

# Aastrom Biosciences, Inc. Reports First Quarter 2004 Financial Results

## -- Company Prepares to Enter Clinical Trials of Bone Graft Product --

Ann Arbor, Michigan, November 10, 2003 – Aastrom Biosciences, Inc. (NasdaqSC: ASTM), announced today financial results for the first fiscal quarter ended September 30, 2003. The Company also reviewed significant clinical and operational milestones achieved during the quarter.

### Aastrom's 1st Quarter Highlights

- The U.S. Food and Drug Administration approved Aastrom's investigational new drug (IND) application, allowing the Company to proceed with clinical trial plans for its bone graft product.
- Aastrom announced two grants from the National Institutes of Health (NIH); one to further the development of its bone graft product, and one supporting the Company's dendritic cell vaccine research. In the current quarter, Aastrom announced yet another NIH grant, providing funding for the development of a stem cell treatment for diabetic circulation disorders.
- In July, Aastrom announced the completion of several financings, including a successful private placement, that brought the Company's cash to a total of \$16 million at that time, a sufficient amount to fund its planned operational and clinical programs well through fiscal year 2004.
- The Company filed registration statements with the SEC during the quarter to proactively create three different channels for raising the necessary capital to complete clinical trials and business development in fiscal years 2005 and 2006. These new equity capital raising opportunities include:
  - Reinstituting the previously successful equity financing arrangement for common stock through Fusion Capital. This program is entirely Aastrom-directed, and is intended to allow the Company to respond quickly to market opportunities.
  - Offering a Direct Stock Purchase Program (DSPP) to currently registered shareholders. This program allows registered shareholders the ability to purchase up to an aggregate of 10 million newly issued shares, unless otherwise noted in the DSPP materials based on state residency.
  - Developing a universal shelf offering that enables several types of financing options. This program is intended to attract longterm institutional investment.
- The Company announced in August that it had completed the CE Mark requirements for its third dendritic cell production kit. These products are part of Aastrom's Cell Production Products business, for the production of a broad range of dendritic cell-based vaccines intended for the treatment of various cancers.

For the quarter ended September 30, 2003, Aastrom reported financial results, including a net loss of \$2.8 million, or \$.04 per common share, up from a net loss of \$2.5 million, or \$.05 per common share for the same period in 2002. Revenues generated by product sales of therapeutic kits, and rentals of the Company's Cell Production Products for the quarter ended September 30, 2003 were \$25,000, up from \$7,000 for the same period in 2002.

Grant funding for the quarter ended September 30, 2003 was \$275,000, compared to \$86,000 in 2002, as a result of increased grant program activity this quarter. Within two consecutive quarters, Aastrom was awarded four separate grants from the National Institutes of Health, to further develop our proprietary cell production technology and our cell therapy products.

Total costs and expenses for the quarter ended September 30, 2003 increased to \$3.2 million, compared to \$2.6 million for the same period in 2002. Expenses reflect increases in costs of sales and rentals to \$12,000 for the quarter ended September 30, 2003 from \$0 for the same period in 2002. The non-cash provision for obsolete and excess inventory increased to \$0.3 million for the quarter ended September 30, 2003 from \$0.1 million for the same period in 2002. Research and development expenses for the quarter ended September 30, 2003 were \$1.4 million, unchanged from the same period in 2002. An increase in selling, general and administrative expenses to \$1.6 million for the quarter ended September 30, 2003 was reported compared to \$1.1 million for the same period in 2002. These increased expenses resulted primarily from a non-cash charge of \$425,000 relating to certain warrants issued in August 2003 for public and investor relations services, and an employee performance-based stock option that vested in September 2003.

Aastrom's Cell Production Products business, led by three dendritic cell production products, focuses on positioning the Company's proprietary technology as a required component of new cell therapies being developed by third parties. The European Union (EU) has issued new requirements regarding the manufacturing of cell products and clinical trials that are still being finalized. These changes have

delayed or in some cases temporarily halted dendritic cell clinical trials in European countries, the result of which has reduced the number of customer opportunities and impacted Aastrom's commercial progress in its new Cell Production Products business.

There have also been changes made to the EU Medicinal Products Prime Directive, which shifted patient-derived cells to the medicinal products category. Although there is no current indication of a problem, these same regulations may in the future delay certain of our current planned clinical trials in Europe.

With FDA approval of its IND application, Aastrom is preparing to begin a multi-center Phase I/II bone grafting clinical trial in the United States. This initial U.S. clinical trial protocol will combine Aastrom's Tissue Repair Cells with an orthopedic matrix provided by the Musculoskeletal Transplant Foundation for tibial non-union fractures. A similar bone graft trial is set to begin at Bergmannsheil University in Bochum, Germany, where Mathys Medical will be the provider of synthetic bone graft matrix.

#### About Aastrom Biosciences, Inc.

Aastrom Biosciences, Inc. (NasdaqSC: ASTM) is a late-stage development company focused on human cell-based therapies. The AastromReplicell<sup>™</sup> System – a patented, integrated system of instrumentation and single-use consumable kits for the production of patient-specific cells – is the Company's core technology for its Prescription Cell Products (PCP) business and its Cell Production Products (CPP) business. The principal focus of the PCP business is the repair or regeneration of tissue intended for large markets such as bone grafting, vascular systems and severe osteoporosis. The CPP business markets the AastromReplicell<sup>™</sup> System to researchers and companies for their production of cells for clinical trials. These two businesses are intended to enable Aastrom to generate multiple paths to revenue. The initial commercial phase of the CPP business for dendritic cell production products is underway in Europe and the United States. For more information, visit Aastrom's website at www.aastrom.com.

This document contains forward-looking statements, including without limitation, statements regarding the anticipated timing of clinical trials and related expenditures, product development objectives, commercial introduction plans, potential product applications, advantages of the AastromReplicell<sup>TM</sup> System and related cell therapy kits, and financing plans which involve certain risks and uncertainties. The forward-looking statements are also identified through use of the words "intended," "may," "plans," 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 results obtained from clinical trial and development activities, regulatory approval requirements, the availability of resources, financial market conditions, competitive products and technologies, the degree to which the Company's products achieve market acceptance, 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-10K, and other filings with the Securities and Exchange Commission.

#### -Financial Table Follows-

AASTROM BIOSCIENCES, INC. (Unaudited)

### CONSOLIDATED STATEMENT OF OPERATIONS DATA:

Q	Quarter ended September 30,		
	<u>2002</u>	<u>2003</u>	
REVENUES: Product sales and rentals Grants and other Total revenues	\$ 7,000 <u>86,000</u> <u>93,000</u>	\$25,000 <u>275,000</u> <u>300,000</u>	
COSTS AND EXPENSES: Cost of product sales and rentals Cost of product sales and rentals provision for obsolete and exces	s -	12,000	
inventory	88,000	253,000	
Research and development Selling, general and administration	1,385,000 ve 1,113,000	1,356,000 1,565,000	
Total costs and expenses	2,586,000	3,186,000	
OTHER INCOME	41,000	48,000	
NET LOSS	\$ <u>(2,452,000)</u> \$	6 <u>(2,838,000)</u>	
NET LOSS PER COMMON SHARE (Basic and Diluted)	∃ <u>\$(.05)</u>	<u>\$(.04)</u>	

Weighted average number of

# CONSOLIDATED BALANCE SHEET DATA:

	June 30, <u>2003</u>	September 30, <u>2003</u>
ASSETS Cash and investments Other current assets Property, net Total assets	\$ 10,512,000 1,341,000 <u>302,000</u> \$ <u>12,155,000</u>	
LIABILITIES AND SHAREHO	DLDERS' EQUITY	,

LIADILITIES AND SHAREHOLDERS EQUIT					
Current liabilities	\$	580,000	\$	643,000	
Shareholders' equity		<u>11,575,000</u>	1	4,315,000	
Total liabilities and					
shareholders' equity	\$	12,155,000	\$ <u>1</u>	14,958,000	

### CONTACTS:

Kris M. Maly or Becky Anderson Investor Relations Department Aastrom Biosciences, Inc. Phone: (734) 930-5777

###