Aastrom

Aastrom Reports Second Quarter Fiscal Year 2009 Financial Results

Continued Clinical Progress Reported From Cardiovascular Programs

ANN ARBOR, Mich., Feb. 6, 2009 (GLOBE NEWSWIRE) -- Aastrom Biosciences, Inc. (Nasdaq:ASTM), a leading regenerative medicine company, today reported financial results for its second fiscal quarter ended December 31, 2008. The Company also reported several clinical and operational achievements since the beginning of the second fiscal quarter, including:

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

  - In November 2008, the first patient was treated in our U.S. Phase II IMPACT-DCM clinical trial evaluating Cardiac Repair Cells (CRCs) in the treatment of dilated cardiomyopathy (DCM), a disease associated with severe chronic heart failure. We plan to report interim data on the first patients treated in this trial by our fiscal year end, June 30, 2009.

  - To date, the trial has enrolled nine patients at the Methodist DeBakey Heart & Vascular Center in Houston, TX, Baylor University Medical Center in Dallas, TX and the University of Utah School of Medicine in Salt Lake City, UT. Initiation of two other clinical sites is in progress. The 40-patient, randomized, controlled, prospective, open-label clinical trial seeks to enroll 20 patients with ischemic DCM and 20 patients with non-ischemic DCM. It is anticipated that patient enrollment will be completed by the end of calendar year 2009.

  - On February 2, 2009, we announced that the IMPACT-DCM trial was placed on clinical hold by the Food and Drug Administration (FDA) due to a serious adverse event associated with anesthesia management during treatment of one patient at one of the active clinical sites, pending the completion of a more comprehensive review of this event. According to the results of an internal review conducted at the clinical site, and a second review by the trial's independent Data Safety Monitoring Board (DSMB), this event has been attributed to anesthesia administration and management in this single patient. Furthermore, these two reviews separately determined that this event was not related to the surgical approach or the use of our CRCs in this procedure. Notwithstanding the hold, the FDA authorized us to proceed with the CRC treatment for one patient previously enrolled in the IMPACT-DCM clinical trial. This patient was treated last week. In addition, follow-up monitoring of patients who have previously been treated in the IMPACT-DCM trial is continuing in accordance with the study protocol.

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

  - To date, our U.S. Phase IIb RESTORE-CLI clinical trial has enrolled 51 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), critical limb ischemia (CLI).

  - During the 4th quarter of calendar year 2009, we expect to

unblind and analyze the clinical data from the first 30 patients enrolled in the study.

* $15 million common stock purchase program:

  - We executed a $15 million common stock purchase program with Fusion Capital Fund II, LLC (Fusion Capital) on October 27, 2008. We have the right, over a 25-month period, to sell shares of our common stock to Fusion Capital from time to time in amounts between $60,000 and $2 million, up to an aggregate of $15 million, when we choose to do so, based on the terms of the agreement.

* NASDAQ compliance period extended:

  - The Listings Qualifications Department of The Nasdaq Stock Market LLC (NASDAQ) notified us that, given the continued extraordinary market conditions, NASDAQ has extended the suspension enforcing the rules requiring a minimum $1.00 per share closing bid price and a minimum market value of publicly held shares through April 19, 2009.

  - As a result of the extension of NASDAQ's suspension and the 60 days left on our previously granted compliance period, we have 60 days after April 19, 2009 to regain compliance with the $1.00 minimum closing bid price rule in order to remain listed on the Nasdaq Capital Market.

"While the economic and capital markets outlook for 2009 remains uncertain, the regenerative medicine and stem cell sectors have gained significant momentum and exposure since the beginning of the year," said George Dunbar, President and Chief Executive Officer of Aastrom. "With the progress we have made to date in our U.S. cardiac and vascular regeneration clinical trials, we have laid the foundation for building shareholder value, and we look forward to reporting developments from our clinical programs as they occur."

Second Fiscal Quarter Ended December 31, 2008 Results

Total revenues for the quarter and six months ended December 31, 2008, consisting of grant revenue and limited product sales, were $28,000 and $55,000, respectively, compared to $84,000 and $171,000 for the same periods in fiscal year 2008.

Total costs and expenses for the quarter and six months ended December 31, 2008 decreased to $4,180,000 and $8,226,000, respectively, from $5,621,000 and $11,108,000 for the same periods in fiscal year 2008.

Research and development expenses decreased to $2,829,000 and $5,555,000, respectively, for the quarter and six months ended December 31, 2008 compared to $3,895,000 and $7,768,000 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. The reprioritization reduced our overall research and development expenses, including salaries and benefits and other purchased services. Research and development expenses for the quarter and six months ended December 31, 2008, included a non-cash charge of $174,000 and $335,000, respectively, compared to $214,000 and $437,000 for the same periods in fiscal year 2008, relating to share-based compensation expense.

Selling, general and administrative expenses decreased to $1,333,000 and $2,649,000, respectively, for the quarter and six months ended December 31, 2008 from $1,725,000 and $3,339,000 for the same periods in fiscal year 2008. These decreases are primarily due to lower salaries and benefits and other purchased services that are the result of the reduction in force that was part of our reprioritization of our clinical programs. For the quarter and six months ended December 31, 2008, selling, general and administrative expenses included a non-cash charge of $219,000 and $421,000, respectively, compared to $344,000 and $670,000 for the same periods in fiscal year 2008, relating to share-based compensation expense.

Interest income for the quarter and six months ended December 31, 2008 decreased to $69,000 and $196,000, respectively, from $386,000 and $751,000 for the same periods in fiscal year 2008. 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 varying yields from our investments.

Interest expense was $20,000 and $41,000, respectively, for the quarter and six months ended December 31, 2008 compared

to $21,000 and $36,000, respectively, 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 December 31, 2008 was $4,103,000, or $.03 per share, compared to a net loss of $5,172,000, or $.04 per share for the same period in fiscal year 2008. Net loss for the six months ended December 31, 2008, was $8,016,000, or $.06 per share, compared to $10,222,000, or $.08 per share for the same period in fiscal year 2008. The decreases in net loss are primarily the result of decreased costs and expenses offset in part on a per share basis by an increase in the weighted average number of common shares outstanding.

At December 31, 2008, we had $16.3 million in cash, cash equivalents and short-term investments as compared to $22.5 million at June 30, 2008. We have reduced operating expenses by a combination of clinical program reprioritizations and fiscal discipline to achieve an average cash utilization of approximately $1.2 million per month for the first six months of the fiscal year ending June 30, 2009. It is anticipated that the average cash utilization will be $1.5 million per month for the second six months of the fiscal year ending June 30, 2009. At January 31, 2009, we had $17.5 million in cash and cash equivalents.

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 applying TRC technology to cardiac and vascular tissue regeneration. The company is currently focused on cardiovascular regeneration and is 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

This document contains forward-looking statements, including, without limitation, statements concerning clinical trial strategies, potential partnering activities, product development objectives, potential advantages of TRC technology and TRC-based products, and potential product applications, which involve certain risks and uncertainties. The forward-looking statements are also identified through use of the words "intends," "expect," "expected," "should," "anticipated," 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 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.

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

CONSOLIDATED STATEMENTS OF OPERATIONS DATA:

	Quarter ended December 31,		Six months ended December 31,	
	2007	2008	2007	2008
REVENUES:				
Total revenues	$ 84	$ 28	$ 171	$ 55
COSTS AND EXPENSES:				
Cost of product sales	1	18	1	22
Research and development	3,895	2,829	7,768	5,555
Selling, general and administrative	1,725	1,333	3,339	2,649
Total costs and expenses	5,621	4,180	11,108	8,226

OTHER INCOME (EXPENSE):				
Interest income	386	69	751	196
Interest expense	(21)	(20)	(36)	(41)
Total other income	365	49	715	155
NET LOSS	$ (5,172)	$ (4,103)	$(10,222)	$ (8,016)
NET LOSS PER COMMON SHARE (Basic and Diluted)	$ (.04)	$ (.03)	$ (.08)	$ (.06)
Weighted average number of common shares outstanding	130,467	134,575	125,537	133,686

CONSOLIDATED BALANCE SHEET DATA:

	June 30, 2008	December 31, 2008
ASSETS		
Cash and cash equivalents	$ 16,492	$ 16,326
Short-term investments	5,970	--
Receivables, net	18	70
Other current assets	1,583	1,372
Property and equipment, net	2,154	1,832
Total assets	$ 26,217	$ 19,600
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities	$ 2,100	$ 1,936
Long-tem debt	783	548
Shareholders' equity	23,334	17,116
Total liabilities and shareholders' equity	$ 26,217	$ 19,600

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