
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 9, 2005

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 9, 2005, we issued a press release announcing financial results and achievements for our first fiscal quarter ended September 30, 2005. 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 9, 2005

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 9, 2005

AASTROM BIOSCIENCES, INC.

By: /s/ Gerald D. Brennan, Jr.
Gerald D. Brennan, Jr.
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 FIRST QUARTER
FISCAL YEAR 2006 FINANCIAL RESULTS**

Ann Arbor, Michigan, November 9, 2005 — Aastrom Biosciences, Inc. (Nasdaq: ASTM) today reported financial results for the first quarter of fiscal year 2006 ended September 30, 2005. The Company also reported several clinical and operational achievements during the quarter ended September 30, 2005, including:

- The expansion of our U.S. Phase I/II clinical trial of our adult stem cell-based Tissue Repair Cells (TRCs) in the treatment of severe long bone open or non-union fractures to include the University of Nebraska Medical Center (UNMC) in Omaha, NE. UNMC is the fifth site engaged in this U.S. multi-center trial, which is currently underway at Lutheran General Hospital, Park Ridge, IL, the University of Michigan Health System, Ann Arbor, MI, William Beaumont Hospital, Royal Oak, MI, and Lutheran Medical Center, Brooklyn, NY.
- The election to the Company's Board of Directors of both Stephen G. Sudovar, former President and CEO of EluSys Therapeutics, Inc. and former President of Roche Laboratories, Inc., and Alan L. Rubino, recently appointed President and Chief Operating Officer of Pharmos Corporation.
- The receipt of a Small Business Innovation Research Phase II grant from the National Institutes of Health (NIH) entitled "Clinical-Scale Production of Osteoprogenitor Cells." The two-year grant award from the National Institute of Diabetes and Digestive and Kidney Diseases totals \$740,000, of which \$324,000 has been received for the first year of this study. This Phase II grant award follows a Phase I grant issued to Aastrom in 2003 by the NIH's National Institute of Arthritis and Musculoskeletal and Skin Diseases.

Following the end of the first quarter of fiscal year 2006, ended September 30, 2005, the Company also achieved these additional milestones:

- Patient enrollment has been initiated at The Heart and Diabetes Center North Rhine-Westphalia, located in Bad Oeynhausen, Germany, for a controlled clinical trial for diabetic limb ischemia. This trial followed the Diabetes Center's receipt of the licenses and the Investigational Medicinal Product Dossier (IMPD) necessary to manufacture and use cells for clinical trials in compliance with the new European Union directives.
- The Phase I/II U.S. bone graft clinical trial for severe fractures has enrolled and treated all 20 of the first stage patients. This trial has been expanded to include an additional 16 patients per an IND amendment approved by the FDA.
- The Company received permission from the Spanish Drug Agency (AEMPS) to commence another non-union fracture bone grafting trial in Barcelona. The Company will provide further details on this study in a subsequent release.

"Since the beginning of the first fiscal quarter we have continued to make progress in developing our therapeutic product candidates and, most importantly, delivered another significant clinical

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milestone with the initiation of our first clinical trial utilizing Aastrom's proprietary TRCs to treat limb ischemia in diabetic patients," commented R. Douglas Armstrong, Ph.D., Chief Executive Officer and Chairman of Aastrom. "We are now active in multiple Phase II level trials utilizing our proprietary TRCs to generate bone and vascular tissue, and we expect to continue to foster opportunities for growth across our business during fiscal year 2006 as we begin to report on the patient data from other clinical trials."

First Quarter Fiscal Year 2006 Ended September 30, 2005 Results

Total revenues for the quarter ended September 30, 2005 were \$180,000, compared to total revenues of \$187,000 for the same period in fiscal year 2005.

Product sales for the quarter ended September 30, 2005 remained unchanged at \$15,000 from the same period in fiscal year 2005, resulting from the sale of therapy kits for clinical trials and research by others. As previously disclosed, this small commercial area has not shown promise, and we have limited our formal marketing efforts promoting the AastromReplicell® System as a stand-alone product. The AastromReplicell System technology continues to be used to manufacture our TRC cell products.

Grant revenues decreased slightly to \$165,000 for the quarter ended September 30, 2005 from \$172,000 for the same period in fiscal year 2005. This decrease is the result of slightly lower grant program activities; however, we continue to pursue grant-funded programs. Grant revenues accounted for 92% of total revenues for both quarters ended September 30, 2005 and 2004, and are recorded on a cost-reimbursement basis. Grant revenues may vary in any period based on timing of grant awards, grant-funded activities, level of grant funding and number of grant awards received.

Total costs and expenses increased to \$3,974,000 for the quarter ended September 30, 2005, from \$2,896,000 for the same period in fiscal year 2005.

The cost of product sales decreased to \$5,000 for the quarter ended September 30, 2005 from \$15,000 for the same period in fiscal year 2005.

Research and development expenses increased to \$1,953,000 for the quarter ended September 30, 2005 from \$1,567,000 for the same period in fiscal year 2005. This increase reflects continued expansion of our research activities to support product utility and future regulatory submissions, product development activities in the area of tissue regeneration, development of centralized facilities for product manufacturing and distribution processes, and on-going and planned bone grafting and vascular repair trials in the U.S. and EU. Research and development expenses for the quarter ended September 30, 2005, also include a non-cash charge of \$78,000 relating to the adoption of Financial Accounting Standards Board Statement No. 123R, "*Share-Based Payment*" (SFAS 123R) on July 1, 2005, which requires us to measure the value of all employee share-based payments and recognize that value as an operating expense.

Selling, general and administrative costs increased for the quarter ended September 30, 2005 to \$2,016,000 from \$1,314,000 for the same period in fiscal year 2005. This increase is due to additional employee costs of approximately \$325,000 that include: bonuses paid to certain employees, an accrual for future performance bonuses and the salary and fringe benefits for a marketing director position that was vacant during the quarter ended September 30, 2004. Costs also increased for the quarter ended September 30, 2005 by approximately \$211,000 due to additional required activities for financial internal controls compliance and certification. In addition, selling, general and administrative expenses for the quarter ended September 30, 2005, included a non-cash charge of \$118,000 relating to the adoption of SFAS 123R on July 1, 2005.

Interest income was \$306,000 for the quarter ended September 30, 2005 compared to \$60,000 for the same period in fiscal year 2005. The fluctuations in interest income are due primarily to

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corresponding changes in the level of cash, cash equivalents and short-term investments during the periods and improved yields from our investments in 2005.

Net loss for the quarter ended September 30, 2005 was \$3,488,000, or \$.03 per common share compared to \$2,649,000 or \$.03 per common share for the same period in fiscal year 2005. The increase in net loss is primarily the result of increased costs and expenses offset on a per share basis by an increase in the weighted average number of common shares outstanding resulting from the sale of our common shares to investors in fiscal year 2005.

At September 30, 2005, the Company had \$29.2 million in cash, cash equivalents and short-term investments as compared to \$32.4 million at June 30, 2005.

Aastrom Conference Call Information

R. Douglas Armstrong, Ph.D., Chief Executive Officer and Chairman and Gerald D. Brennan, Jr., Vice President Administrative & Financial Operations and Chief Financial Officer of Aastrom Biosciences, Inc., will review and discuss the first quarter fiscal year 2006 financial results and the Company's recent progress and future goals today, November 9, 2005, at 11:00 a.m. (EST) when they will host a conference call. Interested parties should call toll-free (877) 407-9205 fifteen minutes before the start of the call to register and identify themselves as registrants of the 'Aastrom Conference Call'. Any registered caller on the toll-free line may ask to be placed in the queue for the Question & Answer session. The call will be simulcast on the web at <http://www.investorcalendar.com/IC/CEPage.asp?ID=96864>. If you are unable to participate during the live webcast, the call will be available for replay at <http://www.investorcalendar.com/> for 60 days.

About Aastrom Biosciences, Inc.

Aastrom Biosciences, Inc. (Nasdaq: ASTM) is developing patient-specific products for the repair or regeneration of human tissues, utilizing the Company's proprietary adult stem cell technology. Aastrom's strategic position in the tissue regeneration sector is enabled by its proprietary Tissue Repair Cells (TRCs), a mix of bone marrow-derived adult stem and progenitor cells manufactured in the AastromReplicell® System, an industry-unique automated cell production system. TRCs are the core component of the products Aastrom is developing for severe bone fractures, ischemic vascular disease, jaw reconstruction and spine fusion, with Phase I/II level clinical trials active in the U.S. and EU for some of these indications.

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, expected milestones, anticipated components of revenue, plans for the current fiscal year and potential product applications, which involve certain risks and uncertainties. The forward-looking statements are also identified through use of the words "planned," "expect," "should," "may," 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,	
	2004	2005
REVENUES:		
Product sales	\$ 15,000	\$ 15,000
Grants and other	172,000	165,000
Total revenues	<u>187,000</u>	<u>180,000</u>
COSTS AND EXPENSES:		
Cost of product sales	15,000	5,000
Cost of product sales and rentals — provision for obsolete and excess inventory	—	—
Research and development	1,567,000	1,953,000
Selling, general and administrative	1,314,000	2,016,000
Total costs and expenses	<u>2,896,000</u>	<u>3,974,000</u>
OTHER INCOME	<u>60,000</u>	<u>306,000</u>
NET LOSS	<u>\$ (2,649,000)</u>	<u>\$ (3,488,000)</u>
NET LOSS PER COMMON SHARE		
(Basic and Diluted)	<u>\$ (.03)</u>	<u>\$ (.03)</u>
Weighted average number of common shares outstanding	<u>82,738,000</u>	<u>102,483,000</u>

CONSOLIDATED BALANCE SHEET DATA:

	June 30, 2005	September 30, 2005
ASSETS		
Cash and cash equivalents	\$ 14,408,000	\$ 23,107,000
Short-term investments	18,006,000	6,055,000
Receivables, net	193,000	169,000
Inventories	116,000	21,000
Other current assets	421,000	874,000
Property and equipment, net	753,000	1,100,000
Total assets	<u>\$ 33,897,000</u>	<u>\$ 31,326,000</u>
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities	\$ 869,000	\$ 1,309,000
Shareholders' equity	33,028,000	30,017,000
Total liabilities and shareholders' equity	<u>\$ 33,897,000</u>	<u>\$ 31,326,000</u>

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