Aastrom Biosciences Reports Third Quarter 2011 Financial Results

ANN ARBOR, Mich., Nov. 8, 2011 (GLOBE NEWSWIRE) -- Aastrom Biosciences, Inc. (Nasdaq:ASTM), the leading developer of patient-specific expanded multicellular therapies for the treatment of severe chronic cardiovascular diseases, today reported financial results for the quarter and nine months ended September 30, 2011.

"Our recent financial results reflect the rapid advancement of our clinical programs this year, including plans to initiate the REVIVE-CLI Phase 3 clinical trial of ixmyelocel-T in the fourth quarter of 2011. This trial will enroll patients with critical limb ischemia who have no other treatment options available," said Tim Mayleben, president and CEO of Aastrom. "We also look forward to presenting the final results from the Phase 2b RESTORE-CLI clinical study on November 14, 2011 at the American Heart Association Scientific Sessions in Orlando, Florida."

Aastrom reported a net loss of $1.9 million, or $0.05 per share, for the third quarter of 2011 compared to a net loss of $5.9 million, or $0.21 per share, for the same period a year ago. For the nine months ended September 30, 2011, Aastrom reported a net loss of $16.9 million, or $0.44 per share, compared to $12.4 million, or $0.45 per share for the same period in 2010.

Research and development expenses for the quarter and nine months ended September 30, 2011 were $5.8 million and $15.4 million, respectively, versus $4.2 million and $10.6 million for the same periods a year ago. The increase in research and development expenses for both periods was primarily attributable to advanced preparations for the Phase 3 REVIVE-CLI clinical program for ixmyelocel-T as well as an increase in non-cash stock-based compensation expense.

General and administrative expenses for the quarter and nine months ended September 30, 2011 were $1.7 million and $5.8 million, respectively, compared to $1.7 million and $4.6 million for the same periods a year ago. The increase in general and administrative expenses for the nine months ended September 30, 2011 was primarily due to an increase in consulting and employee-related expenses, including non-cash stock-based compensation expenses, as well as costs related to the previously announced restatement of the company's historical financial results in the first quarter of 2011.

Other income (expense) for the quarter and nine months ended September 30, 2011 was $5.5 million and $4.3 million, respectively, compared to $(0.1) million and $2.8 million for the same periods a year ago. The fluctuations are due to non-cash changes in the fair value of the company's outstanding warrants, driven by the change in the fair market value of the company's common stock in these periods.

As of September 30, 2011, the company had $11.9 million in cash and cash equivalents, compared to $31.2 million in cash and cash equivalents at December 31, 2010, and 38.6 million shares of common stock outstanding.

Recent Business Highlights

During and since the third quarter of 2011, we have:

- Reached agreement with the U.S. Food and Drug Administration regarding the special protocol assessment for the proposed Phase 3 REVIVE-CLI clinical program for ixmyelocel-T in patients with critical limb ischemia who have no other treatment options, positioning us to launch the Phase 3 trial this quarter.
- Presented 12-month results from the Phase 1/2 IMPACT-DCM dilated cardiomyopathy surgical study at the Heart Failure Society of America meeting. The study showed that treatment with ixmyelocel-T was well-tolerated and consistent with improved myocardium function in patients with DCM, especially those with ischemic cardiomyopathy.
- Reported top-line six-month interim results from the DCM catheter study showing evidence of fewer adverse events and comparable efficacy results compared to the 12-month results from the IMPACT-DCM surgical study. Aastrom plans to initiate a Phase 2b study of ixmyelocel-T in the treatment of DCM in the first half of 2012.
- Received a key composition-of-matter patent from the European Patent Office providing protection throughout the European Union for various claims regarding the composition and production of mixed cell populations which characterize ixmyelocel-T.

Conference Call Information

Aastrom's management will host a conference call to discuss these results at 4:30 p.m. (ET) today. Interested parties should call toll-free (877) 312-5881, or from outside the U.S. (253) 237-1173 and use conference ID 17046596. The call will be available live in the Investors section of Aastrom's website at http://investors.aastrom.com/investors.cfm. A replay of the call will be available until November 12, 2011 by calling (855) 859-2056, or from outside the U.S. at (404) 537-3406 and using conference ID 17046596. A podcast will also be available after the live event at http://investors.aastrom.com/events.cfm.

About Aastrom Biosciences

Aastrom Biosciences is the leader in developing patient-specific, expanded multicellular therapies for use in the treatment of patients with severe, chronic cardiovascular diseases. The company's proprietary cell-processing technology enables the manufacture of ixmyelocel-T, a patient-specific multicellular therapy expanded from a patient's own bone marrow and delivered directly to damaged tissues. Aastrom has advanced ixmyelocel-T into late-stage clinical development, including a planned Phase 3 clinical program to study patients with critical limb ischemia and two Phase 2 clinical trials in patients with dilated cardiomyopathy. For more information, please 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 progress, objectives and expectations, clinical activity timing, intended product development, the performance and contribution of certain individuals 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 or Transition Report on Form 10-K or 10-K/T, 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.

- Financial results follow -

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

CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)

	December 31, 2010	September 30, 2011
ASSETS		
Cash and cash equivalents	$ 31,248	$ 11,947
Other current assets	451	631
Property and equipment, net	1,128	1,494
Total assets	$ 32,827	$ 14,072
LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIT)		
Warrant liabilities	$ 25,954	$ 21,668
Other current liabilities	3,910	3,513
Long-term debt	41	49
Shareholders' equity (deficit)	2,922	(11,158)
Total liabilities and shareholders' equity (deficit)	$ 32,827	$ 14,072

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)

	Quarter Ended September 30,		Nine Months Ended September 30,	
	2010	2011	2010	2011

REVENUES	$ --	$ 9	$ --	$ 18
COSTS AND EXPENSES				
Cost of product sales and rentals	--	2	--	4
Research and development	4,167	5,750	10,631	15,426
Selling, general and administrative	1,686	1,696	4,625	5,794
Total costs and expenses	5,853	7,448	15,256	21,224
LOSS FROM OPERATIONS	(5,853)	(7,439)	(15,256)	(21,206)
OTHER INCOME (EXPENSE)				
(Increase) decrease in fair value of warrants	(99)	5,496	2,808	4,286
Other income, net	20	9	70	41
Total other income (expense)	(79)	5,505	2,878	4,327
NET LOSS	$ (5,932)	$ (1,934)	$ (12,378)	$ (16,879)
NET LOSS PER SHARE				
(Basic and Diluted)	$ (0.21)	$ (0.05)	$ (0.45)	$ (0.44)
Weighted average number of common shares outstanding (Basic and Diluted)	28,255	38,632	27,755	38,624

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