

# Aastrom Biosciences, Inc. Reports Fourth Quarter and Fiscal Year 2006 Financial Results

**Ann Arbor, Michigan, September 13, 2006** -- Aastrom Biosciences, Inc. (Nasdaq: ASTM) today reported financial results for the fourth quarter and fiscal year ended June 30, 2006. The Company also reported several clinical and operational achievements during the quarter, including:

- Completion of the accrual and treatment phase for all 36 patients enrolled in the U.S. Phase I/II multi-center long bone fracture clinical trial.
- Receipt of a local German human pharmaceuticals manufacturing license for the production of the Company's TRC-based cell products for clinical use in compliance with German law and EU clinical trial directives. The newly licensed manufacturing facility was established as a collaboration at the Fraunhofer Institute for Interfacial Engineering and Biotechnology in Stuttgart, Germany, and will be used to expand current clinical trials that use TRC-based products for tissue regeneration.
- Execution of the sale of approximately 15.9 million shares of the Company's common stock in a registered direct placement to a select group of institutional investors at a price of \$1.60 per share for gross proceeds of approximately \$25.5 million.

In July 2006, the Board of Directors appointed George W. Dunbar as President, Chief Executive Officer and Director of Aastrom. Mr. Dunbar brings over 25 years of experience in the healthcare field to the Company, including 15 years in the role of Chief Executive Officer at both established and early-stage healthcare companies in the biotech, pharmaceutical, diagnostic and device sectors. R. Douglas Armstrong, Ph.D., who stepped down as CEO after 15 years, will continue as Chairman of the Board for the remainder of his term. This management team transition supports the Company's continuing goals of establishing strategic alliances, moving product candidates through the clinical and regulatory process, and ultimately bringing its autologous cell products to the marketplace.

The Company is also pleased to announce that effective September 11, 2006, Elmar R. Burchardt, M.D., Ph.D., was appointed to the new position of Vice President Medical Affairs. As previously announced, Dr. Burchardt is responsible for directing all of Aastrom's clinical programs utilizing the Company's proprietary TRC technology, including programs for long bone fractures, critical limb ischemia, spine fusion and osteonecrosis. He will also lead the development of new indication programs, such as a program for cardiac tissue regeneration.

"Aastrom is focused on accelerating the development, the manufacturing and the achievement of regulatory approval of its autologous cell products for use in regenerative medicine using its platform technology. We are targeting areas of high unmet medical need where tissue regeneration may improve the quality of life for many people," stated Mr. Dunbar. "Our number one priority is to move our TRC-based tissue regeneration cell products from research and clinical programs into the marketplace for multiple indications."

Other significant highlights during fiscal year 2006 include the following:

- Clinical:
  - Bone Regeneration:
    - TRCs received an Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) for use in the treatment of osteonecrosis of the femoral head.
    - Bone regeneration results, evidenced by callus formation or bone bridging in the first 7 patients at one clinical site were presented at an orthopedic meeting by Matthew L. Jimenez, M.D., Principal Investigator of Aastrom's U.S. Phase I/II multi-center long bone fracture clinical trial.
    - Positive bone regeneration results were reported in 5 patients evaluated for jaw bone reconstruction in a feasibility clinical trial conducted with the Teknon Hospital Maxillofacial Clinic in Barcelona, Spain.
    - An EU Phase I/II multi-center long bone fracture clinical trial is being conducted at several centers in Barcelona,
       Spain, after being approved by the Spanish Drug Agency (AEMPS).
    - A U.S. Phase I/II spine fusion clinical trial is being conducted at William Beaumont Hospital in Royal Oak, Michigan.

- Vascular Regeneration:
  - Diabetic patients are being enrolled into a controlled clinical trial to treat critical limb ischemia at the Heart and Diabetes Center North Rhine-Westphalia, located in Bad Oeynhausen, Germany.

#### · Operational:

- A collaboration agreement was executed for the development of products for the orthopedics market using Orthovita's synthetic ceramic matrices and ceramic-collagen matrices (VITOSS) and Aastrom's TRCs.

### · Corporate Governance:

- Four senior pharmaceutical and biotech executives were added to the Board of Directors:
  - Stephen G. Sudovar, CEO of SGS Associates, former President and CEO of EluSys Therapeutics, Inc., and former President of Roche Laboratories, Inc.
  - Alan L. Rubino, President and COO of Pharmos Corporation, and former executive at PDI, Inc., and Cardinal Health
  - Nelson M. Sims, former President and CEO of Novavax, Inc., and former President of Eli Lilly Canada, Inc.
  - Robert L. Zerbe, M.D., CEO of QUATRx Pharmaceutical, Inc., and former executive at Eli Lilly and Company, and Pfizer (formerly Parke-Davis)

#### · Financial:

- Received a two-year Phase II NIH grant for \$740,000 extending Aastrom's adult stem cell technology process to other tissues
- Received a two-year Phase II NIH grant for \$798,000 to support further development of Aastrom's stem cell manufacturing systems

## Fiscal Year 2006 Fourth Quarter and Year Ended June 30, 2006 Results

Total revenues for the quarter ended June 30, 2006, consisting of product sales and grant funding, were \$328,000 compared to \$96,000 for the same period in fiscal year 2005. Total revenues for the twelve months ended June 30, 2006 were \$863,000 compared to \$909,000 for the same period in fiscal year 2005.

We no longer market our cell manufacturing platform as a stand-alone product; instead it is predominantly used to manufacture our proprietary TRC-based cell products for regenerative medicine. Therefore, until we receive product registration from a regulatory authority, we do not anticipate significant product sales revenue. Product sales increased slightly for the quarter ended June 30, 2006 to \$17,000 from \$10,000 for the same period in fiscal year 2005, and decreased for the twelve months ended June 30, 2006 to \$159,000 from \$387,000 for the same period in fiscal year 2005.

Grant revenues increased for the quarter and twelve months ended June 30, 2006 to \$311,000 and \$704,000, respectively, from \$86,000 and \$522,000 for the same periods in fiscal year 2005. Grant revenues accounted for 82% of total revenues for the twelve months ended June 30, 2006, compared to 57% for the same period in fiscal year 2005 and are recorded on a cost-reimbursement basis. As we continue to pursue grant funding, grant revenues may vary in any period based on timing of grant awards, grant-funded activities, level of grant funding and number of grant awards received.

Total costs and expenses for the quarter and twelve months ended June 30, 2006 increased to \$5,129,000 and \$18,596,000, respectively, from \$3,701,000 and \$13,326,000 for the same periods in fiscal year 2005.

The cost of product sales decreased for the quarter and twelve months ended June 30, 2006, to \$0 and \$11,000, respectively, from \$8,000 and \$139,000 for the same periods in fiscal year 2005.

As a result of the continued expansion of our research and development activities, including additional staffing requirements, to support future regulatory submissions, on-going and planned tissue regeneration clinical trials in the U.S. and EU, and the development of facilities for product manufacturing and distribution processes, research and development expenses for the quarter and twelve months ended June 30, 2006 increased to \$2,739,000 and \$9,484,000, respectively, from \$1,948,000 and \$7,206,000 for the same periods in fiscal year 2005. Research and development expenses for the quarter and twelve months ended June 30, 2006, also include a non-cash charge of \$12,000 and \$300,000, respectively, pursuant to a new accounting standard, which requires us to measure the fair value of all employee share-based payments and recognize that value as an operating expense.

Selling, general and administrative expenses increased for the quarter and twelve months ended June 30, 2006 to \$2,390,000 and \$9,101,000, respectively, from \$1,745,000 and \$5,972,000 for the same periods in fiscal year 2005. This increase reflects additional staffing requirements, bonuses paid to certain employees, an accrual for performance bonuses, an accrual under the

former CEO's revised employment agreement, and recruitment expenses relating to Board of Director members, an EU marketing director and the search for a new CEO. This increase also reflects additional consulting and marketing activities and increased legal costs associated with patent protection. In addition, selling, general and administrative expenses for the quarter and twelve months ended June 30, 2006, included a non-cash charge of \$231,000 and \$734,000, respectively, related to employee share-based payments.

Net loss for the quarter ended June 30, 2006 was \$4,296,000, or \$.03 per share, compared to a net loss of \$3,360,000, or \$.03 per share for the same period in fiscal year 2005. Net loss for the twelve months ended June 30, 2006, was \$16,475,000, or \$.15 per share, compared to \$11,811,000 or \$.13 per share for the same period in fiscal year 2005. The increase in net loss is primarily the result of increased costs and expenses offset on a per share basis by an increase in the weighted average number of common shares outstanding resulting from sale of our common shares to investors in fiscal year 2005.

At June 30, 2006, the Company had \$43.0 million in cash, cash equivalents and short-term investments as compared to \$32.4 million at June 30, 2005.

#### **Aastrom Conference Call Information**

George W. Dunbar, President and Chief Executive Officer, Gerald D. Brennan, Jr., Vice President Administrative & Financial Operations and Chief Financial Officer, and Elmar R. Burchardt, M.D., Ph.D., Vice President Medical Affairs of Aastrom Biosciences, Inc., will host a conference call to review and discuss the fourth quarter and fiscal year 2006 financial results at 11:00 a.m. (EDT) today, September 13, 2006. Interested parties should call toll-free (877) 407-9205, or from outside the U.S. (201) 689-8054, fifteen minutes before the start of the call to register and identify themselves as registrants of the 'Aastrom Conference Call'. Any registered caller on the toll-free line may ask to be placed in the queue for the Question & Answer session. The call will be simulcast on the web at http://www.vcall.com/IC/CEPage.asp?ID=107349. A podcast of the call may be downloaded from the web at the internet address above. If you are unable to participate during the live call, the webcast will be available for replay at http://www.investorcalendar.com/ for 60 days. Through September 23, 2006, an audio replay of the call will be available by dialing toll-free (877) 660-6853, or from outside the U.S. (201) 612-7415; when prompted on the phone line, the Account # is: 286 and the Conference ID# is: 209872.

### **About Aastrom Biosciences, Inc.**

Aastrom Biosciences, Inc. (Nasdaq: ASTM) is developing autologous cell products for the repair or regeneration of multiple human tissues, based on its proprietary Tissue Repair Cell (TRC) technology. Aastrom's TRC-based products are a unique cell mixture containing stromal, stem and progenitor cell populations, produced outside the body from a small amount of bone marrow taken from the patient. TRC-based products have been used in over 225 patients, and are currently in clinical trials for bone regeneration (long bone fractures and spine fusion) and vascular regeneration (critical limb ischemia) applications. The Company has reported positive interim clinical trial results for TRCs suggesting both the clinical safety and the ability of TRCs to induce tissue regeneration in long bone fractures and jaw bone reconstruction. Recently, the Company's proprietary TRCs received an Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) for use in the treatment of osteonecrosis of the femoral head. In addition, Aastrom is developing plans for a TRC-based therapy for cardiac regeneration.

For more information, visit Aastrom's website at www.aastrom.com.

This document contains forward-looking statements, including without limitation, statements concerning clinical trial plans and expectations, intended product development and commercialization objectives, and potential product applications, which involve certain risks and uncertainties. The forward-looking statements are also identified through use of the words "may," "planned," "plans," "anticipate," 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 the inherent uncertainties associated with clinical trial and product development activities, regulatory approval requirement, 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 fillings with the Securities and Exchange Commission.

-- Financial Table Below --

# AASTROM BIOSCIENCES, INC.

# CONSOLIDATED STATEMENTS OF OPERATIONS DATA:

	Quarter ended June 30, (Unaudited)			Year end June	
	2	2005	2006	2005	
REVENUES:					
Product sales and rentals	S	10,000 \$	17,000	\$ 387,000	
Grants and other		86,000	311,000	522,000	
Total revenues		96,000	328,000	909,000	
COSTS AND EXPENSES:					
Cost of product sales and rentals		8,000	-	139,000	
Cost of product sales and rentals – provision for excess inventory		-	<u>.</u>	9,000	
Research and development		1,948,000	2,739,000	7,206,000	
Selling, general and administrative		1,745,000	2,390,000	5,972,000	
Total costs and expenses		3,701,000	5,129,000	13,326,000	
OTHER INCOME		245,000	505,000	606,000	
NET LOSS	\$	(3,360,000)	(4,296,000)	<u>\$ (11,811,000)</u> =	
NET LOSS PER COMMON SHARE (Basic and Diluted)	S	(.03) \$	(.04)	\$ (.13)	
Weighted average number of shares outstanding (Basic and Diluted)		102,036,000	117,104,000	93,541,000	

CONSOLIDATED BALANCE SHEET DATA:		
	June 30, 2006	
ASSETS		
Cash and cash equivalents	S	9,034,000
Short-term investments		33,963,000
Receivables, net		139,000
Inventories		1,000
Other current assets		528,000
Property, net		1,216,000
Total assets	\$	44,881,000
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities	S	2,539,000
Shareholders' equity		42,342,000
Total liabilities and shareholders' equity	\$	44,881,000

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