# 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, 2007** 

# **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:

- o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

#### Item 2.02 Results of Operations and Financial Condition.

On November 9, 2007, we issued a press release announcing financial results and achievements for our first fiscal quarter ended September 30, 2007. 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.

### (d) Exhibits.

Exhibit No.	Description
99.1	Press Release dated November 9, 2007

#### **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, 2007

#### AASTROM BIOSCIENCES, INC.

By: /s/ Gerald D. Brennan, Jr.

Gerald D. Brennan, Jr.
Vice President, Administrative & Financial Operations and CFO



CONTACTS: Kris M. Maly

Investor Relations Department Aastrom Biosciences, Inc. Phone: (734) 930-5777 Cameron Associates Kevin McGrath Phone: (212) 245-4577

# AASTROM BIOSCIENCES, INC. REPORTS FIRST QUARTER FISCAL YEAR 2008 FINANCIAL RESULTS

— Clinical Progress Reported from Tissue Regeneration Programs —

**Ann Arbor, Michigan, November 9, 2007** — Aastrom Biosciences, Inc. (Nasdaq: ASTM), a leading regenerative medicine company, today reported financial results for the first fiscal quarter ended September 30, 2007. The Company also reported clinical and operational achievements since the beginning of fiscal year 2008, including:

- Positive final results from a U.S. Phase I/II clinical trial designed to collect safety and efficacy data utilizing Bone Repair Cells (BRCs) in the treatment of severe non-union fractures were presented by Matthew L. Jimenez, M.D., of the Illinois Bone & Joint Institute, during a podium presentation at the Orthopaedic Trauma Association annual meeting in Boston, MA:
  - Overall 91% healing rate in 30 of 33 patients with non-union tibia, humerus or femur fractures that had failed to heal after one or more prior medical procedures (average 1.75) one year post-BRC treatment
  - 100% of the patients who have healed are fully weight-bearing, have regained range of motion and are no longer impaired by their injuries
  - Severe bone fracture results supported bone regeneration proof of principle and the initiation of Aastrom's U.S. Phase III osteonecrosis of the femoral head clinical trial
- Encouraging interim results from two German research groups utilizing Aastrom's proprietary Tissue Repair Cell (TRC) Technology platform to
  manufacture autologous stem cell products were presented at the 2nd Congress of the German Society for Stem Cell Research in Würzburg,
  Germany:
  - Interim results from the first 13 patients treated in a multi-arm, Phase I/II, single-center clinical trial to evaluate the safety of Vascular Repair Cells (VRCs) and normal bone marrow cells in the treatment of chronic diabetic foot wounds associated with critical limb ischemia (CLI) were presented by Dr. Bernd Stratmann of the Diabetes Center at the Heart and Diabetes Center in North Rhine-Westphalia (Center), Bad Oeynhausen, Germany. Twelve months post-treatment, all four patients in the interim analysis who were treated with VRCs reported no major amputations, no cell-related adverse events, and healing of all open wounds.
  - Early clinical data involving the first use of Aastrom BRCs to treat patients suffering from osteonecrosis of the femoral head were presented by Ulrich Nöth, M.D. of the Orthopaedic Institute, König-Ludwig-Haus, University of Würzburg, Germany. All four patients tolerated the procedure well, have reported a reduction in hip pain with no signs of disease progression, as determined by MRI and X-Ray, and were back to

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work within 6 months after treatment. In addition, no cell-related adverse events were reported and none of these patients have required hip replacement surgery.

• Completion of a registered direct offering to a select group of unaffiliated institutional investors through BMO Capital Markets Corp. for net proceeds of approximately \$12.5 million

"Overall, we are very pleased with our accomplishments since the beginning of this fiscal year. The positive clinical results reported from our bone and vascular regeneration programs continue to support our proprietary TRC Technology as a novel platform for the production of high-value patient-specific therapeutics," said George Dunbar, President and Chief Executive Officer of Aastrom. "We remain committed to furthering all of our tissue regeneration programs, and look forward to reporting future developments from our planned cardiac and neural clinical activities."

#### First Fiscal Quarter Ended September 30, 2007 Results

Total revenues for the quarter ended September 30, 2007, consisting of grant revenues and product sales, were \$87,000, compared to total revenues of \$104,000 for the same period in fiscal year 2007.

Total costs and expenses increased to \$5,487,000 for the quarter ended September 30, 2007, from \$4,688,000 for the same period in fiscal year 2007.

As a result of the continued expansion of research and development activities to support regulatory submissions, on-going and planned tissue regeneration clinical trials and activities in the U.S. and EU, and the development of facilities for product manufacturing and distribution processes, research and development expenses increased to \$3,873,000 for the quarter ended September 30, 2007 from \$2,304,000 for the same period in fiscal year 2007. Research and development expenses for the quarters ended September 30, 2007 and 2006, also include a non-cash charge of \$224,000 and \$108,000, respectively, relating to share-based compensation expense.

Selling, general and administrative expenses decreased to \$1,614,000 for the quarter ended September 30, 2007 from \$2,384,000 for the same period in fiscal year 2007. This decrease is primarily due to additional employee costs for the quarter ended September 30, 2006 that included: an accrual relating to the former Chief Executive Officer's revised employment agreement, and an accrual and severance payments relating to the former President and Chief Operating Officer's employment agreement. The quarter ended September 30, 2007 did not include any such charges. Selling, general and administrative expenses for the quarters ended September 30, 2007 and 2006, also include a non-cash charge of \$326,000 and \$463,000, respectively, relating to share-based compensation expense.

Interest income was \$365,000 for the quarter ended September 30, 2007 compared to \$527,000 for the same period in fiscal year 2007. The fluctuations in interest income are due primarily to corresponding changes in the level of cash, cash equivalents and short-term investments during the periods and varying yields from our investments.

Interest expense was \$15,000 for the quarter ended September 30, 2007 related to long-term debt for equipment acquired during the fiscal year ended June 30, 2007.

Net loss for the quarter ended September 30, 2007 was \$5,050,000, or \$.04 per common share compared to \$4,057,000, or \$.03 per common share for the same period in fiscal year 2007. The increase in net loss is primarily the result of increased costs and expenses offset in part on a per share basis by an increase in the weighted average number of common shares outstanding.

At September 30, 2007, the Company had \$24.3 million in cash, cash equivalents and short-term investments as compared to \$28.3 million at June 30, 2007. Subsequently, on October 17, 2007, the

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Company completed a registered direct offering of its common shares for net cash proceeds of approximately \$12.5 million. As clinical activities expand, it is expected that the Company's cash utilization will average \$1.7 million per month during fiscal year 2008.

#### **Aastrom Conference Call Information**

George W. Dunbar, President and Chief Executive Officer, Gerald D. Brennan, Jr., Vice President Administrative & Financial Operations and Chief Financial Officer, and Elmar R. Burchardt, M.D., Ph.D., Vice President, Medical Affairs of Aastrom Biosciences, will host a conference call to review and discuss the first quarter fiscal year 2008 financial results at 9:00 a.m. (EST) today, November 9, 2007. 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'. 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 <a href="http://www.vcall.com/IC/CEPage.asp?ID=122490">http://www.vcall.com/IC/CEPage.asp?ID=122490</a>. A podcast of the call may be downloaded from the web at the internet address above. If you are unable to participate during the live call, the webcast will be available for replay at <a href="http://www.investorcalendar.com/">http://www.investorcalendar.com/</a> until February 10, 2008. Also, through November 19, 2007, an audio replay of the call will be available by dialing toll-free (877) 660-6853, or from outside the U.S. (201) 612-7415; when prompted on the phone line, the Account # is: 286 and the Conference ID# is: 259840.

#### **About Aastrom Biosciences, Inc.**

Aastrom is a leader in the development of autologous cell products for the repair or regeneration of human tissue. The company's proprietary Tissue Repair Cell (TRC) Technology involves the use of a patient's own cells to manufacture products to treat a range of chronic diseases and serious injuries affecting bone, vascular, cardiac, and neural tissues. Aastrom's TRC-based products contain increased numbers of stem and early progenitor cells, produced from a small amount of bone marrow collected from the patient. The TRC Technology platform has positioned Aastrom to advance multiple products into clinical development. Currently, the company has a bone regeneration product in Phase III development for the treatment of osteonecrosis of the femoral head (called the ON-CORE trial), a vascular regeneration product in clinical development for the treatment of critical limb ischemia (called the RESTORE-CLI trial), and preclinical research programs targeting unmet needs in cardiac and neural health. Aastrom product candidates to treat osteonecrosis of the femoral head and dilated cardiomyopathy have been designated for orphan drug status by the FDA. For more information, visit Aastrom's website at <a href="https://www.aastrom.com">www.aastrom.com</a>. (astmf)

This document contains forward-looking statements, including without limitation, statements concerning clinical trial plans and expectations, clinical activity timing, intended product development and commercialization objectives, and potential advantages and application of Tissue Repair Cell (TRC) Technology, which involve certain risks and uncertainties. The forward-looking statements are also identified through use of the word "planned," 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, competitive developments, and 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) (In thousands, except per share amounts)

## CONSOLIDATED STATEMENT OF OPERATIONS DATA:

	Quarter ende	Quarter ended September 30,	
	2006	2007	
REVENUES:			
Product sales	\$ 12	\$ 12	
Grants	92	75	
Total revenues	104	87	
COSTS AND EXPENSES:			
Cost of product sales	_	_	
Research and development	2,304	3,873	
Selling, general and administrative	2,384	1,614	
Total costs and expenses	4,688	5,487	
OTHER INCOME (EXPENSE):			
Interest income	527	365	
Interest expense	_	(15)	
Total other income	527	350	
NET LOSS	<u>\$ (4,057)</u>	\$ (5,050)	
NET LOSS PER COMMON SHARE (Basic and Diluted)	<u>\$ (.03)</u>	\$ (.04)	
Weighted average number of common shares outstanding	119,177	120,607	
CONSOLIDATED BALANCE SHEET DATA:			
	June 30, 2007	September 30, 2007	
ASSETS			
Cash and cash equivalents	\$ 13,439	\$ 24,300	
Short-term investments	14,886	_	
Receivables, net	78	71	
Inventories	8	8	
Other current assets	1,766	2,366	
Property and equipment, net	2,671	2,606	
Total assets	\$ 32,848	\$ 29,351	
LIABILITIES AND SHAREHOLDERS' EQUITY			
Current liabilities	\$ 3,500	\$ 3,504	
Shareholders' equity	28,251	24,858	
Total liabilities and shareholders' equity	\$ 32,848	\$ 29,351	
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