief Operating Officer, and Alan M. Wright, Senior Vice President Administrative & Financial Operations and Chief Financial Officer of Aastrom Biosciences, Inc., will review and discuss the fourth quarter fiscal year 2004 financial results and the Company's recent progress and future goals today, September 8, 2004, at 11:00 a.m. (EDT) when they will host a conference call. Interested parties should call (785) 832-1508, 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://phx.corporate-ir.net/playerlink.zhtml?c=85924&s=wm&e=938425>, 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 developing proprietary stem cell-based products for the regenerative repair 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® 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 the bone grafting, peripheral vascular disease and cartilage markets. The Company also markets the AastromReplicell System and disposable dendritic cell production kits to 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.

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*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, 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,” “planned,” “potential,” “believe,” 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 Form10-K and other filings with the Securities and Exchange Commission.***

— Financial Table Follows —

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AASTROM BIOSCIENCES, INC.

CONSOLIDATED STATEMENT OF OPERATIONS DATA:

	Quarter ended June 30,		Year ended June 30,	
	2003	2004	2003	2004
(Unaudited)				
REVENUES:				
Product sales and rentals	\$ 16,000	\$ 4,000	\$ 314,000	\$ 49,000
Grants and other	159,000	206,000	530,000	1,253,000
Total revenues	<u>175,000</u>	<u>210,000</u>	<u>844,000</u>	<u>1,302,000</u>
COSTS AND EXPENSES:				
Cost of product sales and rentals	13,000	5,000	145,000	27,000
Cost of product sales and rentals – provision for obsolete and excess inventory	303,000	—	748,000	253,000
Research and development	1,479,000	1,818,000	5,647,000	6,289,000
Selling, general and administrative	1,148,000	1,190,000	4,017,000	5,390,000
Total costs and expenses	<u>2,943,000</u>	<u>3,013,000</u>	<u>10,557,000</u>	<u>11,959,000</u>
OTHER INCOME	30,000	56,000	134,000	169,000
NET LOSS	<u>\$ (2,738,000)</u>	<u>\$ (2,747,000)</u>	<u>\$ (9,579,000)</u>	<u>\$ (10,488,000)</u>
NET LOSS PER SHARE				
(Basic and Diluted)	<u>\$ (.05)</u>	<u>\$ (.03)</u>	<u>\$ (.19)</u>	<u>\$ (.14)</u>
Weighted average number of common shares outstanding	<u>58,945,000</u>	<u>80,713,000</u>	<u>50,984,000</u>	<u>73,703,000</u>

CONSOLIDATED BALANCE SHEET DATA:

	June 30, 2004
ASSETS:	
Cash and investments	\$16,926,000
Other current assets	906,000
Property, net	334,000
Total assets	<u>\$18,166,000</u>
LIABILITIES AND SHAREHOLDERS' EQUITY:	
Current liabilities	\$ 558,000
Shareholders' equity	17,608,000
Total liabilities and shareholders' equity	<u>\$18,166,000</u>

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