
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, 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 September 8, 2005, we issued a press release announcing financial results and achievements for our fourth fiscal quarter and fiscal year ended June 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 September 8, 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: September 8, 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

P.O. Box 376 • Ann Arbor, Michigan 48106 • Ph: 734-930-5555 • Fax: 734-665-0485

FOR IMMEDIATE RELEASE

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**AASTROM BIOSCIENCES, INC. REPORTS FOURTH QUARTER 2005
FINANCIAL RESULTS**

Ann Arbor, Michigan, September 8, 2005 — Aastrom Biosciences, Inc. (Nasdaq: ASTM) today reported financial results for the fourth quarter and fiscal year ended June 30, 2005. The Company also reported significant clinical and operational achievements of the last quarter and fiscal year. For the quarter ended June 30, 2005, these achievements included:

- Clinical progress:
 - Announced positive results from its feasibility clinical trial conducted in Barcelona, Spain to evaluate the use of Aastrom's Tissue Repair Cells (TRCs) for the treatment of severe long bone non-union fractures. All of the patients treated with TRCs, an autologous bone marrow-derived cell product, exhibited clinical and functional healing, with 5 of 6 treatments showing bone regeneration at the fracture site as determined by radiographic imaging by 6 months. The results were notable in that each patient had failed prior treatment with standard of care methodologies and had a poor prognosis for healing. This feasibility trial suggests that Aastrom's autologous TRCs may offer a new way to achieve local bone regeneration for bone grafting and other clinical indications for bone repair.
- New management appointment:
 - Appointed Gerald D. Brennan, Jr., JD, as Vice President Administrative and Financial Operations and Chief Financial Officer. Mr. Brennan has almost two decades of strong financial and operational expertise gained from his experience in senior management level positions.
- Other notable event:
 - Added to the Russell 3000® Index which measures the performance of the 3,000 largest U.S. companies based on total market capitalization.

Commenting on the year, R. Douglas Armstrong, Ph.D., Chief Executive Officer and Chairman of Aastrom, said, "We made significant strides in fiscal year 2005 and demonstrated our continued commitment to achieve progressive corporate milestones. Of particular note has been the movement of our TRCs into the clinic, and the interim results we have achieved in these patient treatments. The support and interest that we are receiving from the medical field as well as regulatory agencies, should further our clinical progress as we expand our trials and move toward a registration (Phase III) trial."

Dr. Armstrong continued, "As the Company continues to transform from a development company to a company focused on the commercialization of its products, we are strengthening our board and management leadership with new officers and personnel who bring additional expertise in the clinical and product development areas. These activities, combined with the successful financings of the past year, should assist us in delivering on our milestones throughout the coming fiscal year."

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The Company also recently announced changes on the board of directors, including the additions of Stephen G. Sudovar and Timothy M. Mayleben, both of whom bring a wealth of biotechnology and pharmaceutical business experience at the executive and board level. Mr. Sudovar was the President of Roche Laboratories, Inc., U.S., a division of Hoffman La Roche, as well as the CEO of EluSys Therapeutics, Inc., a development stage biotech company, and the founder, President, CEO and Chairman of Pracon Incorporated, a healthcare consulting and communications firm. Mr. Mayleben is an active executive in the biotechnology field, with most recent roles as the CFO, and then COO of Esperion Therapeutics, Inc., now a division of Pfizer Global Research and Development. Mr. Mayleben qualifies as a financial expert for the audit committee under the SEC rules, and meets the NASDAQ financial sophistication requirements.

With new members joining the board, two of our long-term directors, Arthur F. Staubitz and Joseph Taylor, have chosen to retire. Each of these gentlemen served on Aastrom's board for over 6 years. We thank both of them for their contributions and service to the Company. In the coming months, the Company will continue to seek senior executives who could bring medical products industry or other desired experience to Aastrom's board.

Other significant highlights from fiscal year 2005 include the following:

- Clinical progress:
 - Expanded U.S. Phase I/II clinical trial of the Company's TRC product for severe long bone fractures to include a third and fourth site: the Department of Orthopedic Surgery at William Beaumont Hospital, Royal Oak, MI and Lutheran Medical Center, Brooklyn, NY.
 - Achieved an FDA-required early clinical safety benchmark for the Phase I/II U.S. clinical trial of the Company's TRC product intended for the treatment of severe long bone fractures permitting the Company to now treat appendicular, or fresh, non-union fractures, opening the trial to a larger patient population.
 - Signed a clinical trial agreement with the Heart and Diabetes Center North Rhine-Westphalia, located in Bad Oeynhausen, Germany. The clinical trial will evaluate the safety and effect of Aastrom's TRCs in the regeneration of peripheral vascular tissue to treat lower limb ischemia in diabetic patients.
 - Aastrom and the Institut de Terapia Regenerativa Tissular announced the initiation of patient enrollment in a pilot clinical trial with Instituto de Cirugia Maxilofacial e Implantologia in Barcelona, Spain to determine the safety and effect of Aastrom's TRCs in maxillary sinus lift bone graft procedures necessary for dental implants.
- Patents:
 - Received a patent from the U.S. Patent and Trademark Office that provides expanded coverage for the Company's proprietary single-pass perfusion technology to cover enhancing the biological functionality of human dendritic cells produced in cell culture.
- Management:
 - James A. Cour was appointed as President and Chief Operating Officer. Prior to accepting his position with Aastrom, Mr. Cour held executive level management positions with several companies, including Baxter International, Windsor VanGelder Limited and Cytomedix.

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- Janet M. Hock, B.D.S., Ph.D. was named Vice President Global Research and Chief Scientific Officer, responsible for Aastrom's biological research and clinical development programs. Dr. Hock has worked in academic, government and industry settings and has broad experience in the fields of bone formation and skeletal diseases, along with the development of new therapeutic treatments.
- Günter Roskamp, Ph.D. was named as Managing Director of Aastrom's wholly owned German subsidiary, Aastrom Biosciences GmbH (formerly Zellera AG), which supports Aastrom's business operations in the EU.

Fourth Quarter and Twelve Months ended June 30, 2005 Results

Total revenues for the quarter ended June 30, 2005 were \$96,000, compared to \$210,000 for the same period in fiscal year 2004. Total revenues for the twelve months ended June 30, 2005 were \$909,000 compared to \$1,302,000 for the same period in fiscal year 2004.

Product sales and rentals revenues increased to \$10,000 for the quarter ended June 30, 2005 from \$4,000 in the same period in fiscal year 2004. Product sales and rentals revenues increased to \$387,000 for the twelve months ended June 30, 2005 from \$49,000 for the same period in fiscal year 2004. The increase is primarily the result of additional therapy kit sales for clinical trials and research by others, and revenue of \$120,000 from the sale of an AastromReplicell System in fiscal year 2005. Product sales and rentals revenues include rental revenue of \$37,000 and \$0 from the fiscal years ended June 30, 2004 and 2005, respectively. This revenue was generated from AastromReplicell System rental agreements that have since expired or have been terminated. Based upon our current business strategy we do not expect to generate rental revenues in future periods. Our plan is to limit our marketing efforts promoting the AastromReplicell System as a stand-alone product. Rather, we intend to focus on utilizing the AastromReplicell System technology in cell manufacturing facilities to support our TRC development programs. At such time as we satisfy applicable regulatory approval requirements, we expect the sales of our TRC and related cell-based products will constitute nearly all of our product sales revenues.

Revenues for fiscal year 2004 also include \$75,000 in research and development agreements compared to \$0 for fiscal year 2005. This decrease is the result of a one-time \$50,000 fee from our sublicense agreement with Corning Inc. in fiscal year 2004, and an additional fee of \$25,000 in fiscal year 2004 from a development agreement with a European institution.

Grant revenues decreased to \$86,000 for the quarter ended June 30, 2005 from \$206,000 in the same period in fiscal year 2004. Grant revenues decreased to \$522,000 in fiscal year 2005 from \$1,178,000 in fiscal year 2004. Grant revenues in fiscal year 2005 decreased from fiscal year 2004 as a result of decreased activity on the collaborative grant with the Defense Advanced Research Projects Agency (DARPA), and reduced activity on grants from the National Institutes of Health. Grant revenues accounted for 57% of total revenues for fiscal year 2005 and 90% for fiscal year 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 grants awarded.

Total costs and expenses were \$3.7 million for the quarter ended June 30, 2005, compared to \$3.0 million for the same period in fiscal year 2004. Total costs and expenses were \$13.3 million for the twelve months ended June 30, 2005, compared to \$12.0 million for the same period in fiscal year 2004.

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Cost of product sales and rentals were \$8,000 for the quarter ended June 30, 2005, compared to \$5,000 for the same period in fiscal year 2004. Cost of product sales and rentals increased to \$139,000 for the twelve months ended June 30, 2005 from \$27,000 for the same period in fiscal year 2004. For the fiscal year, the fluctuation in cost of product sales and rentals is due to the changes in the volume of product sales. The non-cash provision for excess AastromReplicell System inventories was \$9,000 in fiscal year 2005 and \$253,000 in 2004. As of June 30, 2005, the carrying value of our AastromReplicell System inventories was reduced to zero. Based upon our current business strategy, we do not expect to generate revenues from the sale of AastromReplicell System inventories in future periods.

Research and development expenses increased slightly to \$1.9 million for the quarter ended June 30, 2005 from \$1.8 million for the same period in fiscal year 2004. Research and development expenses increased to \$7.2 million for the twelve months ended June 30, 2005 from \$6.3 million for the same period in fiscal year 2004. These increases reflect expanded research activities to support regulatory submissions and anticipated product registrations, product development activities in the area of tissue regeneration, development of product distribution processes, and ongoing and planned bone grafting trials in the U.S. and the EU. Research and development expenses in 2005 also include a non-cash charge of \$101,000 relating to stock options awarded to an employee whose status changed to a consultant.

Selling, general and administrative expenses increased to \$1.7 million for the quarter ended June 30, 2005 from \$1.2 million for the same period in fiscal year 2004. Selling, general and administrative expenses increased to \$6.0 million for the twelve months ended June 30, 2005 from \$5.4 million for the same period in 2004. These increases are due to additional staffing, consulting and pre-marketing activities in the U.S. and internationally, and increased costs required for financial internal controls compliance and certification. Selling, general and administrative costs in fiscal year 2005 include a non-cash charge of \$59,000 related to a variable stock option that was exercised. Selling, general and administrative costs in fiscal year 2004 include a non-cash charge of \$53,000 relating to certain warrants issued for public and investor relations services, and a \$372,000 non-cash charge related to an employee performance-based stock option that vested.

Net loss for the quarter ended June 30, 2005 was \$3.4 million, or \$.03 per share, compared to a net loss of \$2.7 million, or \$.03 per share for the same period in fiscal year 2004. Net loss for the twelve months ended June 30, 2005, was \$11.8 million, or \$.13 per share, compared to \$10.5 million, or \$.14 per share for the same period in fiscal year 2004.

At June 30, 2005, the Company had \$32.4 million in cash, cash equivalents and short-term investments as compared to \$16.9 million in cash, cash equivalents and marketable securities at June 30, 2004.

“The Company’s strong balance sheet position should allow us to fund the anticipated significant increases in clinical trial expenses in the coming fiscal year. Largely as a result of these anticipated increases, we expect our monthly cash utilization to increase from approximately \$1.0 million per month at the end of fiscal year 2005, to approximately \$1.5 million per month on average during fiscal year 2006,” said Gerald D. Brennan, Jr., Vice President Administrative and Financial Operations and Chief Financial Officer of Aastrom.

Outlook for the Coming Year

Aastrom entered fiscal year 2006 with sufficient funding to support planned clinical and operational goals and objectives, including:

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- The Heart and Diabetes Center North Rhine-Westphalia, located in Bad Oeynhausen, Germany recently received the licenses necessary to proceed with TRC cell manufacturing. Therefore, we expect to initiate the Phase II-level clinical trial for diabetic limb ischemia in first quarter of fiscal year 2006.
- We anticipate obtaining a license to establish our own centralized cell manufacturing facility in Europe.
- We expect to report on results from the five patients enrolled in the clinical trial in Barcelona, Spain to determine the safety and effectiveness of Aastrom's TRCs in maxillary sinus lift bone graft procedures necessary for dental implants in the first half of fiscal year 2006.
- With five sites in the Phase I/II U.S. bone graft clinical trial for severe fractures, we have targeted the accrual and treatment of the first 20 patients by the end of the second quarter of fiscal year 2006.

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 fourth quarter fiscal year 2005 financial results and the Company's recent progress and future goals today, September 8, 2005, at 11:00 a.m. (EDT) when they will host a conference call. Interested parties should call toll-free (877) 407-9205, or from outside the U.S. (201) 689-8054, 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.vcall.com/ClientPage.asp?ID=94806>, and the entire call will be archived for replay at the same site 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, and the AastromReplicell® System, an industry-unique automated cell production platform used to produce cells for clinical use. 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, the expected adequacy of capital resources to support planned activities, 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 "intended," "plan," "expect," "should," "could," "seek," "anticipated," "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.

CONSOLIDATED STATEMENT OF OPERATIONS DATA:

	Quarter ended June 30,		Year ended June 30,	
	2004	2005	2004	2005
	<i>(Unaudited)</i>			
REVENUES:				
Product sales and rentals	\$ 4,000	\$ 10,000	\$ 49,000	\$ 387,000
Research and development agreements	—	—	75,000	—
Grants and other	206,000	86,000	1,178,000	522,000
Total revenues	<u>210,000</u>	<u>96,000</u>	<u>1,302,000</u>	<u>909,000</u>
COSTS AND EXPENSES:				
Cost of product sales and rentals	5,000	8,000	27,000	139,000
Cost of product sales and rentals – provision for excess inventories	—	—	253,000	9,000
Research and development	1,818,000	1,948,000	6,289,000	7,206,000
Selling, general and administrative	1,190,000	1,745,000	5,390,000	5,972,000
Total costs and expenses	<u>3,013,000</u>	<u>3,701,000</u>	<u>11,959,000</u>	<u>13,326,000</u>
OTHER INCOME	56,000	245,000	169,000	606,000
NET LOSS	<u>\$ (2,747,000)</u>	<u>\$ (3,360,000)</u>	<u>\$ (10,488,000)</u>	<u>\$ (11,811,000)</u>
NET LOSS PER SHARE				
(Basic and Diluted)	<u>\$ (.03)</u>	<u>\$ (.03)</u>	<u>\$ (.14)</u>	<u>\$ (.13)</u>
Weighted average number of common shares outstanding	<u>80,713,000</u>	<u>102,036,000</u>	<u>73,703,000</u>	<u>93,541,000</u>

CONSOLIDATED BALANCE SHEET DATA:

	June 30, 2005
ASSETS:	
Cash and cash equivalents	\$ 14,408,000
Short-term investments	18,006,000
Other current assets	730,000
Property, net	753,000
Total assets	<u>\$ 33,897,000</u>
LIABILITIES AND SHAREHOLDERS' EQUITY:	
Current liabilities	\$ 869,000
Shareholders' equity	33,028,000
Total liabilities and shareholders' equity	<u>\$ 33,897,000</u>

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