Aastrom

Aastrom Biosciences Reports Fourth Quarter and Fiscal Year 2009 Financial Results

Adult Stem Cell Patient Treatments Progress in U.S. Phase II Cardiac and Vascular Regeneration Clinical Trials; Patient Enrollment On Track With Guidance

ANN ARBOR, Mich., Sept. 14, 2009 (GLOBE NEWSWIRE) -- Aastrom Biosciences, Inc. (Nasdaq:ASTM), a leading regenerative medicine company, today reported financial results for the fourth quarter and fiscal year ended June 30, 2009. The Company also reported clinical and operational achievements since the beginning of the quarter, including:

* U.S. Phase II cardiac regeneration clinical trial:

  -- On May 5, 2009 we reported that preliminary findings from our U.S. Phase II IMPACT-DCM clinical trial to treat dilated cardiomyopathy (DCM) with our Cardiac Repair Cells (CRCs) were presented at the International Society for Cellular Therapy annual meeting by the study's National Lead Investigator, Dr. Amit N. Patel. IMPACT-DCM is the first clinical trial in the U.S. to evaluate the surgical delivery of autologous cells directly into the human heart muscle for the treatment of congestive heart failure associated with DCM in both ischemic and non-ischemic patients.

    * Three treatment group patients have completed the 3-month follow-up visit; all of these patients improved from New York Heart Association (NYHA) class III to class II. This represents clinically meaningful improvement in these patients. In contrast, the NYHA class did not improve in 2 of 3 control group patients.

    * Overall quality of life scores improved in all treatment group patients based on the Minnesota Living with Heart Failure Questionnaire. Physical and emotional well-being of all treatment patients also improved based on patient responses to this questionnaire. There were no consistent trends in the control group patients.

    * No CRC-related serious adverse events were reported in any of the 4 treatment group patients who have completed at least their 1-month follow-up visit.

  -- To date, the trial has enrolled 21 patients at the following sites:

    * Methodist DeBakey Heart & Vascular Center in Houston, TX
    * Baylor University Medical Center in Dallas, TX
    * University of Utah School of Medicine in Salt Lake City, UT
    * Cleveland Clinic Heart and Vascular Institute in Cleveland, OH, and
    * Emory University Hospital Midtown in Atlanta, GA

  -- The 40-patient, randomized, controlled, prospective, open-label, multi-center clinical trial seeks to enroll 20 patients with ischemic DCM and 20 patients with non-ischemic DCM.

* U.S. Phase IIb vascular regeneration clinical trial:

  -- To date, our U.S. Phase IIb RESTORE-CLI clinical trial has enrolled 73 patients (treatment and placebo control). This clinical 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).

  -- The 150-patient, prospective, controlled, randomized, double-blind, multi-center clinical trial seeks to enroll patients suffering from CLI, the end stage of peripheral arterial disease.

* Compassionate-Use Bone Repair Cell (BRC) treatments in Spain:

  -- In an oral presentation in Dalian, China on August 10, 2009, Dr. Jose Mendonca, Director of the Head and Neck Surgery Unit of Hospital POLUSA in Lugo, Spain and previously a Clinical and Research Fellow in Oral and Maxillofacial Surgery at the UCLA School of Dentistry, reviewed the results of treatment with BRCs in three compassionate-use patients with craniofacial defects, as follows:

    * These patients each presented with different craniofacial defects; all of the patients demonstrated formation of new bone 12 months post-BRC treatment.

    * All patients underwent a minor surgery to insert a dental implant into the newly regenerated jaw bone. Eight weeks later, the dental prosthesis (teeth) was attached to the implant completing the treatment objectives with the restoration of oral function.

* NASDAQ compliance period extended:

  -- On July 13, 2009, the Listings Qualifications Department of the NASDAQ Stock Market LLC (NASDAQ) notified us that it was extending the suspension related to enforcing the rules requiring a minimum $1.00 per share closing bid price and a minimum market value of publicly held shares until July 31, 2009.

  -- As a result of NASDAQ further extending the suspension and the balance of 60 days remaining on our pending compliance period at the time of the initial suspension, we now have until October 1, 2009 to regain compliance with the $1.00 minimum closing bid price rule in order to remain listed on the NASDAQ Capital Market.

  -- If we do not regain compliance during the remainder of our compliance period, NASDAQ will provide written notice that our securities will be delisted from the NASDAQ Capital Market. At such time, we intend to appeal the determination to a NASDAQ Listing Qualifications Panel by requesting an oral hearing. A request for a hearing allows us to remain listed on the NASDAQ Capital Market pending the decision of the NASDAQ Hearing Panel.

  -- Our objective is to preserve our NASDAQ listing. The plan to regain compliance with the minimum $1.00 per share closing bid price will be presented to a NASDAQ Hearing Panel as part of this process.

* Fusion Capital common stock purchase programs:

- -- On June 12, 2009, we executed a new $30 million common stock purchase program with Fusion Capital Fund II, LLC (Fusion Capital). We have the right, over a 25-month period, to sell up to 36 million shares of our common stock to Fusion Capital from time to time in amounts between $100,000 and $4 million, up to an aggregate of $30 million, when we choose to do so, based on the terms of the agreement. This financing program commenced on July 1, 2009; through September 9, 2009 we have issued 10,328,479 shares to Fusion Capital (including 1,714,448 commitment shares) for net proceeds of $3.3 million.

- -- On April 29, 2009, we completed a previous common stock purchase program with Fusion Capital. Over the duration of this program, we issued 25,742,816 shares to Fusion Capital (including 3,050,152 commitment shares) for net proceeds of $8.6 million.

* Executive management transition process:

- -- On September 3, 2009, we announced an executive management process that will strengthen and expand the senior leadership team over the next several months

  * George W. Dunbar, currently Chief Executive Officer, President, Chief Financial Officer 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 Company's Annual Meeting of Shareholders, currently planned for December 14, 2009. In this role he will continue to advise the Company on key financial and strategic development initiatives.

  * Timothy M. Mayleben, a member of the Company's Board of Directors, will remain a Director and will become the new Chief Executive Officer, President and CFO at the time Mr. Dunbar steps down from those positions in December 2009.

  * Nelson M. Sims, who has served as Chairman of the Board of Directors since October 2008, is expected to assume the role of Lead Director.

  * Messrs. Dunbar, Mayleben and Sims intend to work together during the transition process to provide continuity and assure a smooth transition of responsibilities.

"Since focusing our clinical development efforts on cardiac and vascular indications 15 months ago, we have made steady progress recruiting and treating critically ill patients who have limited therapeutic options available to them," said George Dunbar, President and Chief Executive Officer of Aastrom. "We are pleased to learn that several patients treated in our open-label cardiac regeneration trial have been sharing their experiences through reports in the media. These human interest stories are very encouraging, and we look forward to analyzing and reporting interim clinical data from all patients enrolled in the trial. We still anticipate completing patient enrollment in our IMPACT-DCM trial by the end of December 2009."

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

* Cardiac Regeneration:

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

-- We anticipate that patient enrollment in IMPACT-DCM trial will be completed by the end of December 2009.

-- We expect to analyze preliminary 6-month interim data on all 40 IMPACT-DCM patients mid-year calendar 2010.

* Vascular Regeneration:

-- During the 4th quarter of calendar year 2009, we expect to unblind and analyze the interim clinical data from patients enrolled in the RESTORE-CLI study, including the first 30 patients who have completed their 12 month follow-up visit.

-- We anticipate reporting interim clinical data from RESTORE-CLI patients during the first quarter of calendar year 2010.

Fiscal Year 2009 Fourth Quarter and Year Ended June 30, 2009 Results

Total revenues for the quarter and twelve months ended June 30, 2009, consisting of product sales, were $69,000 and $182,000, respectively, compared to $149,000 and $522,000, consisting of grant funding and product revenues, for the same periods in fiscal year 2008.

Total costs and expenses for the quarter and twelve months ended June 30, 2009 decreased to $4,055,000 and $16,351,000, respectively, from $5,142,000 and $21,741,000 for the same periods in fiscal year 2008.

Research and development expenses for the quarter and twelve months ended June 30, 2009 decreased to $2,949,000 and $11,289,000, respectively, compared to $3,449,000 and $15,249,000 for the same periods in fiscal year 2008. These decreases reflect the changes we implemented in May 2008, when we reprioritized our clinical development programs to focus primarily on cardiovascular applications, including dilated cardiomyopathy and critical limb ischemia. The reprioritization reduced our overall research and development expenses, including salaries and benefits, and other purchased services. Research and development expenses for the twelve months ended June 30, 2009 also include a non-cash charge of $579,000 compared to $515,000 for the same period in fiscal year 2008, relating to share-based compensation expense.

Selling, general and administrative expenses for the quarter and twelve months ended June 30, 2009 decreased to $1,041,000 and $4,950,000, respectively, from $1,668,000 and $6,436,000 for the same periods in fiscal year 2008. These decreases are primarily due to lower salaries and benefits as a result of the reduction in force that was part of our clinical development program reprioritization in May 2008 and management and employee changes in 2008. These decreases also include the elimination of the management performance bonus plan and the associated costs for 2009. Selling, general and administrative expenses for the twelve months ended June 30, 2009 included a non-cash charge of $783,000 compared to $1,088,000 for the same period in fiscal year 2008, relating to share-based compensation expense.

Interest income for the quarter and twelve months ended June 30, 2009 was $43,000 and $296,000, respectively, compared to $153,000 and $1,170,000 for the same periods in fiscal year 2008. The fluctuations in interest income are due primarily to corresponding changes in the levels of cash, cash equivalents and short-term investments during the periods.

Interest expense for the quarter and twelve months ended June 30, 2009 was $15,000 and $73,000, respectively, compared to $23,000 and $84,000 for the same periods in fiscal year 2008. Interest expense is related to long-term debt for equipment acquired during the fiscal year ended June 30, 2008.

Net loss for the quarter ended June 30, 2009 was $3,958,000, or $0.03 per share, decreased from a net loss of $4,863,000, or $0.04 per share for the same period in fiscal year 2008. Net loss for the twelve months ended June 30, 2009, was $15,946,000, or $.11 per share, decreased from a net loss of $20,133,000 or $0.16 per share for the same period in fiscal year 2008. The changes in net loss are primarily due to the fluctuations in spending on research and development from year to year.

At June 30, 2009, the Company had $17 million in cash and cash equivalents as compared to $22.5 million at June 30, 2008. It is expected that our cash utilization will average approximately $1.4 million per month during fiscal year 2010.

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 expanded 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. TRC-based products have been used in over 350 patients with over 10 years of positive safety data. The Company's ongoing development activities focus on applying TRC technology to cardiac and vascular tissue regeneration. The Company is currently conducting a Phase II clinical trial with dilated cardiomyopathy (DCM) patients (the IMPACT-DCM trial) and a Phase IIb clinical trial with critical limb ischemia (CLI) patients (the RESTORE-CLI trial).

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

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.

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

CONSOLIDATED STATEMENT OF OPERATIONS DATA:

	Quarter ended June 30,		Year ended June 30,	
	2008	2009	2008	2009
	(Unaudited)			
REVENUES:				
Total revenue	$ 149	$ 69	$ 522	$ 182
COSTS AND EXPENSES:				
Cost of product sales and rentals	25	65	56	112
Research and development	3,449	2,949	15,249	11,289
Selling, general and administrative	1,668	1,041	6,436	4,950
Total costs and expenses	5,142	4,055	21,741	16,351
OTHER INCOME (EXPENSE):				
Interest income	153	43	1,170	296
Interest expense	(23)	(15)	(84)	(73)
Total other income	130	28	1,086	223
NET LOSS	$ (4,863)	$ (3,958)	$(20,133)	$(15,946)
NET LOSS PER SHARE (Basic and Diluted)	$ (.04)	$ (.03)	$ (.16)	$ (.11)

Weighted average number of common shares outstanding	132,761	158,306	129,120	143,016

CONSOLIDATED BALANCE SHEET DATA:

	June 30, 2009
ASSETS:	
Cash and cash equivalents	$ 17,000
Receivables, net	58
Inventories	1
Other current assets	732
Property, net	1,485
Total assets	$ 19,276
LIABILITIES AND SHAREHOLDERS' EQUITY:	
Current liabilities	$ 1,687
Long-term debt	305
Shareholders' equity	17,284
Total liabilities and shareholders' equity	$ 19,276

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