



**PROSPECTUS SUPPLEMENT  
(TO PROSPECTUS DATED DECEMBER 19, 2002)**

You should read this prospectus supplement and the related prospectus carefully before you invest. Both documents contain information you should consider when making your investment decision.

The information contained in this prospectus supplement updates the information in the prospectus filed on December 19, 2002. To the extent that there is a discrepancy between the information contained herein and the information in the initial prospectus, the information contained herein supercedes and replaces such conflicting information.

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

**FORM 10-Q**

(Mark One)

- QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934  
FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2003, OR
- TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934  
FOR THE TRANSITION PERIOD FROM        TO

Commission file number 0-22025

**AASTROM BIOSCIENCES, INC.**

(Exact name of registrant as specified in its charter)

Michigan

94-3096597

(State or other jurisdiction of  
incorporation or organization)

(I.R.S. employer  
identification no.)

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

48106

(Address of principal executive offices)

(Zip code)

(734) 930-5555

(Registrant's telephone number, including area code)

(Former name, former address and former fiscal year, if changed since last report)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

- Yes     - No

Indicate the number of shares outstanding of each of the issuer's classes of common stock as of the latest practicable date.

COMMON STOCK, NO PAR VALUE  
(Class)

56,749,879  
Outstanding at May 7, 2003

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AASTROM BIOSCIENCES, INC.  
Quarterly Report on Form 10-Q  
March 31, 2003

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**PART I - FINANCIAL INFORMATION***Item 1. Financial Statements*AASTROM BIOSCIENCES, INC.  
(a development stage company)CONSOLIDATED CONDENSED BALANCE SHEETS  
(Unaudited)

	June 30, 2002	March 31, 2003
<b>Assets</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 8,605,000	\$ 5,064,000
Short-term investments	1,000,000	—
Receivables, net	120,000	320,000
Inventory, net	1,397,000	1,132,000
Other current assets	225,000	454,000
	<hr/>	<hr/>
Total current assets	11,347,000	6,970,000
<b>PROPERTY, NET</b>	<b>206,000</b>	<b>322,000</b>
	<hr/>	<hr/>
Total assets	<b>\$ 11,553,000</b>	<b>\$ 7,292,000</b>
	<hr/>	<hr/>
<b>Liabilities and Shareholders' Equity</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable and accrued expenses	\$ 589,000	\$ 391,000
Accrued employee expenses	161,000	167,000
	<hr/>	<hr/>
Total current liabilities	750,000	558,000
	<hr/>	<hr/>
<b>SHAREHOLDERS' EQUITY:</b>		
Common stock, no par value; shares authorized – 100,000,000; shares issued and outstanding – 43,726,557 and 52,052,761, respectively	104,600,000	107,372,000
Deficit accumulated during the development stage	(93,797,000)	(100,638,000)
	<hr/>	<hr/>
Total shareholders' equity	10,803,000	6,734,000
	<hr/>	<hr/>
Total liabilities and shareholders' equity	<b>\$ 11,553,000</b>	<b>\$ 7,292,000</b>
	<hr/>	<hr/>

The accompanying notes are an integral part of these financial statements.

AASTROM BIOSCIENCES, INC.  
(a development stage company)CONSOLIDATED CONDENSED STATEMENTS OF OPERATIONS  
(Unaudited)

	Three months ended March 31,		Nine months ended March 31,		March 24, 1989 (Inception) to March 31, 2003
	2002	2003	2002	2003	
<b>REVENUES:</b>					
Product sales and rentals	\$ —	\$ 130,000	\$ 80,000	\$ 298,000	\$ 666,000
Grants	232,000	150,000	570,000	361,000	6,189,000
Research and development agreements	—	—	—	10,000	2,030,000
<b>Total revenues</b>	<b>232,000</b>	<b>280,000</b>	<b>650,000</b>	<b>669,000</b>	<b>8,885,000</b>
<b>COSTS AND EXPENSES:</b>					
Cost of product sales and rentals	—	21,000	—	132,000	173,000
Cost of product sales and rentals - provision for obsolete and excess inventory	40,000	186,000	146,000	445,000	1,876,000
Research and development	1,439,000	1,351,000	4,042,000	4,168,000	85,669,000
Selling, general and administrative	886,000	854,000	2,736,000	2,869,000	26,979,000
<b>Total costs and expenses</b>	<b>2,365,000</b>	<b>2,412,000</b>	<b>6,924,000</b>	<b>7,614,000</b>	<b>114,697,000</b>
<b>LOSS FROM OPERATIONS</b>	<b>(2,133,000)</b>	<b>(2,132,000)</b>	<b>(6,274,000)</b>	<b>(6,945,000)</b>	<b>(105,812,000)</b>
<b>OTHER INCOME (EXPENSE):</b>					
Other income	—	—	—	—	1,237,000
Interest income	61,000	30,000	289,000	104,000	5,172,000
Interest expense	—	—	—	—	(267,000)
<b>Other income</b>	<b>61,000</b>	<b>30,000</b>	<b>289,000</b>	<b>104,000</b>	<b>6,142,000</b>
<b>NET LOSS</b>	<b>\$ (2,072,000)</b>	<b>\$ (2,102,000)</b>	<b>\$ (5,985,000)</b>	<b>\$ (6,841,000)</b>	<b>\$ (99,670,000)</b>
<b>NET LOSS PER SHARE (Basic and Diluted)</b>	<b>\$ (.05)</b>	<b>\$ (.04)</b>	<b>\$ (.14)</b>	<b>\$ (.14)</b>	
<b>Weighted average number of shares outstanding</b>	<b>42,506,000</b>	<b>51,656,000</b>	<b>41,588,000</b>	<b>48,340,000</b>	

The accompanying notes are an integral part of these financial statements.

AASTROM BIOSCIENCES, INC.  
(a development stage company)CONSOLIDATED CONDENSED STATEMENTS OF CASH FLOWS  
(Unaudited)

	Nine months ended March 31,		March 24, 1989 (Inception) to March 31, 2003
	2002	2003	
<b>OPERATING ACTIVITIES:</b>			
Net loss	\$ (5,985,000)	\$ (6,841,000)	\$ (99,670,000)
Adjustments to reconcile net loss to net cash used for operating activities:			
Depreciation and amortization	94,000	90,000	3,417,000
Loss on property held for resale	—	—	110,000
Amortization of discounts and premiums on investments	—	—	(543,000)
Stock compensation expense	—	159,000	823,000
Inventory reserves and write-offs	146,000	445,000	1,674,000
Stock issued pursuant to license agreement	—	—	3,300,000
Changes in assets and liabilities:			
Receivables	(16,000)	(200,000)	(344,000)
Inventory	(415,000)	(277,000)	(2,903,000)
Other current assets	(137,000)	4,000	(221,000)
Accounts payable and accrued expenses	(115,000)	(198,000)	391,000
Accrued employee expenses	21,000	6,000	167,000
Net cash used for operating activities	(6,407,000)	(6,812,000)	(93,799,000)
<b>INVESTING ACTIVITIES:</b>			
Organizational costs	—	—	(73,000)
Purchase of short-term investments	(5,500,000)	—	(62,124,000)
Maturities of short-term investments	4,500,000	1,000,000	62,667,000
Capital purchases	(148,000)	(109,000)	(2,905,000)
Proceeds from sale of property held for resale	—	—	400,000
Net cash (used for) provided by investing activities	(1,148,000)	891,000	(2,035,000)
<b>FINANCING ACTIVITIES:</b>			
Issuance of preferred stock	—	—	51,647,000
Issuance of common stock	7,849,000	2,380,000	46,943,000
Repurchase of common stock	—	—	(49,000)
Payments received for stock purchase rights	—	—	3,500,000
Payments received under shareholder notes	—	—	31,000
Principal payments under capital lease obligations	—	—	(1,174,000)
Net cash provided by financing activities	7,849,000	2,380,000	100,898,000
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	294,000	(3,541,000)	5,064,000
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	10,659,000	8,605,000	—
CASH AND CASH EQUIVALENTS AT END OF PERIOD	\$10,953,000	\$ 5,064,000	\$ 5,064,000

The accompanying notes are an integral part of these financial statements.



**AASTROM BIOSCIENCES, INC.**  
**(A development stage company)**

**NOTES TO CONSOLIDATED CONDENSED FINANCIAL STATEMENTS**  
*(Unaudited)*

**1. Organization**

Aastrom Biosciences, Inc. (Aastrom) was incorporated in March 1989 (Inception), began employee-based operations in 1991, and is in the development stage. We currently operate our business in one reportable segment – research and product development, conducted both on our own behalf and in connection with various collaborative research and development agreements with others, involving the development and sale of processes and products for the *ex vivo* production of human cells for use in cell therapy.

Successful future operations are subject to several technical and business risks, including satisfactory product development, obtaining regulatory approval and market acceptance for our products and our continued ability to obtain future funding.

The Company is subject to certain risks related to the operation of its business and development of its products and product candidates. While available cash and committed financing are expected to fund currently planned activities through the first quarter (ending September 30, 2003) of fiscal year 2004, the Company will need to raise additional funds in order to complete its product development programs and commercialize its new products and product candidates. The Company cannot be certain that such funding will be available on favorable terms, if at all. Some of the factors that will impact the Company's ability to raise additional capital and its overall success include, the rate and degree of progress for its product development programs, the liquidity and volatility of its equity securities, economic conditions affecting the public markets generally or some portion or all of the technology sector, regulatory and manufacturing requirements and uncertainties, technological developments by competitors and other factors. If the Company cannot raise such funds, it may not be able to develop or enhance products, take advantage of future opportunities, or respond to competitive pressures or unanticipated requirements, which would negatively impact its business, financial condition and results of operations.

The Company is currently pursuing additional sources of financing. If the Company cannot obtain significant additional funding prior to or during the first quarter of the fiscal year beginning July 2003, it will likely make substantial reductions in the scope and size of its operations, and may curtail activities, in order to conserve cash until such funding is obtained.

## **2. Basis of Presentation**

The condensed consolidated financial statements included herein have been prepared by us without audit according to the rules and regulations of the Securities and Exchange Commission. Certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles in the United States have been omitted pursuant to such rules and regulations. The financial statements reflect, in the opinion of management, all adjustments necessary to present fairly the financial position and results of operations as of and for the periods indicated. The results of operations for the three and nine months ended March 31, 2003, are not necessarily indicative of the results to be expected for the full year or for any other period.

The consolidated financial statements include the accounts of Aastrom and its wholly-owned subsidiary, Zeller AG (“Zeller”), which is located in Berlin, Germany (collectively, the “Company”). All significant inter-company transactions and accounts have been eliminated in consolidation.

These financial statements should be read in conjunction with the audited financial statements and the notes thereto included in our 2002 Annual Report on Form 10-K, as filed with the Securities and Exchange Commission.

Certain previously reported statement of operations amounts have been reclassified to conform to the current period presentation. During the three months ended, March 31, 2003, the Company began segregating cost of product sales relating to the obsolescence of inventory. These costs previously included in the “Cost of product sales and rentals.” These reclassifications had no impact on previously reported net loss, shareholders’ equity or cash flows.

### 3. Stock-Based Compensation

At March 31, 2003 we have various stock-based employee compensation plans, which are described more fully in our 2002 Annual Report on Form 10-K, as filed with the Securities and Exchange Commission. We have elected to apply Accounting Principles Board Opinion No. 25 and related interpretations in accounting for our employee and directors' stock compensation plans

The summary of significant accounting policies should be read in conjunction with our

	For Nine Months Ended March 31,	
	2002	2003
Reported net loss	\$(5,985,000)	\$(6,841,000)
Add: Stock-based employee compensation expense included in reported net loss, net of related tax effects	—	—
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	(1,181,000)	(773,000)
Pro forma net loss	\$(7,166,000)	\$(7,614,000)
Net loss per common share:		
As reported	\$ (0.14)	\$ (0.14)
Pro forma	\$ (0.17)	\$ (0.16)

consolidated financial statements and related notes and this discussion of our results of operations.

### 4. Shareholders' Equity

We obtained additional equity of \$2,601,000 during the nine months ended March 31, 2003 and issued 8,326,000 common shares in these transactions. These equity financings were transacted under our previously registered shelf offerings and our Employee Stock Purchase Plan. Total offering costs were \$221,000.

### 5. Net Loss Per Common Share

Net loss per common share is computed using the weighted-average number of common shares outstanding during the period. Common equivalent shares are not included in the per share calculation where the effect of their inclusion would be anti-dilutive. The aggregate number of common equivalent shares that have been excluded from the computations of net loss per common share for the three and nine months ended March 31, 2002 and 2003 is approximately 6,475,000 and 3,869,000, respectively.

### Overview of Aastrom

We are a late-stage development company focused on human cell-based therapies. We have identified multiple paths to revenue based on our proprietary *ex vivo* cell production technology, including the near-term Cell Production Products business, and an active Prescription Cell Product pipeline for stem cell tissue repair and cancer and infectious disease treatments.

Our core technology is based on the Company's proprietary AastromReplicell™ System, an integrated system of instrumentation and single-use consumable kits that implements our patented Single-Pass Perfusion process in a fully automated closed-loop culturing system to optimize cell growth and viability. This system provides nutrients to cells by mimicking the natural cell-growth environment, and enabling cells to grow effectively while retaining high biological function, without various cloning approaches. Our programs currently use bone marrow, cord blood and blood cells as starting sources of cells. As such, federal support or other factors relating to embryonal stem cell research have no direct impact on our current product programs. In addition, this system provides GMP-compliant manufacturing and automated process control for the commercial-scale production of human cells. We do not believe that any other comparable system currently exists.

Our Cell Production Products operation has created a path to near-term revenue. The AastromReplicell™ System and DC-I (dendritic cells for fusion and transfection), DCV-I (complex antigen-loaded dendritic cells) and, once CE mark approval is obtained, DCV-II (peptide-loaded dendritic cells) cell production kits are being sold to academic researchers and companies that are developing cancer vaccines. The recent commercialization of our automated cell production instruments and cell-specific production kits is expected to generate revenues although we are not yet able to project the market size and growth for the products.

In addition, we are leveraging our *ex vivo* cell production technology for a growing Prescription Cell Product pipeline focused on two areas: Tissue Repair Cells (TRCs) for stem cell-derived tissue repair and regeneration, and Therapeutic Cells (TCs) for immune system-directed attacks on certain cancers and other infectious diseases.

Using the AastromReplicell™ System, TRCs are grown from a small sample of a patient's bone marrow and, once administered back to the patient, are intended to generate normal tissue. The primary TRC application being evaluated is our OCG-I cells for bone grafting (fusions, fractures or dental defects). We are currently planning and preparing for OCG-I clinical trials in both the United States and Europe. We also have in development OC-I cells for osteoporosis, and SC-I cells for autologous bone marrow transplants in lymphoma patients. The SC-I product has been CE-Marked in Europe and is currently being used by a limited number of centers in Europe to evaluate its use. In the United States, the SC-I therapy reached Phase III trials, although these trials have halted due to a shift in medical practice that reduced patient need and

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availability. The OC-I therapy is currently in a Phase I/II clinical trial. We also believe that the stem cell components of our TRCs may be useful for other medical indications, including the regeneration of cardiac and vascular tissues. Our CB-I clinical trials have been closed out. We have no plans to continue this product development activity at this time, unless entirely funded by grants, due to the limited size of the potential market.

We are led by a seasoned management team, which is advised by a well-respected Technology Review Board, comprised of senior medical, financial and marketing executives with extensive knowledge of our technology and industry. Management is in the process of leading a transition from our genesis as a medical device manufacturer to a contributor and developer in the broader and more potentially lucrative therapeutic sector.

We are developing TC products using human cells to cause the patient's immune system to attack certain cancers and other infectious diseases. Blood-derived dendritic cells, which are the body's crucial mobilizers of the immune T-Cells response, are cultured in the AastromReplicell™ System to produce our proprietary Dendricell™. After being exposed to a particular biological signal, or antigen, the Dendricell™ may act to trigger a cell-mediated immune response in a patient against the cancer cells or viri. The first Dendricell™ clinical trials are planned at Stanford University for a multiple myeloma cancer vaccine and at Duke University for a colorectal cancer vaccine. In addition, we have been in the pre-clinical stage for a T-cell therapeutic targeting the Epstein-Barr Virus.

In addition to our consumable DC-I and DCV-I cell product kits, we have begun marketing our automated cell production instruments in Europe and the United States for research use. Through Zellera AG, Aastrom's wholly owned subsidiary located in Berlin, Germany, we are actively coordinating country-specific sub-distributorships and service networks in Europe.

Since our inception, we have been in the development stage and engaged in research and product development, conducted principally on our own behalf, but also in connection with various collaborative research and development agreements with others. We commenced our initial pilot-scale product launch in Europe of the AastromReplicell™ System with the SC-I kit in April 1999. At approximately this same time, data was released at international meetings that resulted in the majority of the patients who would otherwise have been candidates for the SC-I product, to no longer require the use of the product. This loss of market for the SC-I caused us to reorganize our operations and suspend all marketing activities in October 1999, pending the receipt of additional financing and the completion of the reorganization process. While we've initiated marketing activities in Europe for the CE Marked SC-I, DC-I and the DCV-I products, we do not expect to generate positive cash flows from our consolidated operations for at least the next two to three years and then only if more significant product sales commence. Until that time, we expect that our revenue sources will consist of sales from our Cell Production Product operation to academic and commercial research centers, grant revenue and research funding, milestone payments and licensing fees from potential future corporate collaborators. To date, we have financed our operations through public and private sales of our equity securities. As a development-stage company, we have never been profitable and do not anticipate having net income unless and until significant product sales commence, which is unlikely to occur until we

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obtain significant additional funding. Through March 31, 2003, we have accumulated losses of approximately \$100 million. We cannot provide any assurance that we will be able to achieve profitability on a sustained basis, if at all, obtain the required funding, or complete a corporate partnering or acquisition transaction.

### **Clinical Development**

#### ***Previous Activities***

The AastromReplicell™ System and certain cell products produced using this system have been evaluated in multi-site clinical trials in the U.S. under Investigational Device Exemption (IDE) and Investigational New Drug (IND) from the FDA. The initial goals of our clinical trial program were to obtain a Pre-Market Approval (PMA) in the U.S., necessary to market the AastromReplicell™ System for autologous hematopoietic stem cell support after high-dose cytotoxic therapy for the treatment of patients with carcinoma of the breast and lymphoma, and to support European marketing activities. Recent discussions with the FDA have indicated that the cell products will now require a Biologics License Application (BLA) for product registration, which was not originally expected or planned.

We have conducted clinical trials in the U.S. evaluating bone marrow cells produced in the AastromReplicell™ System from a small starting amount of the patients own bone marrow. Results from initial studies demonstrated the ability of the AastromReplicell™ System to safely and reliably produce stem and progenitor cells that engraft and restore blood system function in breast cancer patients who had undergone very aggressive chemotherapy. Further, the small volume aspirate, along with a purging of contaminated tumor cells during the stem cell production, indicated a way to offer patients a transplant with a lower risk of receiving back tumor cells.

We had initiated a randomized Phase III U.S. clinical trial evaluating the SC-I cells produced with the AastromReplicell™ System to compliment traditional therapies by augmenting stem cells collected from a single Peripheral Blood Stem Cell (PBSC) apheresis procedure. The objectives of this study were to demonstrate that an optimal hematopoietic recovery could be achieved using the SC-I cells with a sub-optimal PBSC dose that otherwise would not provide this desired outcome. This procedure appears to improve the certainty of hematopoietic engraftment by providing a more reliable means of cell collection and blood count recovery.

However, during the course of the Phase III clinical trial of the SC-I cells, medical developments occurred that have influenced our strategy. These developments included:

- 1) The demonstration that bone marrow stem cells collected from the PBSC after mobilization by cytokine(s) and/or chemotherapy resulted in more rapid hematopoietic engraftment compared to stem cells collected directly from the bone marrow.
- 2) The demonstration that only a fraction of patients would be unable to be successfully mobilized for the collection of PBSC using a combination of chemotherapy with augmented dose hematopoietic cytokines.

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- 3) The demonstration that high-dose cytotoxic therapy requiring stem cell support did not result in increased survival benefit for patients with carcinoma of the breast compared with standard, less toxic chemotherapy. Thus eliminating this medical approach.
- 4) The demonstration that dose-dense chemotherapy followed by cytokine supported hematopoietic recovery may be an alternative to PBSC transplantation for patients with carcinoma of the breast.

The results of these medical market developments have substantially reduced the ability to accrue patients in the Phase III trial we had started. Further, these observations indicated to us that the market value of the product studied by the current clinical hematopoietic studies was becoming markedly constrained and much reduced from estimates performed before trial initiation. Given the limited market opportunity, the newly added regulatory requirements, and our available resources, we are no longer pursuing the Phase III trial.

With the greatly reduced market size for the SC-I cells, we pursued and successfully obtained Orphan Product Designation. However, given the large expense to complete the clinical trials for registration, we have decided to not proceed with these trials at this time.

We have also conducted clinical feasibility trials to evaluate umbilical cord blood (CB) cells produced in the AastromReplicell™ System to improve recoveries of pediatric and adult patients requiring donor derived (or allogeneic) stem cell transplants. Results of the pediatric transplants indicated that AastromReplicell™ System-produced cells were safe and well tolerated by the patients. Results from our adult cord blood trial may suggest that the AastromReplicell™ System could increase the quantity of cord blood cells available but do not significantly affect the hematopoietic recovery. We had extended these trials into a comparative adult trial with concurrent controls. Recently, the clinical enthusiasm for the use of CB for the treatment of adults has diminished with the identification of increased morbidity and mortality when compared to pediatric patients receiving CB transplantation. The increased morbidity was due to delayed hematopoietic and immunological recovery. The waning enthusiasm for CB transplants for adults has caused Aastrom to halt its CB comparative trial due to a very diminished market opportunity. Our research has identified alternative approaches with our technology that may be advantageous for patients. We may later pursue a clinical evaluation of one or more of these approaches.

### **Planned Activities**

An increase in the mesenchymal stromal cell content has been noted to be substantial in reviewing the pre-clinical and clinical data for our bone marrow cell products in various Aastrom supported trials. Mesenchymal stromal cells are integral for bone marrow to generate non-hematopoietic tissues such as bone and cartilage. Our bone marrow cell product had been given to one patient, on a compassionate basis, with a congenital genetic defect (hypophosphatasia) which results in a lethal condition of abnormal bone and cartilage formation. This compassionate use treatment, now published in the *Journal of Bone and Mineral Research*, resulted in sustained bone formation in the child that has continued to date after expanded cell infusion. Subsequently, we have demonstrated in the laboratory that our expanded bone marrow

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cell product is capable of forming bone. Based on these pre-clinical and clinical observations, we are now preparing to initiate clinical trials for bone regeneration in patients with severe fractures who require the addition of bone forming cells to their fracture site. The results of the fracture studies may allow our bone marrow cell product (termed "OCG-I") to also be used as an adjunct to spinal fusion surgery after appropriate clinical trials and review by the FDA. The market value of these two orthopedic procedures is substantially greater in comparison to the static and rather limited hematopoietic stem cell market. We are also planning to evaluate OCG-I cells to augment dental bone engraftment treatment as a method to improve the well-being of patients.

Our bone marrow cell product has also been demonstrated in the laboratory to contain a substantial numbers of cells capable of both forming and stimulating blood vessel growth. We are considering concepts of studying expanded bone marrow cells for the treatment of peripheral vascular disease based on clinical observations of efficacy using large volumes of unexpanded bone marrow cells.

The clinical trial direction of our studies has been influenced by observations limiting the scope of hematopoietic stem cell transplantation and by observations that our bone marrow cell products may be suitable as an adjunct to substantial market opportunities in bone and blood vessel regeneration.

### **Critical Accounting Policies**

There are several accounting policies that we believe are significant to the presentation of our consolidated financial statements. The most significant accounting policies include those related to inventory and revenue recognition.

*Inventory.* We value our inventory that consists primarily of finished components of our lead product, the AastromReplicell™ System, at the lower of cost (specific identification using first in, first out) or market. Furthermore, we regularly review inventory quantities on hand and record a provision to write down obsolete and excess inventory to its estimated net realizable value. Based on the aging of inventory at each period end, we utilize a systematic approach to determine our reserve for obsolete and excess inventory. Under this systematic approach, inventory that is less than twelve months old, based on the receipt date, will generally be carried at full value. Inventory quantities in excess of twelve months old are reserved over a six-month period, until the items are either sold or fully reserved. We feel this approach is appropriate given our limited product sales history and the risks associated with our ability to recover the inventory as we are still in the process of establishing our product market. Future technological changes, new product development and actual sales results could result in additional obsolete and excess inventory on hand. This could have a significant impact on the value of our inventory and our reported operating results.

*Revenue recognition.* We generate revenue from grants and research agreements, collaborative agreements and product sales and rentals. Revenue from grants and research agreements is recognized on a cost reimbursement basis consistent with the performance requirements of the related agreements. Revenue from collaborative agreements is recognized



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when the scientific or clinical results stipulated in the agreement have been met and there are no other ongoing obligations on our part. Revenue from product sales is recognized when title to the product transfers and there are no remaining obligations that will affect the customer's final acceptance of the sale, generally after installation and training. If there are remaining obligations, including training or installation, revenue is recognized upon completion of these obligations. Revenue from licensing fees under licensing agreements is recognized as revenue when there are no future performance obligations remaining with respect to such fees. Payments received before all obligations are fulfilled are classified as deferred revenue.

*Accounts receivable.* We make estimates evaluating collectibility of accounts receivable. We continuously monitor collections and payments from our customers and maintain an allowance for estimated credit losses based on any specific customer collection issues we have identified. While such credit issues have not been significant, there is no assurance that we will continue to experience the same low credit losses in the future.

### **Results of Operations**

Revenues, consisting of grant funding and products sales and rentals, for the quarter and nine month period ended March 31, 2003 were \$280,000 and \$669,000, respectively, compared to \$232,000 and \$650,000 for the same periods in 2002. Product sales and rentals increased for the quarter and nine months ended March 31, 2003 to \$130,000 and \$298,000, respectively, over \$0 and \$80,000 for the same periods in 2002, respectively, a result of increased marketing efforts in Europe. Grant revenues have decreased from the prior year as a result of reduced grant program activities. We also recorded \$10,000 in research and development agreements for the nine months ended March 31, 2003, resulting from the sublicense agreement with Corning Inc. We are continuing to pursue grant-funded programs, as well as actively pursuing European and domestic sales and marketing opportunities for research use.

Costs and expenses for the quarter ended March 31, 2003 increased to \$2,412,000 compared to \$2,365,000 for the same period in 2002. The increase in costs and expenses is due to an increase in cost of product sales and rentals to \$21,000 from \$0 and the increase in the non-cash provision for obsolete and excess inventory to \$186,000 from \$40,000. These increases were offset by research and development expense that decreased to \$1,351,000 from \$1,439,000 due primarily to decreased grant funded activities and selling, general and administrative expenses that decreased to \$854,000 from \$886,000. Costs and expenses for the nine months ended March 31, 2003 increased to \$7,614,000 compared to \$6,924,000 for the same period in 2002. Increases in costs and expenses during this period include increases in cost of product sales and rentals to \$132,000 from \$0 and the non-cash provision for obsolete and excess inventory to \$445,000 from \$146,000. Increases in costs and expenses also include research and development expense to \$4,168,000 from \$4,042,000 and selling, general and administrative expenses to \$2,869,000 from \$2,736,000, for the nine months ended March 31, 2003 and 2002, respectively. These increased costs and expenses are the result of continued program development activities, increased marketing activities in the areas of dendritic cell-based vaccines in the European market and preparation of our pending bone grafting trials and additional capital raising expenses. Selling, general and administrative expenses for the nine

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months ended March 31, 2003 includes a non-cash charge of \$159,000 relating to certain warrants issued in August 2002 for investment banking services.

Interest income was \$30,000 and \$104,000 for the quarter and nine months ended March 31, 2003, respectively, compared to \$61,000 and \$289,000 for the same periods in 2002. 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 decreases in yields from our investments.

Our net loss increased to \$2,102,000, and decreased to \$.04 per common share for the quarter ended March 31, 2003 compared to a net loss of \$2,072,000, or \$.05 per common share for the same period in 2002. Similarly, for the nine months ended March 31, 2003, our net loss increased to \$6,841,000, but remained flat at \$.14 per common share compared to \$5,985,000, or \$.14 per common share for the same period in 2002. These increases in our net loss are primarily the result of increased costs and expenses as the result of expanded research and market development activities and, for the purposes of computing per share amounts, were offset by an increase in the weighted average number of common shares outstanding resulting from additional equity financing.

### **Liquidity and Capital Resources**

We have financed our operations since inception primarily through public and private sales of equity securities, which, from inception through March 31, 2003, have totaled approximately \$107 million and, to a lesser degree, through grant funding, payments received under research agreements and collaborations and interest earned on cash, cash equivalents, and short-term investments. These financing sources have historically allowed us to maintain adequate levels of cash and other liquid investments.

Our combined cash, cash equivalents and short-term investments totaled \$5,064,000 at March 31, 2003, a decrease of \$4,541,000 from June 30, 2002. The primary uses of cash, cash equivalents and short-term investments during the nine month period ended March 31, 2003 included \$6,812,000 to finance our operations and working capital requirements. The primary source of cash, cash equivalents and short-term investments was from equity financing transactions, of which net proceeds of \$2,380,000 was raised during the nine month period ended March 31, 2003. This equity financing was transacted under our previously registered shelf offerings of common stock and the Employee Stock Purchase Plan.

Our future cash requirements will depend on many factors, including continued scientific progress in our research and development programs, the scope and results of clinical trials, the time and costs and results involved in obtaining regulatory approvals, competing technological and market developments and the cost of our product commercialization efforts. We do not expect to generate a positive cash flow from operations for at least the next two to three years due to the expected spending for research and development programs and the cost of commercializing our product candidates. We intend to seek additional funding through research and development, or distribution and marketing, agreements with suitable corporate

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collaborators, grants and through public or private financing transactions. Successful future operations are subject to several technical and business risks, including our continued ability to obtain future funding, satisfactory product development, obtaining regulatory approval and market acceptance for our products. We expect that our available cash and committed financing will be sufficient to fund currently planned activities through the first quarter (ending September 30, 2003) of fiscal year 2004. In addition to the agreement with Fusion Capital to purchase our common stock over a period of up to 24 months from October 2002, and the remaining 975,000 shares of common stock available on our extended shelf registration that various parties have expressed interest in purchasing, we are continuing to pursue additional sources of financing. If we cannot obtain significant additional funding prior to or during the first quarter of the fiscal year beginning July 2003, we will likely make substantial reductions in the scope and size of our operations, and may curtail activities, in order to conserve cash until such funding is obtained. These estimates are forward-looking statements based on certain assumptions which could be negatively impacted by the matters discussed under this heading and under the caption "Business Risks" in our 2002 Annual Report on Form 10-K. In order to grow and expand our business, and to introduce our product candidates into the marketplace, we will need to raise additional funds. We will also need additional funds or a collaborative partner, or both, to finance the research and development activities of our product candidates for the expansion of additional cell types. We expect that our primary sources of capital for the foreseeable future will be through collaborative arrangements and through the public or private sale of our debt or equity securities. There can be no assurance that such collaborative arrangements, or any public or private financing, will be available on acceptable terms, if at all, or can be sustained. Several factors will affect our ability to raise additional funding, including, but not limited to, the rate and degree of progress of our product development program, market volatility of our common stock and economic conditions affecting the public markets generally or some portion or all of the technology sector. If adequate funds are not available, we may be required to delay, reduce the scope of, or eliminate one or more of our research and development programs, which may have a material, adverse affect on our business. See "Business Risks" and "Notes to Consolidated Financial Statements" in our 2002 Annual Report on Form 10-K and "Notes to Consolidated Financial Statements" included herein.

### **Supply Chain**

We rely on third parties such as Astro, Moll, Cambrex (formerly Biowhittaker) and Amgen (OEMs) to manufacture our product candidates, component parts and growth factors and other materials used in the cell expansion process. In March 2003, we signed a three-year master supply agreement with Astro Instrumentation, L.L.C., to manufacture our products, component parts, subassemblies and associated spare parts, used in the instrumentation platform of our AastromReplicell™ System.

On September 2002 a major creditor of Moll filed an involuntary petition for Bankruptcy against Moll. On September 19, 2002 Moll announced that it had converted the case to a voluntary Chapter 11 reorganization case and have received a \$50 million, debtor-in-possession financing. To date there has been no significant impact on our supply of components from Moll.

## **Certain Business Considerations**

*Our past losses and expected future losses cast doubt on our ability to operate profitably.*

We were incorporated in 1989 and have experienced substantial operating losses since inception. As of March 31, 2003, we have incurred net losses totaling approximately \$100 million. These losses have resulted principally from costs incurred in the research and development of our cell culture technologies and the AastromReplicell™ System, general and administrative expenses, and the prosecution of patent applications. We expect to incur significant operating losses until product sales increase, primarily owing to our research and development programs, including pre-clinical studies and clinical trials, and the establishment of marketing and distribution capabilities necessary to support commercialization efforts for our products. We cannot predict with any certainty the amount of future losses. Our ability to achieve profitability will depend, among other things, on successfully completing the development of our product candidates, obtaining regulatory approvals, establishing manufacturing, sales and marketing arrangements with third parties, and raising sufficient funds to finance our activities. We may not be able to achieve or sustain profitability.

*Our inability to complete our product development activities successfully would severely limit our ability to operate or finance operations.*

Commercialization in the United States of our product candidates will require substantial clinical trials. While we have commenced initial marketing on a limited basis of the AastromReplicell™ System in Europe, we believe that the United States will be the largest market for our products. We may not be able to successfully complete development of our product candidates, or successfully market our technologies or product candidates. We, and any of our potential collaborators, may encounter problems and delays relating to research and development, regulatory approval and intellectual property rights of our technologies and product candidates. Our research and development programs may not be successful, and our cell culture technologies and product candidates may not facilitate the production of cells outside the human body with the expected result. Our technologies and product candidates may not prove to be safe and efficacious in clinical trials, and we may not obtain the requisite regulatory approvals for our technologies or product candidates and the cells produced in such products. If any of these events occur, we may not have adequate resources to continue operations for the period required to resolve the issue delaying commercialization and we may not be able to raise capital to finance our continued operation during the period required for resolution of that issue.

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*We may not be able to raise the required capital to conduct our operations and develop our products.*

We will require substantial capital resources in order to conduct our operations and develop our products. In October 1999, we were forced to reduce operations based on our declining level of capital resources and our limited financing alternatives available at that time. The previous reduction in our operating activities has delayed our product development programs. We expect that our available cash and financing will be sufficient to fund currently planned activities through the first quarter (ending September 30, 2003) of fiscal year 2004. In addition to the agreement with Fusion Capital to purchase our common stock over a period of up to 24 months from October 2002 and the remaining 975,000 shares of common stock available on our extended shelf registration, we are continuing to pursue additional sources of financing. If we cannot obtain significant additional funding prior to or during the first quarter of the fiscal year beginning July 2003, we will likely make substantial reductions in the scope and size of our operations, and may curtail activities, in order to conserve cash until such funding is obtained. In order to grow and expand our business, and to introduce our new product candidates into the marketplace, we will need to raise additional funds. We will also need additional funds or a collaborative partner, or both, to finance the research and development activities of our product candidates for the expansion of additional cell types.

Our future capital requirements will depend upon many factors, including:

- § continued scientific progress in our research and development programs;
- § costs and timing of conducting clinical trials and seeking regulatory approvals;
- § competing technological and market developments;
- § our ability to establish additional collaborative relationships; and
- § the effect of commercialization activities and facility expansions if and as required.

Because of our long-term funding requirements, we are likely to access the public or private equity markets if and whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time. Further, we may enter into financing transactions at rates, which are at a substantial discount to market. This additional funding may not be available to us on reasonable terms, or at all. If adequate funds are not available, we may be required to further delay or terminate research and development programs, curtail capital expenditures, and reduce business development and other operating activities.

*The issuance of additional common stock for funding has the potential for substantial dilution.*

As noted above, we will need additional equity funding to provide us with the capital to reach our objectives. At current market prices, such an equity issuance would cause a substantially larger number of shares to be outstanding and would dilute the ownership interest of existing stockholders. Pursuant to previously approved shareholder resolutions, the Board of Directors has the authority to increase the maximum number of authorized shares from 100 million to 150 million.

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*Our stock price has been volatile and future sales of substantial numbers of our shares could have an adverse effect on the market price of our shares.*

The market price of shares of our common stock has been volatile, ranging in closing price between \$0.23 and \$0.66 for the first nine months of fiscal year 2003. The price of our common stock may continue to fluctuate in response to a number of events and factors, such as:

- § clinical trial results;
- § the amount of our cash resources and our ability to obtain additional funding;
- § announcements of research activities, business developments, technological innovations or new products by us or our competitors;
- § entering into or terminating strategic relationships;
- § changes in government regulation;
- § disputes concerning patents or proprietary rights;
- § changes in our revenues or expense levels;
- § public concern regarding the safety, efficacy or other aspects of the products or methodologies we are developing;
- § reports by securities analysts; and
- § status of the investment markets.

Any of these events may cause the price of our shares to fall, which may adversely affect our business and financing opportunities. In addition, the stock market in general and the market prices for biotechnology companies in particular have experienced significant volatility that often has been unrelated to the operating performance or financial conditions of such companies. These broad market and industry fluctuations may adversely affect the trading price of our stock, regardless of our operating performance or prospects.

*Our stock may be delisted from Nasdaq that could affect its market price and liquidity.*

We are required to meet certain financial tests (including, but not limited to, a minimum bid price for our common stock of \$1.00) to maintain the listing of our common stock on the Nasdaq Stock Market. Our common stock price has traded below the \$1.00 minimum level and we have been notified that our common stock would be recommended for delisting (subject to any appeal we would file) if we did not regain compliance with this listing requirement prior to May 23, 2003. The end result could be that our stock may be delisted and moved to the OTC Bulletin Board or other quotation system for trading if we are not able to regain compliance or achieve the requirements established in an appeal.

*We must successfully complete our clinical trials to be able to market certain of our products.*

To be able to market cell products in the United States, we must demonstrate, through extensive preclinical studies and clinical trials, the safety and efficacy of our processes and product candidates, for application in the treatment of humans. If our clinical trials are not successful, our products may not be marketable.

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Our ability to complete our clinical trials in a timely manner depends on many factors, including the rate of patient enrollment. Patient enrollment can vary with the size of the patient population, the proximity of suitable patients to clinical sites, perceptions of the utility of cell therapy for the treatment of certain diseases and the eligibility criteria for the study. We have experienced delays in patient accrual in our previous and current clinical trials. If we experience future delays in patient accrual, we could experience increased costs and delays associated with clinical trials, which would impair our product development programs and our ability to market our products. Furthermore, the FDA monitors the progress of clinical trials and it may suspend or terminate clinical trials at any time due to patient safety or other considerations.

*Failure to obtain and maintain required regulatory approvals would severely limit our ability to sell our products.*

We must obtain the approval of the FDA before commercial sales of our product candidates may commence in the United States, which we believe will be the largest market for our products. We may also be required to obtain additional approvals from foreign regulatory authorities to continue or increase our sales activities in those jurisdictions. If we cannot demonstrate the safety, reliability and efficacy of our product candidates, or of the cells produced in such products, we may not be able to obtain required regulatory approvals. Patients receiving cells produced with our technologies and product candidates may not demonstrate long-term engraftment in a manner comparable to cells obtained from current hematopoietic stem cell therapy procedures. If we cannot demonstrate the safety or efficacy of our technologies and product candidates, including long-term sustained engraftment, or if one or more patients die or suffer severe complications, the FDA or other regulatory authorities could delay or withhold regulatory approval of our product candidates.

Finally, even if we obtain regulatory approval of a product, that approval may be subject to limitations on the indicated uses for which it may be marketed. Even after granting regulatory approval, the FDA, other regulatory agencies, and governments in other countries continue to review and inspect marketed products, manufacturers and manufacturing facilities. Later discovery of previously unknown problems with a product, manufacturer or facility may result in restrictions on the product or manufacturer, including a withdrawal of the product from the market. Further, governmental regulatory agencies may establish additional regulations which could prevent or delay regulatory approval of our products.

*Even if we obtain regulatory approvals to sell our products, lack of commercial acceptance would impair our business.*

We are seeking to obtain regulatory approval to market the AastromReplicell™ System for stem cell tissue repair and regeneration, and cancer and infectious disease treatments. Even if we obtain all required regulatory approvals, we cannot be certain that our products and processes will be adopted at a level that would allow us to operate profitably. Our technologies or product candidates may not be employed in all potential applications being investigated, and any reduction in applications would limit the market acceptance of our technologies and product candidates and our potential revenues.

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*Failure of third parties to manufacture component parts or provide limited source supplies would impair our new product development and our sales activities.*

We rely solely on third parties such as Astro, Moll, Cambrex and Amgen to manufacture our product candidates, component parts and growth factors and other materials used in the cell expansion process. We would not be able to obtain alternate sources of supply for many of these items on a short-term basis. If any of our key manufacturers or suppliers fail to perform their respective obligations or if our supply of growth factors, components or other materials is limited or interrupted, we would not be able to conduct clinical trials or market our product candidates on a timely and cost-competitive basis, if at all.

On September 2002 a major creditor of Moll filed an involuntary petition for Bankruptcy against Moll. On September 19, 2002 Moll announced that it had converted the case to a voluntary Chapter 11 reorganization case and had received a \$50 million debtor-in-possession financing. These factors may affect our supply of components.

Furthermore, some of the compounds used by us in our current bone marrow or cord blood cell expansion processes involve the use of animal-derived products. Suppliers or regulatory authorities may limit or restrict the availability of such compounds for clinical and commercial use. Any restrictions on these compounds would impose a potential competitive disadvantage for our products. Our inability to develop or obtain alternative compounds would harm our product development and commercialization efforts.

Finally, we may not be able to continue our present arrangements with our suppliers, supplement existing relationships, establish new relationships or be able to identify and obtain the ancillary materials that are necessary to develop our product candidates in the future. Our dependence upon third parties for the supply and manufacture of these items could adversely affect our ability to develop and deliver commercially feasible products on a timely and competitive basis.

*Given our limited internal sales and marketing capabilities, we need to develop increased internal capability or collaborative relationships to sell, market and distribute our products.*

While we have commenced initial marketing on a limited basis of the AastromReplicell™ System and SC-I, DC-I and DCV-I cell production kits in Europe and domestically for research use, we have only limited internal sales, marketing and distribution capabilities. We intend to get assistance to market our products through collaborative relationships with companies with established sales, marketing and distribution capabilities. While we have entered into such arrangements with respect to Switzerland, Turkey and Italy, we will need to establish additional relationships to be able to achieve the market coverage we desire. Our inability to develop and maintain those relationships would limit our ability to market, sell and distribute our products. Our inability to enter into successful, long-term relationships could require us to develop



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alternate arrangements at a time when we need sales, marketing or distribution capabilities to meet existing demand.

*Any changes in the governmental regulatory classifications of our products could prevent, limit or delay our ability to market or develop our products.*

The FDA establishes regulatory requirements based on the classification of a product. The AastromReplicell™ System may be regulated as a Class III medical device, or the FDA may ultimately choose to regulate the AastromReplicell™ System under another category. Because our product development programs are designed to satisfy the standards applicable to Class III medical devices and biological licensure for our cellular products, any change in the regulatory classification or designation would affect our ability to obtain FDA approval of our products. The AastromReplicell™ System is used to produce different cell mixtures, and each of these cell mixtures will, under current regulations be regulated as biologic products, which require a BLA. Other countries are adopting new strict policies and requirements for cell products. These new requirements may delay, restrict or prevent the sale or use of our products.

*If we do not keep pace with our competitors and with technological and market changes, our products may become obsolete and our business may suffer.*

The market for our products is very competitive, is subject to rapid technological changes and varies for different individual products. For each of our potential products, we believe that there are potentially many competitive approaches being pursued, including some by private companies for which information is difficult to obtain.

Many of our competitors have significantly greater resources, more product candidates and have developed product candidates and processes that directly compete with our products. Our competitors may have developed, or could in the future develop, new technologies that compete with our products or even render our products obsolete. As an example, in the past, published studies have suggested that hematopoietic stem cell therapy may have limited clinical benefit in the treatment of breast cancer, which was a significant portion of the overall hematopoietic stem cell transplant market. This resulted in a substantial decline in the market for the AastromReplicell™ System with our SC-I kit.

Our products are designed to improve and automate the processes for producing cells used in therapeutic procedures. Even if we are able to demonstrate improved or equivalent results, researchers and practitioners may not use our products and we will suffer a competitive disadvantage. As a result, we may be unable to recover the net book value of our inventory. Finally, to the extent that others develop new technologies that address the targeted application for our products, our business will suffer.

*If we cannot attract and retain key personnel, then our business will suffer.*

Our success depends in large part upon our ability to attract and retain highly qualified scientific and management personnel. We face competition for such personnel from other

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companies, research and academic institutions and other entities. Further, in an effort to conserve financial resources, we have implemented reductions in our work force on two separate occasions. As a result of these and other factors, we may not be successful in hiring or retaining key personnel. The Company has a key man life insurance policy for R. Douglas Armstrong, the Chairman, Chief Executive Officer and President of Aastrom. Our inability to replace any other lost key employee could harm our operations.

*If our patents and proprietary rights do not provide substantial protection, then our business and competitive position will suffer.*

Our success depends in large part on our ability to develop or license and protect proprietary products and technologies. However, patents may not be granted on any of our pending or future patent applications. Also, the scope of any of our issued patents may not be sufficiently broad to offer meaningful protection. In addition, our issued patents or patents licensed to us could be successfully challenged, invalidated or circumvented so that our patent rights would not create an effective competitive barrier. Furthermore, we rely on three exclusive, world-wide licenses relating to the production of human cells granted to us by the University of Michigan for certain of our patent rights. If we materially breach such agreements or otherwise fail to materially comply with such agreements, or if such agreements expire or are otherwise terminated by us, we may lose our rights under the patents held by the University of Michigan. At the latest, these licenses will terminate when the patent underlying the license expires. The first of these underlying patents will expire on March 21, 2012. We also rely on trade secrets and unpatentable know-how that we seek to protect, in part, by confidentiality agreements with our employees, consultants, suppliers and licensees. These agreements may be breached, and we might not have adequate remedies for any breach. If this were to occur, our business and competitive position would suffer.

*Intellectual property litigation could harm our business.*

Our success will also depend in part on our ability to develop commercially viable products without infringing the proprietary rights of others. Although we have not been subject to any filed infringement claims, other patents could exist or could be filed which would prohibit or limit our ability to market our products or maintain our competitive position. In the event of an intellectual property dispute, we may be forced to litigate. Intellectual property litigation would divert management's attention from developing our products and would force us to incur substantial costs regardless of whether we are successful. An adverse outcome could subject us to significant liabilities to third parties, and force us to curtail or cease the development and sale of our products and processes.

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*The government maintains certain rights in technology that we develop using government grant money and we may lose the revenues from such technology if we do not commercialize and utilize the technology pursuant to established government guidelines.*

Certain of our and our licensors' research have been or are being funded in part by government grants. As a result of such funding, the U.S. Government has certain rights in the technology developed with the grant. These rights include a non-exclusive, paid-up, world-wide license to use the technology for any governmental purpose. In addition, the government has the right to require us to grant an exclusive license to use the developed technology to a third party if the government determines that:

- § we have not taken adequate steps to commercialize such technology;
- § such action is necessary to meet public health or safety needs; or
- § such action is necessary to meet requirements for public use under federal regulations.

In these instances, we would not receive revenues on the products we developed. Additionally, technology that was partially funded by a federal research grant is subject to the following government rights:

- § products using the technology which are sold in the United States are to be manufactured substantially in the United States, unless a waiver is obtained;
- § the government may force the granting of a license to a third party who will make and sell the needed product if we do not pursue reasonable commercialization of a needed product using the technology; and
- § the U.S. Government may use the technology for its own needs.

If we fail to meet these guidelines, we would lose our exclusive rights to these products and we would lose potential revenue derived from the sale of these products.

*The market for our products will be heavily dependent on third party reimbursement policies.*

Our ability to successfully commercialize our product candidates will depend on the extent to which government healthcare programs, such as Medicare and Medicaid, as well as private health insurers, health maintenance organizations and other third party payors will pay for our products and related treatments. Reimbursement by third party payors depends on a number of factors, including the payor's determination that use of the product is safe and effective, not experimental or investigational, medically necessary, appropriate for the specific patient and cost-effective. Reimbursement in the United States or foreign countries may not be available or maintained for any of our product candidates. If we do not obtain approvals for adequate third party reimbursements, we may not be able to establish or maintain price levels sufficient to realize an appropriate return on our investment in product development. Any limits on reimbursement available from third party payors may reduce the demand for, or negatively affect the price of, our products. For example, in the past, published studies have suggested that stem cell transplantation in breast cancer that constitute a significant portion of the overall stem cell

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therapy market, at the time, may have limited clinical benefit. The lack of reimbursement for these procedures by insurance payors would negatively affect the marketability of our products.

*Potential product liability claims could affect our earnings and financial condition.*

We face an inherent business risk of exposure to product liability claims in the event that the use of the AastromReplicell™ System during research and development efforts, including clinical trials, or after commercialization results in adverse affects. As a result, we may incur significant product liability exposure, which could exceed existing insurance coverage. We may not be able to maintain adequate levels of insurance at reasonable cost and/or reasonable terms. Excessive insurance costs or uninsured claims would increase our operating loss and affect our financial condition.

*Our corporate documents and Michigan law contain provisions that may make it more difficult for us to be acquired.*

Our Board of Directors has the authority, without shareholder approval, to issue additional shares of preferred stock and to fix the rights, preferences, privileges and restrictions of these shares without any further vote or action by our shareholders. This authority, together with certain provisions of our charter documents, may have the affect of making it more difficult for a third party to acquire, or of discouraging a third party from attempting to acquire control of our company. This affect could occur even if our shareholders consider the change in control to be in their best interest.

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### *Forward-looking statements*

This report contains certain forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act. These forward-looking statements include statements regarding:

- § potential strategic collaborations with others;
- § future capital needs;
- § product development and marketing plan;
- § clinical trial plans and anticipated results;
- § anticipation of future losses;
- § replacement of manufacturing sources;
- § commercialization plans; and
- § revenue expectations and operating results.

These statements are subject to risks and uncertainties, including those set forth in this Certain Business Considerations section, and actual results could differ materially from those expressed or implied in these statements. All forward-looking statements included in this registration statement are made as of the date hereof. We assume no obligation to update any such forward-looking statement or reason why actual results might differ.

These business considerations, and others, are discussed in more detail and should be read in conjunction with the “Business Risks” discussed in our 2002 Annual Report of Form 10-K.

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### *Item 3. Quantitative and Qualitative Disclosures About Market Risk*

As of March 31, 2003, our cash and cash equivalents included only money market securities. Due to the short duration of our investment portfolio, an immediate 10% change in interest rates would not have a material effect on the fair market value of our portfolio, therefore, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a sudden change in market interest rates on our securities portfolio.

Our sales to customers in foreign countries are denominated in U.S. dollars. Accordingly, we are not directly exposed to market risks from currency exchange rate fluctuations. We believe that the interest rate risk related to our accounts receivable is not significant. We manage the risk associated with these accounts through periodic reviews of the carrying value for non-collectibility and establishment of appropriate allowances in connection with our internal controls and policies. We do not enter into hedging or derivative instruments.

### *Item 4. Controls and Procedures*

- (a) Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of our disclosure controls and procedures, as such term is defined under Rule 13a-14(c) promulgated under the Securities and Exchange Act of 1934, as amended within 90 days of the filing date of this report. Based on their evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures are effective.
- (b) There have been no significant changes (including corrective actions with regard to significant deficiencies or material weaknesses) in our internal controls or in other factors that could significantly affect these controls subsequent to the date of the evaluation referenced in paragraph (a) above.

**PART II - OTHER INFORMATION**

*Item 1. Legal Proceedings*

From time to time we receive threats or may be subject to litigation matters incidental to our business. However, we are not currently a party to any material pending legal proceedings.

*Item 2. Changes in Securities and Use of Proceeds*

None.

*Item 3. Defaults Upon Senior Securities*

None.

*Item 4. Submission of Matters to a Vote of Security Holders*

None.

*Item 5. Other Information*

None.

*Item 6. Exhibits and Reports on Form 8-K*

(a) Exhibits

See Exhibit Index.

(b) Reports on Form 8-K

None.

**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 thereunto duly authorized.

Date: May 14, 2003

AASTROM BIOSCIENCES, INC.

/s/ R. Douglas Armstrong

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R. Douglas Armstrong, Ph.D.  
President, Chief Executive Officer  
(Principal Executive Officer)

Date: May 14, 2003

/s/ Alan M. Wright

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Alan M. Wright  
Sr. Vice President Administrative & Financial  
Operations, Chief Financial Officer  
(Principal Financial and Accounting Officer)



**CERTIFICATIONS**

I, R. Douglas Armstrong, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Aastrom Biosciences, Inc.;
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
  - a. designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
  - b. evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and
  - c. presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
  - a. all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
  - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officer and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: May 14, 2003

/s/ R. Douglas Armstrong

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R. Douglas Armstrong, Ph.D.  
President, Chief Executive Officer  
(Principal Executive Officer)

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I, Alan M. Wright, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Aastrom Biosciences, Inc.;
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
  - a. designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
  - b. evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and
  - c. presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
  - a. all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
  - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officer and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: May 14, 2003

/s/ Alan M. Wright

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Alan M. Wright  
Sr. Vice President Administrative & Financial  
Operations, Chief Financial Officer  
(Principal Financial and Accounting Officer)

**EXHIBITS**

<b>Exhibit Number</b>	<b>Description</b>
3.1 *	Restated Articles of Incorporation of the Company
3.2 **	Bylaws of the Company
99.1	Certification of President and CEO
99.2	Certification of Senior Vice President Administrative and Financial Operations, CFO

\* Incorporated by reference to the Company's Annual Report on Form 10-K for the fiscal year ended June 30, 2002.

\*\* Incorporated by reference to the Company's Registration Statement on Form S-1 (No. 333-15415), declared effective on February 3, 1997.

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

I, R. Douglas Armstrong, Chief Executive Officer of Aastrom Biosciences, Inc. (the "Registrant"), do hereby certify in accordance with 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) the Quarterly Report on Form 10-Q of the Registrant, to which this certification is attached as an exhibit (the "Report"), fully complies with the requirements of section 13(a) of the Securities Exchange Act of 1934 (15 U.S.C. 78m); and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

Dated: May 14, 2003

/s/ R. Douglas Armstrong

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R. Douglas Armstrong, Ph.D.  
President and Chief Executive  
Officer

CERTIFICATION OF CHIEF FINANCIAL OFFICER

I, Alan M. Wright, Chief Financial Officer of Aastrom Biosciences, Inc. (the "Registrant"), do hereby certify in accordance with 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) the Quarterly Report on Form 10-Q of the Registrant, to which this certification is attached as an exhibit (the "Report"), fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934 (15 U.S.C. 78m); and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

Dated: May 14, 2003

/s/ Alan M. Wright

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Alan M. Wright  
Senior Vice President Administrative  
& Financial Operations,  
Chief Financial Officer, Secretary &  
Treasurer