

# AASTROM BIOSCIENCES INC

## FORM 8-K

(Current report filing)

Filed 05/10/10 for the Period Ending 05/10/10

Address	24 FRANKL LLOYD WRIGHT DR PO BOX 376 ANN ARBOR, MI 48106
Telephone	7349305555
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Symbol	ASTM
SIC Code	2836 - Biological Products, Except Diagnostic Substances
Industry	Biotechnology & Drugs
Sector	Healthcare
Fiscal Year	06/30

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

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**FORM 8-K**

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**CURRENT REPORT**

**Pursuant to Section 13 OR 15(d) of  
The Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported) **May 10, 2010**

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**Aastrom Biosciences, Inc.**

(Exact name of registrant as specified in its charter)

**Michigan**  
(State or other jurisdiction  
of incorporation)

**0-22025**  
(Commission File Number)

**943096597**  
(IRS Employer Identification No.)

**24 Frank Lloyd Wright Drive  
P.O. Box 376  
Ann Arbor, Michigan**  
(Address of principal executive offices)

**48106**  
(Zip Code)

Registrant's telephone number, including area code: **(734) 930-5555**

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(Former name or former address, if changed since last report)

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 May 10, 2010 the Registrant issued a press release, a copy of which is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

**Item 9.01. Financial Statements and Exhibits.**

Exhibit 99.1. Press release dated May 10, 2010

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**SIGNATURE**

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**Aastrom Biosciences, Inc.**

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(Registrant)

*/s/* **TIMOTHY M. MAYLEBEN**

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Timothy M. Mayleben  
*Chief Executive Officer and President*

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**May 10, 2010**

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(Date)

**Exhibit Index**

99.1 Press release dated May 10, 2010

## Aastrom Reports Third Quarter Fiscal Year 2010 Financial Results

ANN ARBOR, Mich., May 10, 2010 (GLOBE NEWSWIRE) -- Aastrom Biosciences, Inc. (Nasdaq:ASTM), the leading developer of autologous cellular therapies for the treatment of severe cardiovascular diseases, today reported financial results for its third fiscal quarter ended March 31, 2010, and also announced progress in its late-stage clinical development programs and corporate operations.

### Third quarter fiscal year 2010 financial results

Total revenues for the quarter and nine months ended March 31, 2010, consisting of product sales, were \$0 and \$89,000, respectively, compared to \$58,000 and \$113,000 for the same periods in fiscal year 2009. The fluctuations in product sales is due to the changes in volume of cell production sales for investigator-sponsored clinical trials in Spain and limited cell manufacturing supplies to a research institute in the U.S.

Total costs and expenses for the quarter and nine months ended March 31, 2010, were \$4,263,000 and \$12,753,000, respectively, compared to \$4,070,000 and \$12,296,000 for the same periods in fiscal year 2009.

Research and development expenses were \$2,845,000 and \$9,039,000, respectively, for the quarter and nine months ended March 31, 2010, compared to \$2,785,000 and \$8,340,000 for the same periods in fiscal year 2009. These increases reflect continued expansion of clinical development activities including the costs associated with recruitment and treatment of the final patients in the IMPACT-DCM Phase 2 clinical trial. Research and development expenses for the nine months ended March 31, 2010, also included a non-cash charge of \$335,000, compared to \$435,000 for the same period in fiscal year 2009, relating to share-based compensation expense.

General and administrative expenses were \$1,418,000 for the quarter ended March 31, 2010, and \$3,680,000 for the nine months ended March 31, 2010, respectively, compared to \$1,260,000 and \$3,909,000 for the same periods in fiscal year 2009. The increase in the quarterly expense is primarily the result of increased legal fees and contract services. For the quarter and nine months ended March 31, 2010, general and administrative expenses included a non-cash charge of \$100,000 and \$90,000, respectively, compared to \$273,000 and \$694,000 for the same periods in fiscal year 2009, relating to share-based compensation expense.

Interest income for the quarter and nine months ended March 31, 2010, was \$34,000 and \$83,000, respectively, compared to \$57,000 and \$253,000 for the same periods in fiscal year 2009. 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 lower interest rates.

Interest expense was \$9,000 and \$33,000, respectively, for the quarter and nine months ended March 31, 2010, compared to \$17,000 and \$58,000, respectively, for the same periods in fiscal year 2009.

Net loss for the quarter ended March 31, 2010, was \$4,238,000 or \$.16 per share, compared to a net loss of \$3,972,000 or \$.24 per share, for the same period in fiscal year 2009. Net loss for the nine months ended March 31, 2010, was \$12,614,000 or \$.55 per share, compared to \$11,988,000 or \$.72 per share, for the same period in fiscal year 2009.

At March 31, 2010, the company had \$22.8 million in cash and cash equivalents and short-term investments compared to \$17 million at June 30, 2009. Cash utilization averaged approximately \$1.3 million per month for the nine months ended March 31, 2010. It is expected that cash utilization will average approximately \$1.4 million per month for the remainder of fiscal year ending June 30, 2010.

### Recent Aastrom developments

Aastrom's U.S. Phase 2 IMPACT-DCM clinical trial (surgical delivery for treatment of dilated cardiomyopathy or DCM) is fully enrolled with 40 patients at five sites across the U.S. The company plans to report 6-month interim data on all patients in the trial during the fourth quarter of calendar year 2010.

Aastrom's second cardiac trial, also a U.S. Phase 2, has been designed to explore a catheter-based delivery of tissue repair cells (TRCs) to treat DCM patients. This trial is currently enrolling patients at two sites and patient treatment is expected to begin in May 2010.

Aastrom's U.S. Phase 2b RESTORE-CLI clinical trial is fully enrolled as of March 2010 with 86 patients at 18 sites across the U.S. This trial is evaluating the use of TRCs in the treatment of patients suffering from critical limb ischemia (CLI), the most severe form of peripheral arterial disease (PAD). In February 2010 a planned interim analysis was performed for this study on 46 patients having completed at least 6 months of the study. According to the interim analysis, the safety profile was similar between the treatment and placebo patients. Based on a composite efficacy endpoint assessing time to treatment failure (including major amputations, doubling of wound size and new gangrene), Aastrom's autologous TRCs were more effective than placebo ( $p=0.0090$ ). Based on the interim findings, we concluded enrollment of new patients in order to complete the study as soon as possible, and to begin planning and discussions with the FDA for a Phase 3 clinical program.

The interim results will be presented by Richard J. Powell, M.D., section chief of vascular surgery at the Dartmouth-Hitchcock Medical Center

in Lebanon, NH and a principal investigator of the study, at the Vascular Annual Meeting® of the Society for Vascular Surgery on June 11, 2010. The company plans to report 6-month interim data on all patients in the trial during the fourth quarter of calendar year 2010.

"In the third quarter of fiscal year 2010, we made outstanding progress in our cardiovascular clinical development programs and we are focused on planned data analyses and presentation of these additional data later this year," said Tim Mayleben, president and CEO of Aastrom. "We look forward to reporting on these milestones throughout 2010."

### NASDAQ capital market listing

On February 18, 2010 the company announced that it had regained compliance with the \$1.00 minimum bid price requirement for continued listing under NASDAQ Listing Rule 5550(a)(2). Accordingly, the company is currently in full compliance with all listing requirements of the NASDAQ Capital Market. On February 18, 2010 the company effected a one-for-eight reverse stock split to increase the per-share trading price of Aastrom's common stock to meet the NASDAQ requirement and to attract greater institutional ownership of the company's shares.

### About Aastrom Biosciences

Aastrom Biosciences is developing autologous cellular therapies for use in the treatment of severe cardiovascular diseases. The company's proprietary cell-processing technology enables the production of cellular therapies using a patient's own bone marrow that can be delivered directly to damaged tissues. Aastrom has advanced this technology into late-stage clinical development and is conducting two Phase 2 clinical trials to treat dilated cardiomyopathy and a Phase 2b clinical trial to treat critical limb ischemia. For more information, please visit Aastrom's website at [www.aastrom.com](http://www.aastrom.com).

The Aastrom Biosciences, Inc. logo is available at <http://www.globenewswire.com/newsroom/prs/?pkgid=3663>

*This document contains forward-looking statements, including without limitation, statements concerning clinical trial plans and expectations, industry presentations on trial results, clinical activity timing and patient enrollment, intended product development and commercialization objectives, disease treatment and progression and expected timing of collecting and analyzing treatment data, 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, Quarterly Reports on Form 10-Q and other filings with the Securities and Exchange Commission. These forward looking statements reflect management's current views and Aastrom does not undertake to update any of these forward-looking statements to reflect a change in its views or events or circumstances that occur after the date of this release except as required by law.*

### AASTROM BIOSCIENCES, INC.

(Unaudited)

(In thousands, except per share amounts)

### CONSOLIDATED STATEMENTS OF OPERATIONS DATA:

	Quarter ended March 31,		Nine months ended March 31,	
	2009	2010	2009	2010
REVENUES:				
Total revenues	\$58	\$--	\$113	\$89
COSTS AND EXPENSES:				
Cost of product sales	25	--	47	34
Research and development	2,785	2,845	8,340	9,039
General and administrative	1,260	1,418	3,909	3,680
Total costs and expenses	4,070	4,263	12,296	12,753
OTHER INCOME (EXPENSE):				
Interest income	57	34	253	83

Interest expense	<u>(17)</u>	<u>(9)</u>	<u>(58)</u>	<u>(33)</u>
Total other income	<u>40</u>	<u>25</u>	<u>195</u>	<u>50</u>
<b>NET LOSS</b>	<b><u>\$(3,972)</u></b>	<b><u>\$(4,238)</u></b>	<b><u>\$(11,988)</u></b>	<b><u>\$(12,614)</u></b>
<b>NET LOSS PER COMMON SHARE</b>				
(Basic and Diluted)	<u>\$(.24)</u>	<u>\$(.16)</u>	<u>\$(.72)</u>	<u>\$(.55)</u>
Weighted average number of common shares				
outstanding	<u>16,821</u>	<u>26,737</u>	<u>16,711</u>	<u>23,016</u>

**CONSOLIDATED BALANCE SHEET DATA:**

	June 30, March 31,	
	<u>2009</u>	<u>2010</u>
<b>ASSETS</b>		
Cash and cash equivalents	\$17,000	\$17,844
Short-term investments	--	5,000
Receivables, net	58	--
Inventory	1	--
Other current assets	732	591
Property, net	<u>1,485</u>	<u>1,134</u>
<b>Total assets</b>	<b><u>\$19,276</u></b>	<b><u>\$24,569</u></b>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities	\$1,687	\$1,810
Long-term debt	305	137
Shareholders' equity	<u>17,284</u>	<u>22,622</u>
<b>Total liabilities and shareholders' equity</b>	<b><u>\$19,276</u></b>	<b><u>\$24,569</u></b>

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