# 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, 2006

# **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))

## TABLE OF CONTENTS

Item 2.02 Results of Operations and Financial Condition Item 9.01 Financial Statements and Exhibits SIGNATURES EXHIBIT 99.1

#### **Table of Contents**

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

On November 9, 2006, we issued a press release announcing financial results and achievements for our first fiscal quarter ended September 30, 2006. 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.

Exhibit No.	Description		
99.1	Press Release dated November 9, 2006		
	2		

#### **Table of Contents**

#### **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, 2006

### AASTROM BIOSCIENCES, INC.

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

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

CONTACTS: Kris M. Maly

Investor Relations Department Aastrom Biosciences, Inc. Phone: (734) 930-5777 Cameron Associates Kevin McGrath Phone: (212) 245-4577 Deanne Eagle (Media) Phone: (212) 554-5463

# AASTROM BIOSCIENCES, INC. REPORTS FIRST QUARTER FISCAL YEAR 2007 FINANCIAL RESULTS

— Company Reports Clinical Progress and Strengthened Management Team —

**Ann Arbor, Michigan, November 9, 2006** — Aastrom Biosciences, Inc. (Nasdaq: ASTM), a late-stage development company focused on the use of autologous cells for regenerative medicine, today reported financial results for the first fiscal quarter ended September 30, 2006. The Company also reported clinical and operational achievements during the quarter, including:

- Additional interim results from 23 patients enrolled in the U.S. Phase I/II multi-center clinical trial for the treatment of severe long bone non-union fractures were presented by one of the Principal Investigators, Thomas R. Lyon, M.D., Chief of Orthopedic Trauma & Clinical Instructor of Orthopedic Surgery at Lutheran Medical Center, in Brooklyn, New York, at the 28th Annual Meeting of the American Society for Bone and Mineral Research (ASBMR).
  - o After being treated with the TRC-based cell product, callus formation was observed in 22 of the 23 patients by six months. Callus formation is the first sign of healing and return of blood flow.
  - o Of these 23 patients, 12 have completed the total one year follow-up observation period. Ten of these 12 patients showed bone bridging at the fracture site, indicating radiographic evidence of healing.
- The appointment of two senior executives strengthened the management team.
  - o George W. Dunbar as President, Chief Executive Officer and Director. Mr. Dunbar brings over 25 years of experience in the healthcare field to the Company, including 15 years in the role of Chief Executive Officer at both established and early-stage healthcare companies in the biotech, pharmaceutical, diagnostic and device sectors.
  - o Elmar R. Burchardt, M.D., Ph.D., as Vice President Medical Affairs. Dr. Burchardt is responsible for directing all of the clinical programs utilizing the Company's proprietary TRC technology, including programs for long bone fractures, critical limb ischemia, spine fusion and osteonecrosis. He will also lead the development of new indication programs, such as a program for cardiac tissue regeneration.

Following the end of the first fiscal quarter, the Company also announced that Ronnda L. Bartel, Ph.D. has joined Aastrom as Vice President of Research and Development. Dr. Bartel is responsible for the product development and manufacturing of Aastrom's TRC-based cell products, as well as the Company's discovery and research efforts.

-more-

"We are determined to provide our TRC-based cell products to physicians and their patients who are in need of new medical approaches for tissue regeneration. We are currently in clinical trials utilizing our platform technology to address regenerative medicine needs in the vascular and bone areas, and are also preparing to move into additional therapeutic areas, including cardiac and neural regeneration," stated Mr. Dunbar. "At this time, Aastrom's value lies in achieving clinical milestones. Under the direction of our strengthened management team, we look forward to reporting on the clinical progress we have slated for accomplishment by the end of 2007."

#### First Fiscal Quarter Ended September 30, 2006 Results

Total revenues for the quarter ended September 30, 2006, consisting of product sales and grant funding, were \$104,000, compared to total revenues of \$180,000 for the same period in fiscal year 2006.

Product sales for the quarter ended September 30, 2006, consisting of the sale of therapy kits for clinical trials and research by others, decreased slightly to \$12,000 from \$15,000 for the same period in fiscal year 2006.

Grant revenues decreased to \$92,000 for the quarter ended September 30, 2006 from \$165,000 for the same period in fiscal year 2006. This decrease is the result of slightly lower grant program activities, and the completion of our activity on the collaborative grant with the Defense Advanced Research Projects Agency (DARPA) in June 2006. Grant revenues accounted for 88% of total revenues for the quarter ended September 30, 2006 and 92% of total revenues for the same period in fiscal year 2006, and are recorded on a cost-reimbursement basis. As we continue to pursue grant-funding, 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 \$4,688,000 for the quarter ended September 30, 2006, from \$3,974,000 for the same period in fiscal year 2006.

The cost of product sales decreased to \$0 for the quarter ended September 30, 2006 from \$5,000 for the same period in fiscal year 2006.

Research and development expenses increased to \$2,304,000 for the quarter ended September 30, 2006 from \$1,953,000 for the same period in fiscal year 2006. This increase reflects continued expansion of our research activities to support future regulatory submissions, on-going and planned tissue regeneration clinical trials in the U.S. and EU and the development of facilities for product manufacturing. Research and development expenses for the quarters ended September 30, 2006 and 2005, also include a non-cash charge of \$108,000 and \$78,000, respectively, relating to share-based compensation expense.

Selling, general and administrative costs increased to \$2,384,000 for the quarter ended September 30, 2006 from \$2,016,000 for the same period in fiscal year 2006. This increase is due to additional employee costs that include: 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. Selling, general and administrative expenses for the quarters ended September 30, 2006 and 2005, also include a non-cash charge of \$463,000 and \$118,000, respectively, relating to share-based compensation expense.

Interest income was \$527,000 for the quarter ended September 30, 2006 compared to \$306,000 for the same period in fiscal year 2006. 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 improved yields from our investments.

-more-

Net loss for the quarter ended September 30, 2006 was \$4,057,000, or \$.03 per common share compared to \$3,488,000 or \$.03 per common share for the same period in fiscal year 2006. 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.

At September 30, 2006, the Company had \$39 million in cash, cash equivalents and short-term investments as compared to \$43 million at June 30, 2006.

#### **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, Inc., will host a conference call to review and discuss the first quarter fiscal year 2007 financial results at 11:00 a.m. (EST) today, November 9, 2006. 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=109389">http://www.vcall.com/IC/CEPage.asp?ID=109389</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> for 60 days. Also, through November 19, 2006, 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: 215272.

#### About Aastrom Biosciences, Inc.

Aastrom Biosciences, Inc. (Nasdaq: ASTM) is developing autologous cell products for the repair or regeneration of multiple human tissues, based on its proprietary Tissue Repair Cell (TRC) technology. Aastrom's TRC-based products are a unique cell mixture containing stromal, stem and progenitor cell populations, produced outside the body from a small amount of bone marrow taken from the patient. TRC-based products have been used in over 230 patients, and are currently in clinical trials for bone regeneration (long bone fractures and spine fusion) and vascular regeneration (critical limb ischemia) applications. The Company has reported positive interim clinical trial results for TRCs suggesting both the clinical safety and the ability of TRCs to induce tissue regeneration in long bone fractures and jaw bone reconstruction. The Company's proprietary TRCs received an Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) for use in the treatment of osteonecrosis of the femoral head. In addition, Aastrom is developing plans for a TRC-based therapy for cardiac regeneration.

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, and potential product applications, which involve certain risks and uncertainties. The forward-looking statements are also identified through use of the words "may," "planned," "plans," 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 —
-more-

### AASTROM BIOSCIENCES, INC.

(Unaudited) (In thousands, except per share amounts)

### CONSOLIDATED STATEMENT OF OPERATIONS DATA:

	Quarter ended	Quarter ended September 30,	
	2005	2006	
REVENUES:			
Product sales	\$ 15	\$ 12	
Grants	165	92	
Total revenues	180	104	
COSTS AND EXPENSES:			
Cost of product sales	5	_	
Research and development	1,953	2,304	
Selling, general and administrative	2,016	2,384	
Total costs and expenses	3,974	4,688	
OTHER INCOME	306	527	
NET LOSS	<u>\$ (3,488)</u>	\$ (4,057)	
NET LOSS PER COMMON SHARE (Basic and Diluted)	<u>\$ (.03)</u>	<u>\$ (.03)</u>	
Weighted average number of common shares outstanding	102,483	119,177	
CONSOLIDATED BALANCE SHEET DATA:			
	June 30, 2006	September 30, 2006	
ASSETS			
Cash and cash equivalents	\$ 9,034	\$ 11,724	
Short-term investments	33,963	27,283	
Receivables, net	139	104	
Inventories	1	_	
Other current assets	528	819	
Property and equipment, net	1,216	1,223	
Total assets	<u>\$ 44,881</u>	\$ 41,153	
LIABILITIES AND SHAREHOLDERS' EQUITY			
Current liabilities	\$ 2,539	\$ 2,141	
Shareholders' equity	42,342	39,012	
Total liabilities and shareholders' equity	\$ 44,881	\$ 41,153	