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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 SEPTEMBER 30, 2003, OR

o 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 - o

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act).
Yes - o 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	71,275,849
(Class)	Outstanding at November 12, 2003

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AASTROM BIOSCIENCES, INC.
Quarterly Report on Form 10-Q
September 30, 2003

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PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

AASTROM BIOSCIENCES, INC.
(a development stage company)

CONSOLIDATED CONDENSED BALANCE SHEETS

	June 30, 2003	September 30, 2003 (Unaudited)
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	$ 10,512,000	$ 13,110,000
Receivables, net	350,000	373,000
Inventory, net	806,000	545,000
Other current assets	185,000	625,000
Total current assets	11,853,000	14,653,000
PROPERTY, NET	302,000	305,000
Total assets	$ 12,155,000	$ 14,958,000
Liabilities and Shareholders' Equity		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	$ 406,000	$ 463,000
Accrued employee benefits	174,000	180,000
Total current liabilities	580,000	643,000
SHAREHOLDERS' EQUITY:		
Common stock, no par value; shares authorized - 100,000,000; shares issued and outstanding - 64,812,422 and 71,244,315, respectively	114,951,000	120,529,000
Deficit accumulated during the development stage	(103,376,000)	(106,214,000)
Total shareholders' equity	11,575,000	14,315,000
Total liabilities and shareholders' equity	$ 12,155,000	$ 14,958,000

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 September 30,		March 24, 1989 (Inception) to September 30, 2003
	2002	2003	
REVENUES:			
Product sales and rentals	$ 7,000	$ 25,000	$ 707,000
Research and development agreements	—	—	2,030,000
Grants	86,000	275,000	6,623,000
Total revenues	93,000	300,000	9,360,000
COSTS AND EXPENSES:			
Cost of product sales and rentals	—	12,000	400,000
Cost of product sales and rentals – provision for obsolete and excess inventory	88,000	253,000	2,230,000
Research and development	1,385,000	1,356,000	88,504,000
Selling, general and administrative	1,113,000	1,565,000	29,692,000
Total costs and expenses	2,586,000	3,186,000	120,826,000
LOSS FROM OPERATIONS	(2,493,000)	(2,886,000)	(111,466,000)
OTHER INCOME (EXPENSE):			
Other income	—	—	1,237,000
Interest income	41,000	48,000	5,250,000
Interest expense	—	—	(267,000)
Total other income	41,000	48,000	6,220,000
NET LOSS	$ (2,452,000)	$ (2,838,000)	$(105,246,000)
COMPUTATION OF NET LOSS APPLICABLE TO COMMON SHARES:			
NET LOSS	$ (2,452,000)	$ (2,838,000)	
NET LOSS PER COMMON SHARE (Basic and Diluted)	$ (.05)	$ (.04)	
Weighted average number of common shares outstanding	44,886,000	70,662,000	

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)

	Three months ended September 30,		March 24, 1989 (Inception) to September 30, 2003
	2002	2003	
OPERATING ACTIVITIES:			
Net loss	$(2,452,000)	$ (2,838,000)	$(105,246,000)
Adjustments to reconcile net loss to net cash used for operating activities:			
Depreciation and amortization	28,000	29,000	3,475,000
Loss on property held for resale	—	—	110,000
Amortization of discounts and premiums on investments	—	—	(543,000)
Stock compensation expense	159,000	425,000	1,424,000
Inventory write downs and reserves	88,000	253,000	2,230,000
Stock issued pursuant to license agreement	—	—	3,300,000
Changes in assets and liabilities:			
Receivables	3,000	(23,000)	(397,000)
Inventory	(176,000)	8,000	(2,871,000)
Other current assets	(279,000)	(440,000)	(625,000)
Accounts payable and accrued expenses	79,000	57,000	463,000
Accrued employee benefits	6,000	6,000	180,000
Net cash used for operating activities	(2,544,000)	(2,523,000)	(98,500,000)
INVESTING ACTIVITIES:			
Organizational costs	—	—	(73,000)
Purchase of short-term investments	—	—	(62,124,000)
Maturities of short-term investments	—	—	62,667,000
Capital purchases	—	(32,000)	(2,947,000)
Proceeds from sale of property held for resale	—	—	400,000
Net cash used for investing activities	—	(32,000)	(2,077,000)
FINANCING ACTIVITIES:			
Issuance of preferred stock	—	—	51,647,000
Issuance of common stock	869,000	5,153,000	59,732,000
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	869,000	5,153,000	113,687,000
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(1,675,000)	2,598,000	13,110,000
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	8,605,000	10,512,000	—
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 6,930,000	$13,110,000	$ 13,110,000

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 late-stage development. The Company operates its business in one reportable segment – research and product development, conducted both on its 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 its products and the Company's 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 investments are expected to finance currently planned activities at least through the end of fiscal year 2004, the Company will need to raise additional funds in order to complete its product development programs and commercialize its first 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 include, but are not limited to, the rate and degree of progress demonstrated in its product development programs, the liquidity and volatility of its equity securities, regulatory and manufacturing requirements and uncertainties, technological developments by competitors, and the general availability of capital in the private and public debt and equity market. If the Company cannot raise additional 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.

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 (consisting only of normal, recurring 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 months ended September 30, 2003, are not necessarily indicative of the results to be expected for the full year or for any other period.

These financial statements should be read in conjunction with the audited financial statements and the notes thereto included in our 2003 Annual Report on Form 10-K for the year ended June 30, 2003, as filed with the Securities and Exchange Commission.

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

Certain previously reported statement of operations amounts have been reclassified to conform to the current period presentation. In March 2003, the Company began segregating cost of product sales relating to the obsolescence of inventory. These costs previously were 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 Employee Compensation

The Company has a stock incentive plan that is described more fully in Note 3 to the consolidated financial statements included in our Annual Report on Form 10-K for the year ended June 30, 2003. The Company accounts for this plan under the recognition and measurement principles of APB Opinion No. 25, “Accounting for Stock Issued to Employees” and related Interpretations. The following table illustrates the effect on net loss and net loss per share if we had applied the fair value recognition provisions of Statement of Financial Accounting Standards (SFAS) No. 123, “Accounting for Stock-Based Compensation”:

	For Three Months Ended September 30,	
	2002	2003
Reported net loss	$(2,452,000)	$(2,838,000)
Add: Stock-based employee compensation expense included in reported net loss, net of related tax effects	—	372,000
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	(928,000)	(921,000)
Pro forma net loss	$(3,380,000)	$(3,387,000)
Net loss per common share:		
As reported	$ (0.05)	$ (0.04)
Pro forma	$ (0.08)	$ (0.05)

4. Shareholders' Equity

During the three months ended September 30, 2003, the Company issued 6,405,840 shares of common stock to multiple investors and 26,053 shares of common stock to employees as part of the Employee Stock Purchase Plan, for net proceeds of approximately $5,153,000. As part of one of these transactions, the Company issued warrants to private placement investors, exercisable for 4 years to purchase up to 1,264,706 shares of common stock at a price of $1.23, as well as warrants to purchase up to 1,011,765 shares of common stock at $1.50 per share prior to October 31, 2003 that expired, unexercised. In addition, warrants to purchase 303,529 shares of common stock were issued to a private placement agent, exercisable for 4 years at a price of $1.23. The Company also issued warrants to two individuals, who performed investor and public relations services, exercisable for one year to purchase up to an aggregate of 100,000 shares of common stock at a price of $0.50.

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 periods ended September 30, 2002 and 2003 is approximately 8,611,000 and 6,031,000, respectively.

6. Recent Accounting Developments

In November 2002, the FASB issued Interpretation No. 45, "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others." This interpretation elaborates on the disclosures required in financial statements concerning obligations under certain guarantees. It also clarifies the requirements related to the recognition of liabilities by a guarantor at the inception of certain guarantees. The disclosure

requirements of this interpretation were effective for Aastrom on December 31, 2002 but did not require any additional disclosures. The initial recognition and measurement provisions of the interpretation are effective to guarantees issued or modified after December 31, 2002. The adoption of Interpretation No. 45 did not have a material impact on the financial position or results of operations of Aastrom.

In January 2003, the FASB issued Interpretation No. 46, “Consolidation of Variable Interest Entities, an interpretation of ARB No. 51.” This interpretation provides guidance on: 1) the identification of entities for which control is achieved through means other than through voting rights, known as “variable interest entities” (VIEs); and 2) which business enterprise is the primary beneficiary and when it should consolidate the VIE. This new model for consolidation applies to entities: 1) where the equity investors (if any) do not have a controlling financial interest; or 2) whose equity investment at risk is insufficient to finance that entity’s activities without receiving additional subordinated financial support from other parties. In addition, this interpretation requires that both the primary beneficiary and all other enterprises with a significant variable interest in a VIE make additional disclosures. For VIEs created or acquired prior to February 1, 2003, the provisions of the interpretation were initially to be applied no later than the beginning of the first interim or annual reporting period beginning after June 15, 2003, with a subsequent deferral period of application no later than December 15, 2003. Certain disclosures were effective immediately. The adoption of Interpretation No. 46 did not have a material impact on the financial position or results of operations of Aastrom.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

Overview of Aastrom

Aastrom Biosciences, Inc. (Aastrom) was incorporated in March 1989 (Inception), began employee-based operations in 1991. 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.

We are a late-stage development company that has strategically moved from a business model that was originally based on the Bone Marrow Transplantation market to a company focused on human cell-based therapies. We have identified a multiple path strategy to pursue revenue based on our proprietary *ex vivo* cell production technology, including the near-term Cell Production Products operation, and an active Prescription Cell Product pipeline for stem cell tissue repair and regeneration, 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 enables 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 modest near-term revenue. The AastromReplicell™ System and DC-I (dendritic cells for fusion and transfection), DCV-I (complex antigen-loaded dendritic cells) and 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 or potential revenues or revenue growth for these products. The European Union has recently issued new requirements regarding the manufacturing of cell products and clinical trials. These changes have delayed or in some cases temporarily halted dendritic cell clinical trials in Europe, which has reduced the number of customer opportunities and affected our progress in our Cell Production Products business.

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 with its patented single-pass perfusion, 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). In August 2003, the FDA approved our IND application to begin a multi-center Phase I/II clinical trial for bone grafting. 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 kit has been CE-Marked in Europe and is currently being evaluated by a limited number of centers in Europe. 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 availability. 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 product development of the CB-I kit at this time, unless entirely funded by grants, due to the limited size of the potential market.

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 are in the pre-clinical stage for a T-cell therapeutic targeting the Epstein-Barr Virus.

In addition to our consumable DC-I, DCV-I and DCV-II 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.

While we have initiated marketing activities in Europe for the CE Marked SC-I, DC-I, DCV-I and the DCV-II 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 we can successfully generate significant product sales. In the next two to three years, 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 and licensing fees from potential future corporate collaborators. To date, we have financed our operations primarily 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. Achieving this objective will require significant

additional funding. Through September 30, 2003, we have accumulated losses of approximately $105 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 to achieve our operating objectives, or complete additional corporate partnering or acquisition transactions.

Clinical Development

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

Planned Activities

In reviewing the pre-clinical and clinical data for our bone marrow cell products in various Aastrom supported trials, we have noted a substantial increase in the mesenchymal stromal cell content. 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. The results of compassionate use treatment, now published in the *Journal of Bone and Mineral Research*, demonstrated sustained bone formation in the child that has continued after expanded cell infusion. Subsequently, we have demonstrated in the laboratory that our expanded bone marrow cell product is capable of forming bone. Based on these pre-clinical and clinical observations, we are now preparing to initiate clinical trials, both in the U.S. and Europe, 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 for these two orthopedic procedures is substantial. 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 number 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 preliminary results of our pre-pivotal trials may not be indicative of results that will be obtained from subsequent patients in the trials or from more extensive trials. Further, our pre-pivotal or pivotal trials may not be successful, and we may not be able to obtain the required biologic license application (BLA) registration or required foreign regulatory approvals for the AastromReplicell™ System in a timely fashion, or at all. See “Certain Business Considerations.”

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 or lymphoma, and to support European marketing activities. The FDA has 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 patient's 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 possible 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.

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 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 that Phase III trial. With the greatly reduced market size for the SC-I cells, we successfully obtained Orphan Product Designation.

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 rate of hematopoietic recovery. We had extended these trials into a comparative adult trial with concurrent controls. 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 the very diminished market opportunity. Our research has identified alternative approaches with our technology using stromal cells for *ex vivo* production of CB cells. We may later pursue a clinical evaluation of one or more of these approaches.

Strategic Relationships

In June 2003, we announced a strategic alliance with the Musculoskeletal Transplant Foundation (MTF) to jointly develop and commercialize innovative treatments for the regeneration of tissues such as bone and cartilage. The collaboration aligns us with the leading provider of allograft, or donor-derived tissue, materials (matrices) with a focus on forming a coordinated business and clinical approach for new products and treatments needed in orthopedic medicine.

Under the terms of the alliance, Aastrom and MTF will coordinate and fund the development of products that are based on combinations of MTF’s matrices and our Tissue Repair Cells (TRCs). The companies will share in the development and clinical trial expense of these treatment approaches and products, and will adopt a coordinated promotion and marketing strategy for future products. In addition to the initial focus of allograft-based bone graft treatments employing combination products, the companies will explore new approaches

for the regeneration of joint cartilage, as well as effective combinations of TRCs with MTF's new ceramic technology.

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, revenue recognition and accounts receivable.

Inventory. We value our inventory, that consists primarily of finished components of our lead product, the AastromReplicell™ Cell Production System, at the lower of cost (specific identification using the first in, first out method) 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 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 risk 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, product sales and rentals and licensing arrangements. 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 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 (which we believe to be significant), 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 credit losses in the future.

The summary of significant accounting policies should be read in conjunction with our consolidated financial statements and related notes and this discussion of our results of operations, as well as in conjunction with our audited financial statements contained in our 2003 Annual Report on Form 10-K.

Results of Operations

Revenues for the quarter ended September 30, 2003 were $300,000, which consisted of grant revenues and product sales and rentals, compared to revenues of $93,000 for the same period in 2002. Grant revenues have increased from the prior year as a result of additional grant awards from the National Institutes of Health. Product sales and rentals increased slightly to $25,000 for the quarter ended September 30, 2003 from $7,000 for the same period in 2002. This increase is primarily due to sales of our therapy kits. We continue to pursue grant-funded programs as well as European sales and marketing opportunities.

Costs and expenses for the quarter ended September 30, 2003 increased to $3,186,000, compared to $2,586,000 for the same period in 2002. Increases in costs and expenses during this period include increases in cost of product sales and rentals to $12,000 in the first quarter of fiscal year 2004 from $0 in the first quarter of fiscal year 2003 and an increase in the non-cash provision for obsolete and excess AastromReplicellä System inventory to $253,000 in the first quarter of 2004 from $88,000 in the first quarter of fiscal year 2003. The increase in costs and expenses also includes selling, general and administrative expenses that increased to $1,565,000 in the first quarter of fiscal year 2004 from $1,113,000 in the comparable period of fiscal year 2003. This is the result of a non-cash charge of $53,000 relating to certain warrants issued in August 2003 for public and investor relations services, and a $372,000 non-cash charge related to an employee performance-based stock option that vested in September 2003. Research and development expenses for the quarter ended September 30, 2003 decreased slightly to $1,356,000 from $1,385,000 in the comparable period of fiscal year 2003, as we continue research and product development activities in the areas of dendritic-cell based vaccines, tissue regeneration and preparation for our pending bone grafting trials.

Interest income was $48,000 for the quarter ended September 30, 2003 compared to $41,000 for the same period 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.

Aastrom’s net loss was $2,838,000, or $.04 per common share for the quarter ended September 30, 2003 compared to $2,452,000, or $.05 per common share for the same period in 2002. This increase in net loss is primarily the result of increased costs and expenses offset on a per share basis by an increase in the weighted average number of common shares outstanding resulting from the additional equity financing as addressed in the “Liquidity and Capital Resources” discussion below.

Liquidity and Capital Resources

We have financed our operations since inception primarily through public and private sales of equity securities, which, from inception through September 30, 2003, have totaled approximately $121 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 to continue our operations at planned levels.

Our combined cash, cash equivalents and short-term investments totaled $13,110,000 at September 30, 2003, an increase of $2,598,000 from June 30, 2003. The primary uses of cash, cash equivalents and short-term investments during the quarter ended September 30, 2003 included $2,523,000 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 $5,153,000 was raised during the quarter. This equity financing was obtained under multiple transactions 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 involved in obtaining regulatory approvals, the costs involved in filing, prosecuting and enforcing patents, competing technological and market developments and the cost of product commercialization. We do not expect to generate a positive cash flow from operations for at least the next several 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 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 financing will be sufficient to fund currently planned activities through our 2004 fiscal year (ending June 30, 2004). However, 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 are currently pursuing additional sources of financing. These estimates are forward-looking statements based on certain assumptions which could be negatively impacted by the matters discussed under “Certain Business Considerations” and under the caption “Business Risks” in our 2003 Annual Report on Form 10-K. 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, 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 2003 Annual Report on Form 10-K and “Notes to Consolidated Financial Statements” and “Certain Business Considerations” included herein.

New Accounting Standards

In November 2002, the FASB issued Interpretation No. 45, “Guarantor’s Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others.” This interpretation elaborates on the disclosures required in financial statements concerning obligations under certain guarantees. It also clarifies the requirements related to the recognition of liabilities by a guarantor at the inception of certain guarantees. The disclosure requirements of this interpretation were effective for Aastrom on December 31, 2002 but did not require any additional disclosures. The initial recognition and measurement provisions of the interpretation are effective to guarantees issued or modified after December 31, 2002. The adoption of Interpretation No. 45 did not have a material impact on the financial position or results of operations of Aastrom.

In January 2003, the FASB issued Interpretation No. 46, “Consolidation of Variable Interest Entities, an interpretation of ARB No. 51.” This interpretation provides guidance on: 1) the identification of entities for which control is achieved through means other than through voting rights, known as “variable interest entities” (VIEs); and 2) which business enterprise is the primary beneficiary and when it should consolidate the VIE. This new model for consolidation applies to entities: 1) where the equity investors (if any) do not have a controlling financial interest; or 2) whose equity investment at risk is insufficient to finance that entity’s activities without receiving additional subordinated financial support from other parties. In addition, this interpretation requires that both the primary beneficiary and all other enterprises with a significant variable interest in a VIE make additional disclosures. For VIEs created or acquired prior to February 1, 2003, the provisions of the interpretation were initially to be applied no later than the beginning of the first interim or annual reporting period beginning after June 15, 2003, with a subsequent deferral period of application no later than December 15, 2003. Certain disclosures were effective immediately. The adoption of Interpretation No. 46 did not have a material impact on the financial position or results of operations of Aastrom.

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 September 30, 2003, we have incurred cumulative net losses totaling approximately $105 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.

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 cell 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 of cells and equipment 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 and regulatory agencies in other countries continue to review and inspect marketed products, manufacturers and manufacturing facilities, which may create additional regulatory burdens. 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, regulatory agencies may establish additional regulations that could prevent or delay regulatory approval of our products.

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.

The European Union has recently issued new requirements regarding the manufacturing of cell products and clinical trials. These changes have delayed or in some cases temporarily halted dendritic cell clinical trials in Europe, which has reduced the number of customer opportunities and affected our progress in our Cell Production Products business. Additionally, recent changes to the European Union Medical Products Prime Directive shifted patient-derived cells to the medicinal products category. These new regulations may delay some of our current planned clinical trials in Europe.

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 cell 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.

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 our 2004 fiscal year (ending June 30, 2004). However, 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. Accordingly, we are continuing to pursue additional sources of financing.

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 in the future, 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.

Our stock price has been volatile and future sales of substantial numbers of our shares could have an adverse affect 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 $1.77 during the twelve month period ended September 30, 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.

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

To be able to market Prescription 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.

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.

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

We are seeking to obtain regulatory approval to market stem cell tissue repair and regeneration treatments, 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 tissue repair products will face competition from existing, and/or potential other new treatments in the future which could limit revenue potential. It may be necessary to increase the yield and/or cell type purity, for certain of our AastromReplicell™ System cell processes to gain commercial acceptance. 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.

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.

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.

Our stock may be delisted from Nasdaq, which could affect its market price and liquidity.

We are required to meet certain financial tests (including 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 may be recommended for delisting (subject to any appeal we would file) if we do not maintain compliance with the Nasdaq requirements within specified periods and subject to permitted extensions. If our common stock were delisted, it could be more difficult to buy or sell our common stock and to obtain accurate quotations, and the price of our stock could suffer a material decline. Delisting would also impair our ability to raise capital.

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, DCV-I and DCV-II 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 alternate arrangements at a time when we need sales, marketing or distribution capabilities to meet existing demand.

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 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.

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 for breast cancer, that constituted a significant portion of the overall stem cell 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.

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 plans;
- clinical trial plans and anticipated results;
- anticipation of future losses;
- 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. In some cases, you can identify these statements by our use of forward-looking words such as “may,” “will,” “should,” “anticipate,” “expect,” “estimate,” “plan,” “believe,” “potential,” or “intend.” All forward-looking statements included in this report 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 2003 Annual Report of Form 10-K.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

As of September 30, 2003, our cash and cash equivalents included money market securities and commercial paper. 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 President and Chief Financial Officer, we evaluated the effectiveness of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) promulgated under the Securities and Exchange Act of 1934, as amended. Based on this evaluation, our President and Chief Financial Officer concluded that our disclosure controls and procedures are effective as of the end of the period covered by this quarterly report.

(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

In July 2003, we issued 5,058,824 shares of common stock in a private placement transaction to nine institutional investors, for total cash consideration of $4,300,000. As part of this transaction, we also issued the investors warrants to purchase 1,264,706 shares of common stock at a $1.23 per share through July 9, 2007 and warrants to purchase 1,011,765 shares of common stock at $1.50 per share through October 31, 2003 that expired, unexercised. We paid the placement agent a cash commission of $307,468 and also issued the placement agent warrants to purchase 303,529 shares of common stock at $1.23 per share through July 9, 2007. In August 2003, we issued warrants to purchase an aggregate of 100,000 shares of common stock at $0.50 per share through August 4, 2004 to two individuals who had performed investor and public relations services for Aastrom. These securities were issued in private transactions to purchasers who acquired these securities for investment purposes and were exempt from registration pursuant to Section 4(2) of the Securities Act.

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

During the quarter ended September 30, 2003 we submitted the following reports on Form 8-K:

(1) July 10, 2003 (Press Release relating to consummation of financing transactions)

(2) August 26, 2003 (Earnings Release)

(3) September 2, 2003 (Press Release relating to FDA approval of Aastrom's application for a multi-center Phase I/II clinical trial)

(4) September 15, 2003 (Regulation FD disclosure of investor presentation slides)

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.

AASTROM BIOSCIENCES, INC.

Date: November 13, 2003

/s/ R. Douglas Armstrong

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

Date: November 13, 2003

/s/ Alan M. Wright

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

EXHIBITS

Exhibit Number	Description
3.1	Restated Articles of Incorporation of the Company, as amended
3.2 *	Bylaws of the Company
31	Rules 13a-14(a) and 14(d)-14a Certifications
32	Section 1350 Certifications

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

Exhibit 3.1

RESTATED ARTICLES OF INCORPORATION
FOR USE BY DOMESTIC PROFIT CORPORATIONS

1. The present name of the corporation is:

Aastrom Biosciences, Inc.

2. The identification number assigned by the Bureau is:

529-456

3. All former names of the corporation are:

Ann Arbor Stromal, Inc.

4. The date of filing the original Articles of Incorporation was:

March 24, 1989

The following Restated Articles of Incorporation supersede the Article of Incorporation as amended and shall be the Articles of Incorporation for the corporation:

ARTICLE I

The name of the corporation is:

Aastrom Biosciences, Inc.

ARTICLE II

The purpose or purposes for which the corporation is formed are:

To engage in any activity within the purpose for which corporations may be organized under the Michigan Corporation Act.

ARTICLE III

The total authorized shares:

Common Shares 150,000,000 Preferred shares 5,000,000

A statement of all or any of the relative rights, preferences and limitations of the shares of each class is as follows:

See Rider attached hereto and made a part hereof.

ARTICLE IV

1. The address of the registered office is:

Domino's Farms Lobby L, 24 Frank Lloyd Wright Dr. Ann Arbor, Michigan 48105

(Street Address) (City) (ZIP Code)

2. The mailing address of the registered office, if different than above:

P.O. Box 376 Ann Arbor, Michigan 48106

(Street Address or P.O. Box) (City) (ZIP Code)

3. The name of the resident agent: Michael Durski

ARTICLE V (OPTIONAL. DELETE IF NOT APPLICABLE)

ARTICLE VI (OPTIONAL. DELETE IF NOT APPLICABLE)

ARTICLE VII (ADDITIONAL PROVISIONS, IF ANY, MAY BE INSERTED HERE; ATTACH ADDITIONAL PAGES IF NEEDED.)

See Rider attached hereto and made a part hereof.

RIDER TO ARTICLE III

ARTICLE III

PART A: COMMON STOCK

Section 1. Voting Rights.

a. One Vote Per Share. The holders of shares of Common Stock shall be entitled to one vote for each share so held with respect to all matters voted on by the holders of shares of Common Stock of the Corporation.

b. Two-Thirds Consent. Consent of the holders of at least two-thirds (2/3) of the outstanding shares of Common Stock shall be required for (i) any action which results in a consolidation or merger which would be treated as a liquidation, dissolution or winding up of the Corporation under Section 2 of this Part A of this Article III, or which results in the liquidation, sale or assignment of all or substantially all of the assets of the Corporation; (ii) any amendment to these Articles of Incorporation; or (iii) any amendment by the shareholders of the Corporation of the Bylaws of the Corporation (the Board of Directors of the Corporation, as provided in Section 3 of Article VII, shall have the authority to amend the Bylaws of the Corporation without the consent of the shareholders of the Corporation).

Section 2. Liquidation Rights. Subject to preferences applicable to any outstanding shares of Preferred Stock, all distributions made or funds paid to the holders of Common Stock upon the occurrence of any voluntary or involuntary liquidation, dissolution or winding up of the affairs of the Corporation shall be made on the basis of the number of shares of Common Stock held by each of them. A consolidation or merger of the Corporation with or into another corporation or entity shall be regarded as a liquidation, dissolution or winding up of the Corporation within the meaning of this Section 2 unless such consolidation or merger is not intended to effect a change in the ownership or control of the Corporation or of its assets and is not intended to alter materially the business or assets of the Corporation, including, by way of example and without limiting the generally of the foregoing: (i) a consolidation or merger which merely changes the identity, form or place of organization of the Corporation, or which is between or among the Corporation and any of its direct or indirect subsidiaries, or (ii) following such merger or consolidation, shareholders of the Corporation immediately prior to such event own not less than 51% of the voting power of such corporation immediately after such merger or consolidation on a pro rata basis.

Section 3. Dividends. Dividends may be paid on the Common Stock as and when declared by the Board of Directors, subject to preferences applicable to any outstanding shares of Preferred Stock.

PART B: PREFERRED STOCK

The Preferred Stock may be issued from time to time in one or more series. The Board of Directors of the Corporation is hereby authorized, within the limitations and restrictions

stated in these Restated Articles of Incorporation, to fix or alter the dividend rights, dividend rate, conversion rights, voting rights, rights and terms of redemption (including sinking fund provisions), the redemption price or prices, and the liquidation preferences of any wholly unissued series of Preferred Stock, and the number of shares constituting any such series and the designation thereof, or any of them, and to increase or decrease the number of shares of any series subsequent to the issue of shares of that series but not below the number of shares of such series then outstanding. In case the number of shares of any series shall be so decreased, the shares constituting such decrease shall resume the status which they had prior to the adoption of the resolution originally fixing the number of shares of such series.

RIDER TO ARTICLE VII

ARTICLE VII

1. Director Liability. A director of the Corporation shall not be personally liable to the Corporation or its shareholders for monetary damages for breach of fiduciary duty as a director. However, this provision does not eliminate or limit the liability of a director for any of the following:

(a) any breach of the director's duty of loyalty to the Corporation or its shareholders;

(b) any acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;

(c) a violation of Section 551(1) of the Michigan Business Corporation Act, as amended (the "MBCA");

(d) a transaction from which the director derived an improper personal benefit; or

(e) an act or omission occurring before the date these Articles of Incorporation became effective in accordance with the pertinent provisions of the MBCA.

Any repeal, amendment or other modification of this Article VII shall not adversely affect any right or protection of a director of the Corporation existing at the time of such repeal, amendment or other modification.

If the MBCA is amended, after this Article becomes effective, to authorize corporate action further eliminating or limiting personal liability of directors, then the liability of directors shall be eliminated or limited to the fullest extent permitted by the MBCA as so amended.

2. Control Share Acquisitions. Chapter 7B of the MBCA, known as the "Stacy, Bennett, and Randall shareholder equity act," does not apply to control share acquisitions of shares of the Corporation.

3. Amendment of Bylaws. In furtherance and not in limitation of the powers conferred by statute, the Board of Directors of the Corporation is expressly authorized to make, alter or repeal the Bylaws of the Corporation.

EXHIBIT 31

CERTIFICATION

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 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 report;

3. Based on my knowledge, the financial statements, and other financial information included in this 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 report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, 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 report is being prepared;

   (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 13, 2003

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

CERTIFICATION

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 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 report;

3. Based on my knowledge, the financial statements, and other financial information included in this 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 report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, 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 report is being prepared;

   (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely

affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 13, 2003

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

EXHIBIT 32

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Aastrom Biosciences, Inc. (the "Company") on Form 10-Q for the quarter ended September 30, 2003, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, R. Douglas Armstrong, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 ("Section 906"), that:

(1) 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 Company.

November 13, 2003

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

A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to Aastrom Biosciences, Inc. and will be retained by Aastrom Biosciences, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Aastrom Biosciences, Inc. (the "Company") on Form 10-Q for the quarter ended September 30, 2003, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Alan M. Wright, Senior Vice President and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 ("Section 906"), that:

(1) 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 Company.

November 13, 2003

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

A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to Aastrom Biosciences, Inc. and will be retained by Aastrom Biosciences, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.