Aastrom

Aastrom Reports Second Quarter Fiscal Year 2010 Financial Results

Company Advances Clinical Development Programs for Investigational Therapies to Treat Severe Cardiovascular Diseases

ANN ARBOR, Mich., Feb. 10, 2010 (GLOBE NEWSWIRE) -- Aastrom Biosciences, Inc. (Nasdaq:ASTM), a leading developer of autologous cellular therapies for the treatment of severe, chronic cardiovascular diseases, today reported financial results for its second fiscal quarter ended December 31, 2009, and also announced progress in its late-stage clinical development programs and corporate operations.

Second quarter fiscal year 2010 financial results

Total revenues for the quarter and six months ended December 31, 2009, consisting of product sales, were $16,000 and $89,000, respectively, compared to $28,000 and $55,000 for the same periods in fiscal year 2009.

Total costs and expenses for the quarter and six months ended December 31, 2009, were $4,601,000 and $8,490,000, respectively, compared to $4,180,000 and $8,226,000 for the same periods in fiscal year 2009.

Research and development expenses increased to $3,283,000 and $6,194,000, respectively, for the quarter and six months ended December 31, 2009, compared to $2,829,000 and $5,555,000 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 patients in the IMPACT-DCM and RESTORE-CLI Phase 2 clinical trials. Research and development expenses for the quarter and six months ended December 31, 2009, included a non-cash charge of $175,000 and $361,000, respectively, compared to $174,000 and $335,000 for the same periods in fiscal year 2009, relating to share-based compensation expense.

General and administrative expenses decreased to $1,316,000 and $2,262,000, respectively, for the quarter and six months ended December 31, 2009, from $1,333,000 and $2,649,000 for the same periods in fiscal year 2009. These decreases are primarily due to an offset of $279,000 to the stock compensation expense that was recorded in the first quarter of fiscal year 2010. This offset reversed previously recognized stock compensation expense for certain options held by George W. Dunbar that were forfeited when he stepped down as chief executive officer, president and chief financial officer on December 14, 2009, as these options were no longer expected to vest. For the quarter and six months ended December 31, 2009, general and administrative expenses included a non-cash charge of $127,000 and $268,000, respectively, compared to $219,000 and $421,000 for the same periods in fiscal year 2009, relating to share-based compensation expense.

Interest income for the quarter and six months ended December 31, 2009, decreased to $21,000 and $49,000, respectively, from $69,000 and $196,000 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 varying yields from the company's investments.

Interest expense was $11,000 and $24,000, respectively, for the quarter and six months ended December 31, 2009, compared to $20,000 and $41,000, respectively, for the same periods in fiscal year 2009.

Net loss for the quarter ended December 31, 2009, was $4,575,000 or $.03 per share, compared to a net loss of $4,103,000 or $.03 per share, for the same period in fiscal year 2009. Net loss for the six months ended December 31, 2009, was $8,376,000 or $.05 per share, compared to $8,016,000 or $.06 per share, for the same period in fiscal year 2009.

At December 31, 2009, the company had $14.7 million in cash and cash equivalents compared to $17 million at June 30, 2009. Cash utilization averaged approximately $1.2 million per month for the six months ended December 31, 2009. It is expected that cash utilization will average approximately $1.4 million per month for the remainder of fiscal year ending June 30, 2010. After the completion of the public offering of common stock and warrants in January 2010, the company had approximately $25.5 million in cash and cash equivalents on January 31, 2010.

The company received approximately $12.4 million in net proceeds, after underwriting discounts and commissions and other offering expenses, from the sale of 52,077,100 units (including 5,923,100 units sold to the underwriter pursuant to the exercise of its over-allotment option) consisting of an aggregate of 52,077,100 shares of the company's common stock, Class A Warrants to purchase an aggregate of 39,057,825 shares of common stock and Class B Warrants to purchase an aggregate of 26,038,550 shares of common stock. The units were sold at a public offering price of $0.26 per unit. Oppenheimer & Co. Inc. acted as the sole underwriter for the offering.

Recent Aastrom business developments

Our U.S. Phase 2 IMPACT-DCM clinical trial (surgical delivery for treatment of dilated cardiomyopathy or DCM) has enrolled 40 patients at five sites across the U.S. We anticipate reporting 6-month interim data from this trial upon completion of 6-month follow-up visits for all patients during the third quarter of calendar year 2010. We also announced approval by FDA to initiate a second randomized, controlled, prospective, open-label, Phase 2 clinical trial investigating the delivery of Cardiac Repair Cells (CRCs) via catheter injection for the treatment of DCM. We expect to initiate patient enrollment in this clinical trial during the first quarter of calendar year 2010.

Our U.S. Phase 2b RESTORE-CLI clinical trial continues to evaluate the use of Vascular Repair Cells (VRCs) in the treatment of patients suffering from critical limb ischemia (CLI), the most severe form of peripheral arterial disease (PAD). As planned, the first 30 patients in the RESTORE-CLI trial have completed 12-month follow-up visits and 46 patients have completed 6-month follow-up visits. We expect to report top-line data from the interim analysis in the first quarter of calendar year 2010.

"We continue to make good progress in our cardiovascular clinical programs and we expect to continue to work aggressively to advance these programs in 2010. This is an important year for our company as we will announce full or interim Phase 2 data from both our RESTORE-CLI and IMPACT-DCM clinical trials and plan to build on the encouraging early results of our surgical delivery IMPACT-DCM trial by initiating an additional Phase 2 catheter-delivery DCM clinical trial," said Tim Mayleben, president and CEO of Aastrom. "We look forward to reporting results from our late-stage clinical programs throughout the year."

The company also recently announced several management changes. In December 2009, Timothy M. Mayleben was named chief executive officer, president and chief financial officer of Aastrom. George W. Dunbar, formerly president and CEO of Aastrom, was named chairman of the Aastrom board of directors. In addition, Harold C. Urschel, Jr., M.D., was appointed to the board of directors on October 14, 2009, and was re-elected by Aastrom shareholders at the annual meeting of shareholders held on December 14, 2009, together with all of the other continuing directors.

Annual meeting of shareholders

Aastrom shareholders approved all five proxy proposals up for vote at the annual meeting of shareholders held December 14, 2009, including the proposal to grant discretionary authority to Aastrom's board of directors to amend the company's Restated Articles of Incorporation to effect a reverse stock split of Aastrom's authorized, issued and outstanding common stock. A webcast of annual meeting presentations is available at http://www.investorcalendar.com/IC/CEPage.asp?ID=151462 until March 15, 2010.

NASDAQ capital market listing

On October 2, 2009, Aastrom 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). Aastrom announced on February 9, 2010, that its board of directors had approved a one-for-eight reverse stock split of the company's common stock which is to be effective on February 18, 2010. The reverse stock split is intended to increase the per share trading price of Aastrom's common stock to satisfy the $1.00 minimum bid price requirement and to attract greater institutional ownership of the company's shares, however there can be no assurance that these objectives will be achieved.

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.

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, Quarterly Reports on Form 10-Q 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,	
	2008	2009	2008	2009
REVENUES:				
Total revenues	$28	$16	$55	$89
COSTS AND EXPENSES:				
Cost of product sales	18	2	22	34
Research and development	2,829	3,283	5,555	6,194
General and administrative	1,333	1,316	2,649	2,262
Total costs and expenses	4,180	4,601	8,226	8,490
OTHER INCOME (EXPENSE):				
Interest income	69	21	196	49
Interest expense	(20)	(11)	(41)	(24)
Total other income	49	10	155	25
NET LOSS	$(4,103)	$(4,575)	$(8,016)	$(8,376)
NET LOSS PER COMMON SHARE				
(Basic and Diluted)	$(.03)	$(.03)	$(.06)	$(.05)
Weighted average number of common shares outstanding	134,575	173,707	133,686	169,570

CONSOLIDATED BALANCE SHEET DATA:

	June 30, 2009	December 31, 2009
ASSETS		
Cash and cash equivalents	$17,000	$14,739
Receivables, net	58	23
Inventory	1	--
Other current assets	732	622
Property, net	1,485	1,240
Total assets	$19,276	$16,624

LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities	$1,687	$2,072
Long-term debt	305	194
Shareholders' equity	17,284	14,358
Total liabilities and shareholders' equity	$19,276	$16,624

CONTACT: Berry & Company
Media:
Stephen Zoegall
(212) 253-8881
szoegall@berrypr.com

Aastrom Biosciences
Investors:
Kimberli O'Meara
(734) 930-5777
mail@aastrom.com