#### **Table of Contents**

### 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): August 29, 2008

# **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

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

On August 29, 2008, we issued a press release announcing financial results and achievements for our fourth fiscal quarter and fiscal year ended June 30, 2008. 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.

99.1 Press Release dated August 29, 2008

Description

#### 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: August 29, 2008

#### AASTROM BIOSCIENCES, INC.

By: /s/ George W. Dunbar, Jr.

George W. Dunbar, Jr. Chief Executive Officer and President

2



CONTACTS: Kris M. Maly or Kimberli O'Meara Investor Relations Department Aastrom Biosciences, Inc. Phone: (734) 930-5777 Kevin McGrath Cameron & Associates (Investors) Phone: (212) 245-4577

Stephen Zoegall Berry & Company (Media) Phone: (212) 253-8881

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

Ann Arbor, Michigan, August 29, 2008 — Aastrom Biosciences, Inc. (Nasdaq: ASTM), a leading regenerative medicine company, today reported financial results for the fourth quarter and fiscal year ended June 30, 2008. The Company also reported clinical and operational achievements during the quarter, including:

- Encouraging clinical data from the first two patients treated with Aastrom's autologous stem cell therapy for dilated cardiomyopathy (DCM), a type of severe chronic heart failure. This milestone marked the first human application of the Company's Cardiac Repair Cell (CRC) product to regenerate damaged heart tissue in patients with severely impaired cardiac function.
- Authorization by U.S. Food and Drug Administration (FDA) to initiate a 40-patient U.S. Phase II IMPACT-DCM clinical trial to study the use of CRCs for the treatment of DCM. The randomized, controlled, prospective, open-label study will seek to enroll 20 patients with ischemic DCM and 20 patients with non-ischemic DCM at five clinical sites in the U.S.

"These two milestones represent a turning point for Aastrom," said George Dunbar, President and Chief Executive Officer of Aastrom. "The patients we have treated and intend to treat with our CRC product are critically ill and currently have no options other than a heart transplant. The clinical data we gathered from two compassionate use patients in Europe, along with FDA authorization to initiate our cardiac program in the U.S., strongly support our decision to make our cardiac program our top priority. In addition to advancing our cardiac program, we are continuing to move our vascular program forward with our ongoing RESTORE-CLI clinical trial for critical limb ischemia. We remain optimistic about both of these important clinical trials and look forward to providing updates as we achieve clinical milestones."

# Other significant clinical achievements involving our Tissue Repair Cell-based (TRC) products for tissue regeneration during fiscal year 2008 include:

- Encouraging results from two German research groups utilizing Aastrom's proprietary 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 Bone Repair Cells (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. Dr. Nöth reported all four patients tolerated the procedure well, had a reduction in hip pain with no signs of disease progression, as determined by MRI and X-ray, and were back to work within six months after treatment. In addition, no cell-related adverse events were reported and none of these patients have required hip replacement surgery.
- Positive final results from a U.S. Phase I/II clinical trial designed to collect safety and efficacy data utilizing BRCs in the treatment of severe nonunion 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:
  - o Healing in 30 of 33 patients (a 91% healing rate) 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
  - o 100% of the patients who have healed were fully weight-bearing, have regained range of motion and are no longer impaired by their injuries

#### Anticipated clinical milestones for the next 12 months and beyond include the following:

- Cardiac Regeneration:
  - o Initiate patient treatments in U.S. Phase II IMPACT-DCM trial (Sept. 2008)
  - o Complete patient enrollment in IMPACT-DCM trial (4Q2009)
  - o Approval to initiate cardiac clinical trial activity in the EU (2H2009)
- Vascular Regeneration:
  - o Complete enrollment of first 30 patients into U.S. Phase IIb RESTORE-CLI trial (4Q2008)
  - o Analyze RESTORE-CLI trial interim data 12 months after 30<sup>th</sup> patient treatment (2H2009)
- Neural Regeneration:
  - o Initiate spinal cord injury clinical activity

#### Fiscal Year 2008 Fourth Quarter and Year Ended June 30, 2008 Results

Total revenues for the quarter and twelve months ended June 30, 2008, consisting of minimal product sales, consisting of manufacturing supplies to academic collaborators in the U.S. and cell-based products to EU-based physicians, and grant funding, were \$149,000 and \$522,000, respectively, compared to \$165,000 and \$685,000 for the same periods in fiscal year 2007.

Total costs and expenses for the quarter and twelve months ended June 30, 2008 increased to \$5,142,000 and \$21,741,000, respectively, from \$5,388,000 and \$20,154,000 for the same periods in fiscal year 2007.

Research and development expenses for the quarter and twelve months ended June 30, 2008 were \$3,449,000 and \$15,249,000, respectively, compared to \$3,480,000 and \$11,443,000 for the same periods in fiscal year 2007. These changes reflect the continued expansion of our research and development activities to support regulatory submissions, on-going and planned tissue regeneration clinical trials in the U.S. and EU. In May 2008, we reprioritized our clinical development programs to focus primarily on cardiovascular applications including dilated cardiomyopathy and critical limb ischemia. We have discontinued further patient enrollment into our Phase III ON-CORE (osteonecrosis) bone regeneration trial. We do not anticipate initiating new clinical bone activity, reactivating the Phase III ON-CORE trial or initiating formal clinical trials in the neural area without additional financial resources. While the decision to reprioritize was driven by economic factors, the clinical programs were prioritized based on anticipated time to market and the relative clinical and market potential. Research and development expenses for the twelve months ended June 30, 2008 also include a non-cash charge of \$515,000 compared to \$702,000 for the same period in fiscal year 2007, relating to share-based compensation expense.

Selling, general and administrative expenses decreased for the quarter and twelve months ended June 30, 2008 to \$1,668,000 and \$6,436,000, respectively, from \$1,896,000 and \$8,682,000 for the same periods in fiscal year 2007. These decreases reflect lower salaries and benefits as a result of management and employee changes; decreases in relocation and recruitment expenses; reduced supplemental compensation relating to the 2007 management performance bonuses; and the elimination of the management performance bonus plan and the associated costs for 2008. Selling, general and administrative expenses for the twelve months ended June 30, 2008 included a non-cash charge of \$1,088,000 compared to \$2,104,000 for the same period in fiscal year 2007, relating to share-based compensation expense.

Interest income for the quarter and twelve months ended June 30, 2008 was \$153,000 and \$1,170,000, respectively, compared to \$394,000 and \$1,875,000 for the same periods 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.

Net loss for the quarter ended June 30, 2008 was \$4,863,000, or \$0.04 per share, compared to a net loss of \$4,829,000, or \$0.04 per share for the same period in fiscal year 2007. Net loss for the twelve months ended June 30, 2008, was \$20,133,000, or \$.16 per share, compared to \$17,594,000 or \$0.15 per share for the same period in fiscal year 2007. The increases in net losses are primarily the result of increased research and development expenses offset on a per share basis by an increase in the weighted average number of common shares outstanding.

At June 30, 2008, the Company had \$22.5 million in cash, cash equivalents and short-term investments as compared to \$28.3 million at June 30, 2007. The global economy and capital markets have been challenging for the small cap biotech sector for the past year. This situation makes the timing and potential for future equity financings uncertain. As a result, we have reduced costs and expenses in an attempt to achieve an estimated average cash utilization of approximately \$1.2 million per month for the fiscal year ending June 30, 2009, through a combination of development and clinical program reprioritizations and adjustments focusing on our cardiac regeneration program, along with reductions in overhead and staff.

### Aastrom Conference Call Information

George W. Dunbar, President, Chief Executive Officer and Chief Financial Officer, Elmar R. Burchardt, M.D., Ph.D., Vice President, Medical Affairs, and Julie Caudill, Controller of Aastrom Biosciences, Inc., will host a conference call to review and discuss the fourth quarter and fiscal year ended 2008 financial results at 11:00 a.m. (EDT) today, August 29, 2008. 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

<u>http://www.investorcalendar.com/IC/CEPage.asp?ID=133137</u>. 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 <u>http://www.investorcalendar.com/</u> for 60 days. Through September 12, 2008, 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: 293771.

#### 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. 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. Ongoing development activities are focused on applications of the technology to cardiac and vascular regeneration. The Company currently has a cardiovascular regeneration product in Phase II development for the treatment of dilated cardiomyopathy (DCM) (called the IMPACT-DCM trial) and critical limb ischemia (called the RESTORE-CLI trial).

#### For more information, visit Aastrom's website at www.aastrom.com. (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, adequacy of existing capital to support operations for a specified time, future capital needs, and potential advantages and application of Tissue Repair Cell (TRC) Technology, all of which involve certain risks and uncertainties. These statements are often, but are not always, made through the use of words or phrases such as "anticipates," "intends," "estimates," "plans," "expects," "we believe," "we intend," and similar words or phrases, or future or conditional verbs such as "will," "would," "should," "potential," "could," "may," or similar expressions. 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 —

# AASTROM BIOSCIENCES, INC. (in thousands, except per share amounts)

### CONSOLIDATED STATEMENT OF OPERATIONS DATA:

	Quarter end 2007	2008	Year ended June 30, 2007 2008	
REVENUES:	(Unau	dited)		
Total revenue	\$ 165	\$ 149	\$ 685	\$ 522
COSTS AND EXPENSES:				
Cost of product sales and rentals	12	25	29	56
Research and development	3,480	3,449	11,443	15,249
Selling, general and administrative	1,896	1,668	8,682	6,436
Total costs and expenses	5,388	5,142	20,154	21,741
OTHER INCOME	394	130	1,875	1,086
NET LOSS	\$ (4,829)	\$ (4,863)	\$ (17,594)	\$ (20,133)
NET LOSS PER SHARE				
(Basic and Diluted)	\$ (.04)	\$ (.04)	\$ (.15)	\$ (.16)
Weighted average number of common shares outstanding	119,766	132,761	119,523	129,120

## CONSOLIDATED BALANCE SHEET DATA:

	Jun	ne 30, 2008
ASSETS:		
Cash and cash equivalents	\$	16,492
Short-term investments		5,970
Receivables, net		18
Other current assets		1,583
Property, net		2,154
Total assets	\$	26,217
LIABILITIES AND SHAREHOLDERS' EQUITY:		
Current liabilities	\$	2,100
Long-term debt		783
Shareholders' equity		23,334
Total liabilities and shareholders' equity	\$	26,217

###