



---

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 10, 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:

- 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))
- 
-

## **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 September 10, 2007, we issued a press release announcing financial results and achievements for our fourth fiscal quarter and fiscal year ended June 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.**

| <u>Exhibit No.</u> | <u>Description</u>                     |
|--------------------|--|
| 99.1               | Press Release dated September 10, 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: September 10, 2007

**AASTROM BIOSCIENCES, INC.**

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

Gerald D. Brennan, Jr.

Vice President, Administrative &  
Financial Operations and CFO

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 FOURTH QUARTER AND  
FISCAL YEAR 2007 FINANCIAL RESULTS**

**Ann Arbor, Michigan, September 10, 2007** — Aastrom Biosciences, Inc. (Nasdaq: ASTM), a regenerative medicine company, today reported financial results for the fourth quarter and fiscal year ended June 30, 2007. The Company also reported clinical and operational achievements during the quarter, including:

- Completion of 12 month post-treatment patient follow-up in U.S. Phase I/II multi-center severe fracture clinical trial; final data is being analyzed and is expected to be presented by Dr. Matthew Jimenez at the Orthopaedic Trauma Association annual meeting on October 18, 2007 in Boston, MA
- Initiation of RESTORE-CLI trial (U.S. Phase IIb prospective, controlled, randomized, double-blind, multi-center clinical trial) to treat up to 120 patients suffering from the most severe form of peripheral arterial disease, critical limb ischemia (CLI); treatment of first patient announced in June 2007
- Receipt of U.S. Food & Drug Administration (FDA) approval of the Investigational New Drug (IND) application to initiate the ON-CORE trial (U.S. Phase III clinical trial) for the treatment of up to 120 patients with osteonecrosis of the femoral head; initiating clinical sites

“Receiving FDA approval to initiate our RESTORE-CLI and ON-CORE trials represents significant clinical milestones for Aastrom and for patients suffering from diseases and disorders that currently have limited treatment options,” said George Dunbar, President and Chief Executive Officer of Aastrom. “In addition to these two clinical trials, we are also preparing for clinical activities in the cardiac and spinal cord injury areas. Our multiple regenerative medicine therapeutic programs lay the foundation for future value creation, and we look forward to providing updates as we make clinical progress.”

**Other significant clinical achievements during fiscal year 2007 include the following:**

- Initiation of patient treatments in a pivotal clinical trial in Spain for osteonecrosis of the femoral head in Spain
- Receipt of Orphan Drug Designation from U.S. FDA for the treatment of dilated cardiomyopathy (DCM), a severe chronic cardiac disease
- Positive interim data reported from U.S. long bone non-union fracture trial at the annual meeting of the American Academy of Orthopaedic Surgeons; as of February 2007, multiple bone bridges, which are evidence of healing, were observed in 90% of patients who had completed the 12 months follow-up
- Completion of patient enrollment in the EU Phase I/II long bone fracture clinical trial

-more-

---

**Anticipated clinical milestones for fiscal year 2008 and beyond include the following:**

- Bone Regeneration — Bone Repair Cells (BRCs):
  - Report final U.S. Phase I/II long bone fracture clinical trial results (expected 10/18/07)
  - Report early EU compassionate use osteonecrosis patient data (expected 10/4/07)
- Vascular Regeneration — Vascular Repairs Cells (VRCs):
  - Report interim data from CLI patients treated in the EU clinical trial (expected 10/4/07)
  - Analyze RESTORE-CLI trial interim data — 12 months after 30<sup>th</sup> patient treatment
- Cardiac Regeneration — Cardiac Repair Cells (CRCs):
  - Initiate EU cardiac clinical activity
  - Analyze interim EU cardiac data — 6 months after patient treatments
  - Submit U.S. IND for cardiac clinical trial
- Neural Regeneration — Neural Repair Cells (NRCs):
  - Initiate EU spinal cord injury clinical activity

“As outlined above, Aastrom is focused on developing personalized stem cell therapies to address unmet medical needs,” continued Mr. Dunbar. “This means developing therapies that repair or restore damaged tissues rather than just treating symptoms with continuous care. We are excited to be a leader in the field of regenerative medicine, shaping the future for physicians and their patients.”

**Fiscal Year 2007 Fourth Quarter and Year Ended June 30, 2007 Results**

Total revenues for the quarter ended June 30, 2007, consisting of product sales and grant funding, were \$165,000 compared to \$328,000 for the same period in fiscal year 2006. Total revenues for the twelve months ended June 30, 2007 were \$685,000 compared to \$863,000 for the same period in fiscal year 2006.

Total costs and expenses for the quarter and twelve months ended June 30, 2007 increased to \$5,388,000 and \$20,154,000, respectively, from \$5,129,000 and \$18,596,000 for the same periods in fiscal year 2006.

As a result of the continued expansion of research and development activities to support regulatory submissions, on-going and planned tissue regeneration clinical trials in the U.S. and EU, and the development of facilities for product manufacturing and distribution processes, research and development expenses for the quarter and twelve months ended June 30, 2007 increased to \$3,480,000 and \$11,443,000, respectively, from \$2,739,000 and \$9,484,000 for the same periods in fiscal year 2006. Research and development expenses for the quarter and twelve months ended June 30, 2007 also include a non-cash charge of \$210,000 and \$702,000, respectively, compared to \$12,000 and \$300,000 for the same periods in fiscal year 2006, relating to share-based compensation expense.

-more-

---

Selling, general and administrative expenses decreased for the quarter and twelve months ended June 30, 2007 to \$1,896,000 and \$8,682,000, respectively, from \$2,390,000 and \$9,101,000 for the same periods in fiscal year 2006. These decreases reflect lower salaries and benefits as a result of management and employee changes and decreases in relocation and recruitment expenses. Selling, general and administrative expenses for the quarter and twelve months ended June 30, 2007 included a non-cash charge of \$448,000 and \$2,104,000, respectively, compared to \$231,000 and \$734,000 for the same periods in fiscal year 2006, relating to share-based compensation expense.

Interest income for the quarter and twelve months ended June 30, 2007 was \$394,000 and \$1,875,000, respectively, compared to \$505,000 and \$1,258,000 for the same periods 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 to improved yields from investments.

Net loss for the quarter ended June 30, 2007 was \$4,829,000, or \$.04 per share, compared to a net loss of \$4,296,000, or \$.04 per share for the same period in fiscal year 2006. Net loss for the twelve months ended June 30, 2007, was \$17,594,000, or \$.15 per share, compared to \$16,475,000 or \$.15 per share for the same period in fiscal year 2006. 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, 2007, the Company had \$28.3 million in cash, cash equivalents and short-term investments as compared to \$43.0 million at June 30, 2006. As clinical activities expand, it is expected that the Company's monthly average cash burn will increase to \$1.7 million 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, Inc., will host a conference call to review and discuss the fourth quarter and fiscal year ended 2007 financial results at 4:30 p.m. (EDT) today, September 10, 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 <http://www.vcall.com/IC/CEPage.asp?ID=119955>. 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 <http://www.investorcalendar.com/> for 60 days. Through September 21, 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: 252325.

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

Aastrom is a regenerative medicine company developing autologous cell products for the repair or regeneration of bone, vascular, cardiac and neural tissues, based on its proprietary Tissue Repair Cell (TRC) Technology. Aastrom's TRC-based products contain a unique cell mixture of stem and early progenitor cells, produced from a small amount of bone marrow collected from the patient. TRC-based products have been used in over 250 patients to date and are being clinically evaluated for bone regeneration to treat osteonecrosis of the femoral head (U.S.: ON-CORE Phase III trial and Spain: pivotal trial), and vascular regeneration in patients with critical

-more-

---



limb ischemia (U.S.: RESTORE-CLI Phase IIb trial and Germany: Phase I/II trial). Aastrom has recently completed a U.S. Phase I/II severe non-union fracture clinical trial, and is also developing programs to address cardiac and neural regeneration indications. TRC-based products have received Orphan Drug Designation from the FDA for use in the treatment of osteonecrosis of the femoral head and the treatment of dilated cardiomyopathy, a severe chronic heart disease.

For more information, visit Aastrom's website at [www.aastrom.com](http://www.aastrom.com). (astmf)

***This document contains forward-looking statements, including without limitation, statements concerning planned clinical trials and activities and anticipated timing of clinical events, product development objectives, and potential product applications, which involve certain risks and uncertainties. The forward-looking statements are also identified through use of the words "expected," "anticipated," "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 potential patient accrual difficulties, clinical trial results, potential product development difficulties, the effects of competitive therapies, regulatory approval requirements, the availability of financial and other 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:**

|  | <u>Quarter ended June 30,</u> |                   | <u>Year ended June 30,</u> |                    |
|--|-------------------------------|-------------------|----------------------------|--------------------|
|  | <u>2006</u>                   | <u>2007</u>       | <u>2006</u>                | <u>2007</u>        |
|  | <i>(Unaudited)</i>            |                   |                            |                    |
| <b>REVENUES:</b>                                     |                               |                   |                            |                    |
| Total revenue  | \$ 328                        | \$ 165            | \$ 863                     | \$ 685             |
| <b>COSTS AND EXPENSES:</b>                           |                               |                   |                            |                    |
| Cost of product sales and rentals                    | —                             | 12                | 11                         | 29                 |
| Research and development                             | 2,739                         | 3,480             | 9,484                      | 11,443             |
| Selling, general and administrative                  | 2,390                         | 1,896             | 9,101                      | 8,682              |
| Total costs and expenses                             | 5,129                         | 5,388             | 18,596                     | 20,154             |
| <b>OTHER INCOME</b>                                  | <u>505</u>                    | <u>394</u>        | <u>1,258</u>               | <u>1,875</u>       |
| <b>NET LOSS</b>                                      | <u>\$ (4,296)</u>             | <u>\$ (4,829)</u> | <u>\$ (16,475)</u>         | <u>\$ (17,594)</u> |
| <b>NET LOSS PER SHARE</b>                            |                               |                   |                            |                    |
| (Basic and Diluted)                                  | <u>\$ (.04)</u>               | <u>\$ (.04)</u>   | <u>\$ (.15)</u>            | <u>\$ (.15)</u>    |
| Weighted average number of common shares outstanding | <u>117,104</u>                | <u>119,766</u>    | <u>106,314</u>             | <u>119,523</u>     |

**CONSOLIDATED BALANCE SHEET DATA:**

|  | <u>June 30, 2007</u> |
|--|----------------------|
| <b>ASSETS:</b>                               |                      |
| Cash and cash equivalents                    | \$ 13,439            |
| Short-term investments                       | 14,886               |
| Receivables, net                             | 78                   |
| Inventories                                  | 8                    |
| Other current assets                         | 1,766                |
| Property, net                                | 2,671                |
| Total assets                                 | <u>\$ 32,848</u>     |
| <b>LIABILITIES AND SHAREHOLDERS' EQUITY:</b> |                      |
| Current liabilities                          | \$ 3,500             |
| Long-term debt                               | 1,097                |
| Shareholders' equity                         | 28,251               |
| Total liabilities and shareholders' equity   | <u>\$ 32,848</u>     |

###