

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K
CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported) August 16, 2001

Aastrom Biosciences, Inc.

(Exact name of registrant as specified in charter)

Michigan

0-22025

94-3096597

(State or other jurisdiction
of incorporation)

(Commission
File Number)

(IRS Employer
Identification No.)

24 Frank Lloyd Wright Drive, P.O. Box 376, Ann Arbor Michigan 48106

(Address of principal executive offices)

(Zip Code)

Registrant's telephone number, including area code (734) 930-5555

Not Applicable

(Former name or former address, if changed since last report)

Item 5. Other Events.

On August 16, 2001 Aastrom issued a press release reporting its fourth quarter and year-end 2001 financial results, as well as other developments and achievements. A copy of the press release is included as Exhibit 99 to this report.

Item 7. Financial Statements and Exhibits.

(c) Exhibits

Exhibit 99 - Press Release dated August 16, 2001.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Aastrom Biosciences, Inc.

Date: August 16 , 2001

By: /s/ Todd E. Simpson

Vice President, Finance and Administration
and Chief Financial Officer (Principal
Financial and Accounting Officer)

FOR IMMEDIATE RELEASE

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AASTROM ANNOUNCES FOURTH QUARTER AND YEAR-END
2001 FINANCIAL RESULTS

Ann Arbor, MI, August 16, 2001 - Aastrom Biosciences, Inc. (Nasdaq: ASTM) announced today financial results for its fourth quarter and fiscal year ended June 30, 2001. For the quarter ended June 30, 2001, the Company reported a net loss of \$1.9 million, compared to a net loss of \$1.3 million for the same period last year. For fiscal year 2001, the Company reported a net loss of \$5.9 million, down 37% from a net loss of \$9.4 million in 2000. Net loss per common share for the quarter and year ended June 30, 2001 was \$.05 and \$.17, respectively, compared to \$.04 and \$.41, respectively, in 2000.

Revenues for the year ended June 30, 2001 were \$.9 million, compared to \$1.1 million in 2000. Revenues consisted primarily of funding received under research grants totaling \$.8 million for the year ended June 30, 2001, down from \$1.0 million for the year ended June 30, 2000. Costs and expenses decreased to \$7.5 million in 2001 from \$10.9 million in 2000. Aastrom management noted that the decrease in costs and expenses for the year was principally the result of decreased research and development costs for the AastromReplicell/TM/ System which decreased from \$6.3 million in 2000 to \$5.0 million in 2001, as the product line transitioned from development to commercial production. Additionally, general and administrative expense decreased from \$3.4 million in 2000 to \$2.5 million in 2001, reflecting planned decreases following cost reduction measures implemented mid-year 2000.

"During the past fiscal year, we continued to demonstrate outstanding leadership in the field of cell therapeutics," said R. Douglas Armstrong, Ph.D., President and CEO of Aastrom Biosciences. "Our dendritic cell product program progressed from the early stages of development to external beta site evaluation and we are now beginning early European pre-launch activities. Our Dendricell(TM) products are being developed in different formats for broad use in the emerging field of dendritic cell-based vaccines for the treatment of cancer."

Dr. Armstrong continued, "We have also steadily achieved goals in other areas throughout the year by initiating the clinical evaluation of our OC-I bone progenitor cell product in osteoporosis patients, and building our base of collaboration partners with the addition of Karmanos Cancer Institute at Wayne State University, the Beth Israel Deaconess Medical Center at Harvard Medical School, and Neoprobe Corporation. We also took a major step in effectively developing the European market, by recently activating Zellera AG, our wholly-owned German subsidiary, to serve as our operational base in Europe. Zellera, led by newly appointed Managing Director Holger Beckmann, will immediately lead support for our new European sales and marketing activities. Further, since May of this year, we have completed \$8 million in new equity financing to help fund our development activities."

The Company also reported that Todd Simpson, Vice President Finance and Administration and Chief Financial Officer, will leave Aastrom to pursue other opportunities. The Company has begun the process of hiring a new Chief Financial Officer and Mr. Simpson will continue to assist Aastrom during a transition period.

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Aastrom's Fiscal Year 2001 Highlights:

Collaboration/Product Developments:

- . A Phase I/II clinical trial to evaluate the therapeutic capabilities of Aastrom's bone progenitor cell product in the treatment of severe osteoporosis and other degenerative bone diseases was initiated at the University of Michigan.
- . A ten-fold improvement in stem cell production in the AastromReplicell(TM) System with a new cord blood therapy, prompted the Company to initiate a Phase I/II clinical study of its CB-II cord blood cell therapy product. This trial is evaluating the rate of normal blood cell recovery and survival in leukemia patients following a transplant of cord blood cells.
- . The Center for Cell Therapy (CCT) was established through collaborative efforts between Aastrom and the Barbara Ann Karmanos Cancer Institute at Wayne State University to develop new cell-based therapies. The CCT is initially being funded by a Michigan Economic Development Corporation award of a \$2.2 million Michigan Life Sciences Corridor grant.
- . A controlled clinical trial to evaluate Aastrom's CB-I cord blood cell therapy in the treatment of adult leukemia patients was initiated in February 2001. The multi-centered trial is designed to assess the effect that Aastrom's therapy has on enabling successful recovery of blood and immune system function following aggressive chemotherapy or radiation.
- . Aastrom's dendritic cell program moved forward quickly with the commencement of external clinical beta site evaluations in the United States. Among the first to conduct evaluations of the DC-I dendritic cell product for use in vaccines to treat various forms of cancer were the Barbara Ann Karmanos Cancer Institute at Wayne State University (Detroit, MI) and Beth Israel Deaconess Medical Center (Boston, MA), a Harvard Medical School teaching hospital.
- . Aastrom expanded its dendritic cell program to include German researchers using the DC-I product in pre-clinical evaluations, moving Aastrom closer to attaining an important objective of making its cell product broadly available for dendritic cell-based cancer vaccines.
- . A new patent entitled "Portable Cell Growth Cassette for Use in Maintaining and Growing Biological Cells" was issued to Aastrom, providing coverage for inoculating, maintaining, growing and harvesting human cells ex vivo in a cassette chamber format, without exposing the cells to the external environment.
- . Aastrom and Neoprobe Corporation initiated a collaboration to develop a new immune system cell therapy product for the treatment of cancer. Neoprobe's proprietary lymph node lymphocyte cell technology will be integrated with Aastrom's patented AastromReplicell(TM) System and lymphocyte production technologies for the intended production of a clinically usable cell therapy product.

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Commercialization Developments:

- . Aastrom activated its wholly-owned subsidiary, Zeller AG, in Berlin, Germany, under the direction of Holger Beckmann, who was named Managing Director in charge of European business operations. Zeller is intended to provide Aastrom with a greater capability to access and support the commercial market for its CE Mark-approved cell therapy products, as well as increase the opportunity for research and collaboration in Europe.

Financing Developments:

- . Federal funding was awarded to Aastrom to further the development of umbilical cord blood-derived cells for use in stem cell transplants for the treatment of leukemia and other blood diseases. The grant, from the National Heart, Lung and Blood Institute of the National Institute of Health (NIH), provides up to \$829,000 over two years, and will be a research collaboration with investigators at Duke University Medical Center.
- . Aastrom received additional federal funding from the National Cancer Institute, providing up to \$756,000 over two years. This NIH grant will support Aastrom's dendritic cell program that is producing dendritic cells, a type of blood cell, to trigger an immune response against specific cancer targets. Duke University Medical Center will partner with Aastrom in this research.
- . Since May 2001, Aastrom has completed \$8 million in new equity financing.

Leadership Developments:

- . Aastrom broadened the depth of its Board of Directors with the appointment of Alan M. Wright and Fabrizio Bonanni. Mr. Wright, Executive Vice President, CFO and Chief Administrative Officer of CMS Energy, and its principal subsidiary, Consumers Energy, brings extensive financial and business development experience to Aastrom. Dr. Bonanni, Senior Vice President of Amgen Corporation, strengthens Aastrom with additional experience in developing and commercializing medical devices and therapeutics.
- . To enhance Aastrom's commitment to position itself as a leading provider of cell-based therapeutics, Audrey Hutter joined the Company as Vice President Market Operations, to direct the Company's global sales and marketing efforts. In addition, Dr. Steven Wolff, M.D. joined Aastrom as Vice President Medical Research to oversee clinical and biological research activities, while furthering Aastrom's development of research collaborations in the field of cell therapeutics.

Aastrom is a leader in the development of proprietary cell therapeutics and cell products based on its dual-technology platforms: patented "single-pass perfusion" providing cells with enhanced biological function, and patented GMP-compliant system automation facilitating the delivery of cells for therapeutic use into medical practice. These technologies are integrated into the AastromReplicell(TM) System that is designed to uniquely standardize and automate the processes

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involved in producing high quality therapeutic cells. Aastrom is developing the Dendricell(TM) products for use in the rapidly emerging dendritic cell-based cancer vaccine market, and the OC-I bone progenitor cell product for the treatment of degenerative bone diseases such as osteoporosis. The AastromReplicell(TM) System, the SC-I bone marrow stem cell product and the CB-I cord blood cell product have received CE Mark approval necessary for European marketing and are in late-stage U.S. clinical trials. These products are not available for sale at this time in the U.S., except for research or investigational use.

Please visit our website at www.aastrom.com

This document contains forward-looking statements, including without limitation, statements concerning product development objectives, clinical trial results, commercial introduction plans, and potential advantages of the AastromReplicell(TM) System, which involve certain risks and uncertainties. The forward-looking statements are also identified through use of the words "intends," "designed," "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, competitive products and technologies, and the degree to which the Company's products achieve market acceptance. 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.

CONSOLIDATED STATEMENT OF OPERATIONS DATA:

	Quarter ended June 30,		Year ended June 30,	
	2000	2001	2000	2001
	(Unaudited)			
REVENUES:				
Product sales and rentals.....	\$ -	\$ -	\$ 169,000	\$ 85,000
Grants and other.....	149,000	246,000	981,000	814,000
Total revenues.....	149,000	246,000	1,150,000	899,000
COSTS AND EXPENSES:				
Cost of product sales and rentals.....	-	-	1,251,000	13,000
Research and development.....	874,000	1,543,000	6,289,000	4,983,000
Selling, general and administrative.....	768,000	710,000	3,364,000	2,482,000
Total costs and expenses.....	1,642,000	2,253,000	10,904,000	7,478,000
OTHER INCOME.....	145,000	118,000	364,000	653,000
NET LOSS.....	<u>\$(1,348,000)</u>	<u>\$(1,889,000)</u>	<u>\$(9,390,000)</u>	<u>\$(5,926,000)</u>
NET LOSS APPLICABLE TO COMMON SHARES.....	<u>\$(1,348,000)</u>	<u>\$(1,889,000)</u>	<u>\$(9,598,000)</u>	<u>\$(5,926,000)</u>
NET LOSS PER COMMON SHARE (Basic and Diluted).....	<u>\$(.04)</u>	<u>\$(.05)</u>	<u>\$(.41)</u>	<u>\$(.17)</u>
Weighted average number of common shares outstanding..	<u>31,777,000</u>	<u>34,761,000</u>	<u>23,344,000</u>	<u>34,030,000</u>

CONSOLIDATED BALANCE SHEET DATA:

	June 30, 2001
ASSETS	
Cash and investments.....	\$ 10,659,000
Other current assets.....	1,067,000
Property, net.....	179,000
Total assets.....	<u>\$ 11,905,000</u>
LIABILITIES AND SHAREHOLDERS' EQUITY	
Current liabilities.....	\$ 1,011,000
Shareholders' equity.....	10,894,000
Total liabilities and shareholders' equity.....	<u>\$11,905,000</u>

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