Aastrom

Aastrom Biosciences Reports First Quarter Fiscal Year 2010 Financial Results

Focus on Cardiovascular Regeneration Sets Foundation for Continued Clinical Progress

ANN ARBOR, Mich., Nov. 6, 2009 (GLOBE NEWSWIRE) -- Aastrom Biosciences, Inc. (Nasdaq:ASTM), a leading developer of autologous cell products for the treatment of chronic cardiovascular diseases, today reported financial results and operational updates for the first fiscal quarter ended September 30, 2009. Aastrom continues to operate in a capital-efficient manner while advancing its cardiovascular clinical programs.

Operational highlights since the beginning of the quarter include:

-- U.S. cardiac regeneration program:

- U.S. Phase II IMPACT-DCM clinical trial (surgical delivery)
  - To date, this clinical trial has enrolled 29 patients at five sites across the U.S. The IMPACT-DCM trial is the first trial to evaluate the surgical delivery of Cardiac Repair Cells (CRCs) directly into the human heart muscle for the treatment of congestive heart failure associated with dilated cardiomyopathy (DCM) in both ischemic and non-ischemic patients.
- Anticipated U.S. Phase II clinical trial for DCM patients (catheter delivery)
  - Expansion of clinical program to evaluate CRCs in the treatment of severe heart failure patients associated with DCM in both ischemic and non-ischemic patients is underway.
  - Investigational New Drug (IND) application has been submitted to the U.S. Food and Drug Administration (FDA) to initiate second clinical trial to treat DCM patients. This trial is designed to explore a catheter-based approach for the delivery of CRCs to treat DCM patients, in addition to the ongoing surgical delivery approach in the IMPACT-DCM trial.

-- U.S. vascular regeneration program:

- U.S. Phase IIb RESTORE-CLI clinical trial
  - To date, this clinical trial has enrolled 76 patients at 18 sites across the U.S. The RESTORE-CLI trial is evaluating Vascular Repair Cells (VRCs) in the treatment of patients suffering from the most severe form of peripheral arterial disease (PAD), a condition known as critical limb ischemia (CLI).
  - As planned, the first 30 patients in the RESTORE-CLI trial completed their 12-month follow-up visits.

-- Board of Directors and Executive Management strengthened:

- Harold C. Urschel, Jr., M.D. was elected to the Board of

Directors on October 14, 2009. Dr. Urschel is currently Chair of Cardiovascular & Thoracic Surgical Research, Education & Clinical Excellence at Baylor University Medical Center in Dallas, Texas. He is also a Professor of Cardiovascular & Thoracic Surgery at the University of Texas, Southwestern Medical School and has been a Visiting Professor at a number of medical centers in the U.S. and abroad, and is an honorary member of the Thoracic Surgery faculty of the University of Toronto and the Harvard Medical School. Dr. Urschel has been President of several major medical and surgical societies, including the Society of Thoracic Surgeons, American College of Chest Physicians, International Academy of Chest Physicians, Southern Thoracic Surgical Association, and the Texas Surgical Society. In addition, Dr. Urschel served on the Board of Directors of Electronic Data Systems from inception until it was acquired by General Motors.

- George W. Dunbar, currently Chief Executive Officer (CEO), President, Chief Financial Officer (CFO) and a Director of Aastrom, will transition out of day-to-day management and is expected to assume the role of Chairman of the Board immediately after the Annual Meeting of Shareholders on December 14, 2009.

- Timothy M. Mayleben, a member of Aastrom's Board of Directors will remain a Director and become the new CEO, President and CFO in December 2009. Mr. Mayleben is a seasoned life sciences industry professional with extensive senior management leadership experience.

-- NASDAQ Capital Market Listing:

- On October 2, 2009, received a Staff Determination letter from the NASDAQ Stock Market (NASDAQ) indicating that Aastrom had not regained compliance with the $1.00 minimum closing bid price requirement for continued listing set forth in NASDAQ Listing Rule 5550(a)(2).

- Requested an oral hearing, which stays the delisting of Aastrom's securities through the hearing process. NASDAQ has scheduled the hearing for November 12, 2009.

- At the hearing, intend to request continued listing on the NASDAQ Capital Market based upon Aastrom's plan for regaining compliance with the minimum bid price requirement. The Panel has the authority, if it deems appropriate, to grant Aastrom up to an additional 180 days from the date of the Staff Determination letter of October 2, 2009, or until March 31, 2010, to implement the plan of compliance. The plan will include a discussion of the events that the Company believes will enable it to regain compliance in this time frame, along with a commitment to effect a reverse stock split, if necessary.

"We continue to make considerable clinical progress as a leader in the development of autologous cell products for patients suffering from chronic cardiovascular diseases. Our CRCs and VRCs have provided early benefits to critically ill patients, and enrollment into our cardiac and vascular clinical trials remains on track. We continue to expand our clinical programs while maintaining our focus on cardiovascular diseases as evidenced by the addition of a second cardiac regeneration trial to explore a catheter-based approach for the delivery of CRCs to treat DCM patients," said George Dunbar, President and Chief Executive Officer of Aastrom. "We look forward to sharing the results from these clinical trials in the months ahead."

Anticipated clinical milestones for the next 12 months include the following:

-- U.S. cardiac regeneration program:

- IMPACT-DCM clinical trial's National Lead Investigator, Amit N. Patel, MD, will present interim data from the Phase II trial as keynote speaker at the American Heart Association Scientific Sessions in November 2009.

- Initiation of clinical site training for the cardiac catheter trial anticipated during December 2009.

- All 40 patients expected to be enrolled in the IMPACT-DCM trial by the end of December 2009.

- Report of interim data from the IMPACT-DCM clinical trial expected during the first quarter of calendar year 2010.

- Report of preliminary 6-month interim data expected once all 40 IMPACT-DCM patients have completed their 6-month follow-up visits.

-- U.S. vascular regeneration program:

- Unblinding and analysis of interim data from a subset of RESTORE-CLI patients expected to occur during the fourth quarter of calendar year 2009.

- Report of interim clinical data from subset of RESTORE-CLI patients expected during the first quarter of calendar year 2010.

First Fiscal Quarter Ended September 30, 2009 Results

Total revenues for the quarter ended September 30, 2009, consisting of product sales, were $73,000 compared to total revenues of $27,000 for the same period in fiscal year 2009.

Total costs and expenses decreased to $3,889,000 for the quarter ended September 30, 2009, from $4,046,000 for the same period in fiscal year 2009.

Research and development expenses increased to $2,911,000 for the quarter ended September 30, 2009 from $2,726,000 for the same period in fiscal year 2009. This increase reflects continued expansion of clinical development activities including the costs associated with recruitment and treatment of patients in the IMPACT-DCM clinical trial. Research and development expenses for the quarters ended September 30, 2009 and 2008 also include a non-cash charge of $186,000 and $162,000, respectively, relating to share-based compensation expense.

Selling, general and administrative expenses decreased to $946,000 for the quarter ended September 30, 2009 from $1,316,000 for the same period in fiscal year 2009. This decrease is primarily due to an offset to the stock compensation expense for the quarter ended September 30, 2009 for a reversal of $279,000 of previously-recognized expense for certain options held by George W. Dunbar that will be forfeited when he steps down on December 14, 2009. This expense was reversed in the quarter ended September 30, 2009 as these options are no longer expected to vest. Selling, general and administrative expenses for the quarters ended September 30, 2009 and 2008 also include a non-cash charge of $140,000 and $201,000, respectively, relating to share-based compensation expense.

Interest income was $28,000 for the quarter ended September 30, 2009 compared to $127,000 for the same period in fiscal year 2009. The fluctuations in interest income are due primarily to corresponding changes in the level of cash and cash equivalents during the periods.

Interest expense was $13,000 for the quarter ended September 30, 2009 compared to $21,000 for the same period in fiscal year 2009.

Net loss for the quarter ended September 30, 2009 was $3,801,000, or $0.02 per common share compared to $3,913,000, or

$0.03 per common share for the same period in fiscal year 2009. The changes in net loss is primarily the result of fluctuations in spending of research and development expenses, and in part on a per share basis by an increase in the weighted average number of common shares outstanding.

At September 30, 2009, Aastrom had $17.4 million in cash and cash equivalents compared to $17 million at June 30, 2009. It is expected that cash utilization will average approximately $1.4 million per month during fiscal year 2010.

About Aastrom Biosciences, Inc.

Aastrom is a leader in regenerative medicine developing autologous cell products for the treatment of chronic cardiovascular diseases. The Company's proprietary Tissue Repair Cell (TRC) technology expands the numbers of stem and early progenitor cells from a small amount of bone marrow collected from the patient. Bone marrow provides a rich source of diverse cell populations, is easily accessible and allows Aastrom to produce a personalized treatment for site-specific delivery to the patient's diseased tissues. Aastrom has treated more than 350 patients in various clinical trials over 10 years without any product safety issues. The Company is currently conducting a Phase II cardiac regeneration clinical trial (the IMPACT-DCM trial) in patients with dilated cardiomyopathy (DCM - severe chronic heart failure) and a Phase IIb vascular regeneration clinical trial (the RESTORE-CLI trial) in patients with critical limb ischemia (CLI - the most severe form of peripheral arterial disease).

For more information, visit Aastrom's website at 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, 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.

AASTROM BIOSCIENCES, INC.

(Unaudited)

(In thousands, except per share amounts)

CONSOLIDATED STATEMENT OF OPERATIONS DATA:

	Quarter ended September 30,	
	2008	**2009**
REVENUES:		
Product sales	$ 27	$ 73
Total revenues	27	73
COSTS AND EXPENSES:		
Cost of product sales	4	32
Research and development	2,726	2,911
Selling, general and administrative	1,316	946
Total costs and expenses	4,046	3,889
OTHER INCOME (EXPENSE):		
Interest income	127	28
Interest expense	(21)	(13)
Total other income, net	106	15

NET LOSS	$ (3,913)	$ (3,801)
NET LOSS PER COMMON SHARE		
(Basic and Diluted)	$ (.03)	$ (.02)
Weighted average number of common shares outstanding	132,796	165,433

CONSOLIDATED BALANCE SHEET DATA:

	June 30, 2009	September 30, 2009
ASSETS		
Cash and cash equivalents	$ 17,000	$ 17,357
Receivables, net	58	519
Inventory	1	--
Other current assets	732	902
Property and equipment, net	1,485	1,388
Total assets	$ 19,276	$ 20,166
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities	$ 1,687	$ 2,087
Long-term debt	305	249
Shareholders' equity	17,284	17,830
Total liabilities and shareholders' equity	$ 19,276	$ 20,166

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