SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

☒ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2004, 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 o – No

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	81,127,735
(Class)	Outstanding at May 12, 2004

AASTROM BIOSCIENCES, INC.
Quarterly Report on Form 10-Q
March 31, 2004

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PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

AASTROM BIOSCIENCES, INC.
(a development stage company)

CONSOLIDATED CONDENSED BALANCE SHEETS
(Unaudited)

	June 30, 2003	March 31, 2004
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	$ 10,512,000	$ 10,426,000
Receivables, net	350,000	276,000
Inventories, net	806,000	678,000
Other current assets	185,000	483,000
Total current assets	11,853,000	11,863,000
PROPERTY and EQUIPMENT, NET	302,000	308,000
Total assets	$ 12,155,000	$ 12,171,000
Liabilities and Shareholders' Equity		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	$ 406,000	$ 380,000
Accrued employee benefits	174,000	165,000
Total current liabilities	580,000	545,000
SHAREHOLDERS' EQUITY:		
Common stock, no par value; shares authorized – 150,000,000; shares issued and outstanding – 64,812,422 and 73,127,735, respectively	114,951,000	122,743,000
Deficit accumulated during the development stage	(103,376,000)	(111,117,000)
Total shareholders' equity	11,575,000	11,626,000
Total liabilities and shareholders' equity	$ 12,155,000	$ 12,171,000

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 March 31,		Nine months ended March 31,		March 24, 1989 (Inception) to March 31,
	2003	2004	2003	2004	2004
REVENUES:					
Product sales and rentals	$ 130,000	$ 10,000	$ 298,000	$ 45,000	$ 727,000
Grants	150,000	331,000	361,000	972,000	7,320,000
Research and development agreements	—	75,000	10,000	75,000	2,105,000
Total revenues	280,000	416,000	669,000	1,092,000	10,152,000
COSTS AND EXPENSES:					
Cost of product sales and rentals	21,000	5,000	132,000	22,000	410,000
Cost of product sales and rentals - provision for obsolete and excess inventory	186,000	—	445,000	253,000	2,230,000
Research and development	1,351,000	1,660,000	4,168,000	4,471,000	91,619,000
Selling, general and administrative	854,000	1,279,000	2,869,000	4,200,000	32,327,000
Total costs and expenses	2,412,000	2,944,000	7,614,000	8,946,000	126,586,000
LOSS FROM OPERATIONS	(2,132,000)	(2,528,000)	(6,945,000)	(7,854,000)	(116,434,000)
OTHER INCOME (EXPENSE):					
Other income	—	—	—	—	1,237,000
Interest income	30,000	28,000	104,000	113,000	5,315,000
Interest expense	—	—	—	—	(267,000)
Other income	30,000	28,000	104,000	113,000	6,285,000
NET LOSS	$ (2,102,000)	$ (2,500,000)	$ (6,841,000)	$ (7,741,000)	$(110,149,000)
NET LOSS PER SHARE (Basic and Diluted)	$ (.04)	$ (.03)	$ (.14)	$ (.11)	
Weighted average number of shares outstanding (Basic and Diluted)	51,656,000	72,204,000	48,340,000	71,384,000	

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)

	Nine months ended March 31,		March 24, 1989 (Inception) to March 31,
	2003	2004	2004
OPERATING ACTIVITIES:			
Net loss	$(6,841,000)	$ (7,741,000)	$ (110,149,000)
Adjustments to reconcile net loss to net cash used for operating activities:			
Depreciation and amortization	90,000	91,000	3,537,000
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	445,000	253,000	2,230,000
Stock issued pursuant to license agreement	—	—	3,300,000
Changes in assets and liabilities:			
Receivables	(200,000)	74,000	(300,000)
Inventory	(277,000)	(125,000)	(3,004,000)
Other current assets	4,000	(298,000)	(483,000)
Accounts payable and accrued expenses	(198,000)	(26,000)	380,000
Accrued employee benefits	6,000	(9,000)	165,000
Net cash used for operating activities	(6,812,000)	(7,356,000)	(103,333,000)
INVESTING ACTIVITIES:			
Organizational costs	—	—	(73,000)
Purchase of short-term investments	—	—	(62,124,000)
Maturities of short-term investments	1,000,000	—	62,667,000
Capital expenditures	(109,000)	(97,000)	(3,012,000)
Proceeds from sale of property held for resale	—	—	400,000
Net cash provided by (used for) investing activities	891,000	(97,000)	(2,142,000)
FINANCING ACTIVITIES:			
Issuance of preferred stock	—	—	51,647,000
Issuance of common stock	2,380,000	7,367,000	61,946,000
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	2,380,000	7,367,000	115,901,000
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(3,541,000)	(86,000)	10,426,000
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	8,605,000	10,512,000	—
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 5,064,000	$10,426,000	$ 10,426,000

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 developed 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 2005, the Company will need to raise additional funds in order to complete its product development programs, clinical trials 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 markets. 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 the Company 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 of America 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 and nine months ended March 31, 2004, 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 the Company's 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 and rentals 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 loss from operations, 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 the Company's 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 the Company had applied the fair value recognition provisions of Statement of Financial Accounting Standards (SFAS) No. 123, "Accounting for Stock-Based Compensation" using the Black-Scholes valuation model. Other models recently suggested could yield different results.

	Three Months Ended March 31,		Nine Months Ended March 31,	
	2003	2004	2003	2004
Reported net loss	$(2,102,000)	$(2,500,000)	$(6,841,000)	$(7,741,000)
Add: Stock-based employee compensation expense included in reported net income, 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	(348,000)	(244,000)	(773,000)	(701,000)
Pro forma net loss	$(2,450,000)	$(2,744,000)	$(7,614,000)	$(8,070,000)
Earnings per share:				
As reported	$ (.04)	$ (.03)	$ (.14)	$ (.11)
Pro forma	$ (.05)	$ (.04)	$ (.16)	$ (.11)

4. Shareholders' Equity

During the nine month period ended March 31, 2004, the Company issued 8,077,673 shares of common stock to multiple investors, 46,106 shares of common stock as part of our Employee Stock Purchase Plan, our employee stock option plan and our Direct Stock Purchase Plan and 191,534 shares of common stock through the exercise of certain warrants, for total net proceeds of approximately $7,367,000. As part of one of these transactions, the Company issued warrants to investors who purchased common stock in a private placement. These warrants, included four-year warrants, expiring July 3, 2007, to purchase up to 1,264,706 shares of common stock at a price of $1.23 per share and, warrants to purchase up to 1,011,765 shares of common stock at $1.50 per share that expired unexercised on October 31, 2003. In addition, the Company issued warrants to purchase 303,529 shares of common stock to a private placement agent, exercisable on or before July 3, 2007, at an exercise price of $1.23 per share. 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 per share.

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 quarter and nine months ended March 31, 2003 and 2004 is approximately 3,869,000 and 5,922,000, respectively.

6. Recent Accounting Pronouncements

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, as of December 15, 2003, did not have a material impact on the financial position or results of operations of Aastrom.

In May 2003, Emerging Issues Task Force Issue No. 00-21 (EITF 00-21), "Accounting for Revenue Arrangements with Multiple Deliverables" was finalized. This EITF issue addresses certain aspects of accounting by a vendor for arrangements under which it will perform multiple revenue-generating activities. The guidance in the consensus is effective for revenue arrangements entered into in fiscal periods beginning after June 15, 2003. The adoption of this standard did not have a material impact on the financial position or results of operations of Aastrom.

In May 2003, the FASB issued SFAS No. 150, "Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity." SFAS No. 150 requires that an issuer classify certain financial instruments within its scope as a liability (or an asset in some circumstances). The adoption of this standard will not impact the current financial position or results of operations of Aastrom.

7. Subsequent Event

In early April 2004, the Company issued 8,000,000 shares of its common stock through a registered direct offering to institutional investors, for cash proceeds of approximately $8,500,000, net of offering costs of approximately $600,000. As part of this transaction, the Company issued warrants to the institutional investors, exercisable for 5 years, or until April 5, 2009, subject to mandatory exercise at the Company's option, in certain circumstances of stock price escalation after April 5, 2006, to purchase up to 2.4 million shares of common stock at an exercise price of $1.65 per share. In addition, the Company issued warrants to the placement agent, exercisable for 5 years, or until April 5, 2009, subject to mandatory exercise at the Company's option, in certain circumstances of stock price escalation after April 5, 2005, to purchase up to 560,000 shares of common stock at an exercise price of $1.65 per share.

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

Overview

We are a late-stage development company that is focused on the development of processes and products for the *ex vivo* production and sale of human cell products for use in cell therapy.

We develop proprietary Prescription Cell Products (PCP) for the regenerative repair of damaged human tissues and other medical disorders. Our lead PCP products are Tissue Repair Cells (TRC), which are a unique mixture of bone marrow-derived stem and progenitor cells, produced *ex vivo*. TRCs have been proven safe in patients and to effectively generate certain normal human tissues in clinical trials.

We have also developed of our proprietary AastromReplicell™ System, which is a patented, integrated system of instrumentation and single-use consumable kits for the commercial production of human cells. Although the AastromReplicell™ System is now CE Marked, we continue to enhance and expand its capabilities for broader commercial utility. The AastromReplicell™ System technology is used to manufacture our proprietary PCP products and can be sold independently for therapeutic dendritic cell production, the basis of our Cell Production Products (CPP) business. We currently market our CPP dendritic cell vaccine products in Europe and in the United States on a limited basis. Our strategy provides multiple paths to revenue, with the CPP business generating early modest revenue to augment the planned therapeutic PCP pipeline, which is our primary business direction.

Our commercial production pathway of our Prescription Cell Products is enabled through the AastromReplicell™ System platform. This proprietary and automated clinical cell production system combines patented GMP-compliant automated cell production with patented "single pass perfusion." Single pass perfusion is our technology for growing large quantities of highly robust human cells outside the body. These cells include adult stem cells, immune system cells, and cells for forming solid tissues such as bone.

Prescription Cell Products

We are leveraging our *ex vivo* cell production technology for a growing Prescription Cell Product pipeline by focusing on our Tissue Repair Cells (TRCs) for stem cell-derived tissue repair and regeneration.

Tissue Repair Cells

Using the AastromReplicell™ System, TRCs are grown from a small sample of a patient's bone marrow. Once administered back to the patient, the cells are intended to generate normal tissue. The primary TRC application we are initially pursuing is bone grafting (spinal fusions, long bone fractures or jaw bone reconstruction). In August 2003, the FDA approved our Investigational New Drug (IND) application to begin a multi-center Phase I/II clinical trial for bone grafting. Our bone grafting clinical trials have recently been initiated in the U.S. and Europe for the treatment of tibial non-union fractures, and we expect to announce additional clinical sites for this application. The initiation of European clinical studies for jawbone construction needed for dental implants are pending the finalization of applicable cell production licensing requirements.

The clinical trial direction of our development effort has been influenced by observations that our bone marrow cell products may be suitable as a treatment for bone and blood vessel regeneration, each of which may represent a substantial market opportunity. 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 cell types that can generate connective tissues

including bone and cartilage. In addition, our bone marrow cell product has 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 this compassionate use treatment, now published in the *Journal of Bone and Mineral Research*, demonstrated bone formation in the child.

We also believe that the stem cell components of our TRCs may be useful for other medical indications, including the regeneration of vascular tissues and cartilage.

Cell Production Products

Our Cell Production Products operation seeks to market and sell 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 to academic researchers and companies that are developing dendritic cell-based cancer vaccines. We expect that the recent commercialization of our automated cell production instruments and cell-specific production kits should enable us 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 directives that affect 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 adversely affected our progress in our Cell Production Products business. Marketing in Europe is directed through Zellera AG, our wholly-owned subsidiary located in Berlin, Germany.

Various third-party therapeutic cell companies and academic researchers are developing 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, can be cultured in the AastromReplicell™ System to produce potential therapeutic cells. After being exposed to a particular biological signal, or antigen, the cells produced using Aastrom's proprietary technology may act to trigger a cell-mediated immune response against the patient's cancer cells. There has been some recent, but limited use of clinical trials using dendritic cells produced in the AastromReplicell™ System by independent third parties.

While we have initiated marketing activities in Europe for the CE Marked SC-I, DC-I, DCV-I and the DCV-II products and AastromReplicell™ System instrumentation, at this point in our current business development, we cannot project when we will generate positive cash flows from our consolidated operations. In the next two to three years, we expect that our revenue sources will consist of sales from our Cell Production Products business to academic and commercial research centers, grant revenue, research funding and licensing fees from potential future corporate collaborators, and potentially the sale of TRCs in certain non-U.S. countries. 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. Our ability to achieve profitability on a sustained basis, if at all, or to obtain the required funding to achieve our operating objectives, or complete additional corporate partnering transactions is subject to a number of risks and uncertainties. Please see the section entitled “Certain Business Considerations”.

Our programs currently use bone marrow, cord blood and blood cells as starting sources of cells. As such, federal support of other factors relating to embryonal stem cell research have no direct impact on our current product programs.

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 both contribute in certain development and clinical trial expenses of these treatment approaches and products, and intend to adopt a coordinated promotion and marketing strategy for future products.

Competitive Environment

The biotechnology and medical device industries are characterized by rapidly evolving technology and intense competition. Aastrom's competitors include major multinational medical device companies, pharmaceutical companies, specialty biotechnology companies and chemical and medical products companies operating in the fields of tissue engineering, tissue regeneration, orthopedics and cell-based therapies. Many of these companies are well-established and possess technical, research and development, financial, and sales and marketing resources significantly greater than Aastrom. In addition, many smaller biotech and specialty medical products companies have formed strategic collaborations, partnerships and other types of joint ventures with larger, well established industry competitors that afford these companies potential research and development and commercialization advantages in product areas currently being pursued by Aastrom. Academic institutions, governmental agencies and other public and private research organizations are also conducting and financing research activities which may produce products directly competitive to those being commercialized by Aastrom. Moreover, many of these competitors may be able to obtain patent protection, obtain FDA and other regulatory approvals and begin commercial sales of their products before Aastrom.

Aastrom's potential commercial products address a broad range of existing and emerging markets, in which cell-based therapy is a new and as of yet, unproven, commercial strategy. In a large part, Aastrom faces primary competition from existing devices and products. Some of Aastrom's competitors in orthopedic device and tissue engineered orthopedic applications have longer operating histories and substantially greater resources. These include Stryker Corp., Medtronic, Wright Medical, Smith &Nephew, Osteotech, Interpore Cross, J&J/DePuy, Zimmer and Synthes/Mathys Medical. Other well-established competitors, such as CONMED, IntegraLife Sciences, Arthrex and Implex Corporation compete in orthopedics with a variety of other tissue substitution products. A number of other companies have developed tissue-derived products for these markets, including Regeneration Technologies, Allosource, Lifecell Corporation, NovaBone, IsoTis Orthobiologics, Co.don and OrthoVita.

In the general area of cell-based therapies, including orthopedics and other tissue regeneration applications, Aastrom competes with a variety of companies, most of whom are specialty medical products or biotechnology companies. Some of these, such as Genzyme Corporation and Fidia SA are well-established and have substantial technical and financial resources compared to Aastrom. However, as cell-based products are only just emerging as viable medical therapies, many of Aastrom's direct competitors are smaller biotechnology and specialty medical products companies. These include Orthologic/Chrysalis Biotechnologies, Biosyntech, Inc., Osiris Therapeutics, Isto Technologies, Interface Biologics, MacroPore Biosurgery and Raymedica.

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

Total revenues, consisting of grant funding, research and development agreements and product sales and rentals, for the quarter and nine months ended March 31, 2004 were $416,000 and $1,092,000, respectively, compared to $280,000 and $669,000 for the same periods in 2003. Grant revenues increased for the quarter and nine months ended March 31, 2004 to $331,000 and $972,000, respectively, compared to $150,000 and $361,000 for the same periods in 2003. Grant revenues have increased from the prior year periods as a result of increased activity on the collaborative grant with the Defense Advanced Research Projects Agency (DARPA) and

additional grant awards from the National Institutes of Health. We also recognized $75,000 of revenues for the quarter and nine months ended March 31, 2004 resulting from our performance under research and development agreements compared to $0 and $10,000 for the same periods in 2003. This increase is the result of a $50,000 fee from the sublicense agreement with Corning Inc. compared to a $10,000 fee in fiscal year 2003, and an additional $25,000 fee in fiscal year 2004 from a development agreement with a European institution. Product sales and rentals decreased to $10,000 and $45,000 for the quarter and nine months ended March 31, 2004, respectively, from $130,000 and $298,000 for the same periods in 2003. This decrease is primarily due to extended internal evaluations at potential customer sites that have delayed sales of our instrumentation and therapy kits in fiscal year 2004. We continue to pursue grant-funded programs as well as actively pursuing European and domestic sales and marketing opportunities.

Total costs and expenses for the third fiscal quarter ended March 31, 2004 increased to $2,944,000, compared to $2,412,000 for the same quarter in fiscal year 2003. Costs and expenses during the third quarter of fiscal year 2004 included an increase in selling, general and administrative expenses to $1,279,000 from $854,000 for the same quarter in fiscal year 2003. This increase reflects continued expansion of marketing activities to further our commercialization efforts in Europe and additional costs relating to capital raising efforts that were not related to specific transactions. Research and development expenses for the third quarter ended March 31, 2004 increased to $1,660,000 from $1,351,000 in the comparable period of fiscal year 2003. This increase is the result of increased activities on our grant funded activities. Cost of product sales and rentals declined to $5,000 in the third quarter of fiscal year 2004 from $21,000 in the third quarter of fiscal year 2003 due to the decline in volume of product sales. The non-cash provision for obsolete and excess AastromReplicell™ System inventory declined from $186,000 in the third quarter of fiscal year 2003 to zero in the third quarter of fiscal year 2004 because as of September 30, 2003, we had written the carrying value of all of our AastromReplicell™ System inventory down to zero. We have not written down the carrying value of any of our remaining inventories, which consist primarily of cell cassettes, as our assessment of the value realizable in sales of these inventories continues to support the carrying values.

Total costs and expenses for the nine months ended March 31, 2004 increased to $8,946,000 compared to $7,614,000 for the same period in fiscal year 2003. The increase is primarily due to selling, general and administrative expenses that increased to $4,200,000 for the nine month period ended March 31, 2004 from $2,869,000 in the comparable period of fiscal year 2003. This is the result of continued marketing efforts in Europe, additional costs relating to capital raising, 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 increased to $4,471,000 for the nine months ended March 31, 2004 from $4,168,000 in the comparable period of fiscal year 2004. Research and product development activities are continuing in the areas of dendritic-cell based vaccines, tissue regeneration and preparation for and the conduct of our pending bone grafting trials in the United States and Europe. Cost of product sales and rentals declined to $22,000 in the first nine months of fiscal year 2004 from $132,000 in the first nine months of fiscal year 2003 due to the decline in the

volume of product sales. The non-cash provision for obsolete and excess AastromReplicell™ System inventory declined from $445,000 in the first nine months of fiscal year 2003 to $253,000 in the first nine months of fiscal year 2004 because as of September 30, 2003, we had written the carrying value of all of our AastromReplicell™ System inventory down to zero. We have not written down the carrying value of any of our remaining inventories, which consist primarily of cell cassettes, as our assessment of the value realizable in sales of these inventories continues to support the carrying values.

Interest income was $28,000 and $113,000 for the quarter and nine months ended March 31, 2004, respectively, compared to $30,000 and $104,000 for the same periods in fiscal year 2003. 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.

We have recorded no income tax provision, because we do not expect to pay income taxes in the U.S. or in foreign jurisdictions in fiscal year 2004.

Our net loss increased to $2,500,000, and decreased to $.03 per common share for the quarter ended March 31, 2004 compared to a net loss of $2,102,000, or $.04 per common share for the same period in fiscal year 2003. Similarly, for the nine months ended March 31, 2004, our net loss increased to $7,741,000, and decreased to $.11 per common share compared to $6,841,000, or $.14 per common share for the same period in fiscal year 2003. 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 financings, 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 March 31, 2004, have totaled approximately $123 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 $10,426,000 at March 31, 2004, a decrease of $86,000 from June 30, 2003. The primary uses of cash, cash equivalents and short-term investments during the nine months ended March 31, 2004 included $7,356,000 to finance our operations and working capital requirements. The primary source of cash, cash equivalents and short-term investments was from equity financing transactions, with net proceeds of $7,367,000. This equity financing was obtained under multiple transactions in which we sold our common shares and warrants to purchase common shares to investors, as well as our Employee Stock Purchase Plan and the stock option plan.

In early April 2004, we issued 8,000,0000 shares of common stock through a registered direct offering to institutional investors, for cash proceeds of approximately $8,500,000, net of offering costs of approximately $600,000. As part of this transaction, we issued warrants to the institutional investors, exercisable for 5 years to purchase up to 2.4 million shares of common stock at an exercise price of $1.65 per share. In addition, we issued warrants to the placement agent, exercisable for 5 years, to purchase up to 560,000 shares of common stock at an exercise price of $1.65 per share.

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, including the financing completed in April 2004, will be sufficient to fund currently planned activities through our 2005 fiscal year (ending June 30, 2005). 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. 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. 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.

There can be no assurance that such collaborative arrangements, or any public or private financing, will be available on acceptable terms, if at all, or can be sustained. Several factors will affect our ability to raise additional funding, including, but not limited to, the rate of progress in our product development programs, 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, financial condition and results of operations. 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 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, as of December 15, 2003, did not have a material impact on the financial position or results of operations of Aastrom.

In May 2003, Emerging Issues Task Force Issue No. 00-21 (EITF 00-21), "Accounting for Revenue Arrangements with Multiple Deliverables" was finalized. This EITF issue addresses certain aspects of accounting by a vendor for arrangements under which it will perform multiple revenue-generating activities. The guidance in the consensus is effective for revenue arrangements entered into in fiscal periods beginning after June 15, 2003. The adoption of this standard did not have a material impact on the financial position or results of operations of Aastrom.

In May 2003, the FASB issued SFAS No. 150, "Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity." SFAS No. 150 requires that an issuer classify certain financial instruments within its scope as a liability (or an asset in some circumstances). The adoption of this standard will not impact the current 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 March 31, 2004, we have incurred cumulative net losses totaling approximately $110 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. Although the AastromReplicell™ System is considered to be unregulated manufacturing equipment in the U.S., the FDA may reconsider this and classify the System 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 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 biologic license application (BLA).

New directives (laws) have recently become effective in the European Union that may affect 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. The recent changes to the European Union Medicinal Products Prime Directive shifted patient-derived cells to the medicinal products category. These new laws 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. 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 2005 fiscal year (ending June 30, 2005). 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 $0.30 and $1.77 during the twelve month period ended March 31, 2004. 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, or imposition of additional regulation, 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.

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.

Use of animal-derived materials could harm our product development and commercialization efforts.

Some of the compounds we use 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. Regulatory authorities in the EU are reviewing the safety issues related to the use of animal derived materials which we currently use in our production process. It is unknown at this time what actions, if any, the authority may take as to animal derived materials specific to medicinal products distributed in the EU. Our inability to develop or obtain alternative compounds would harm our product development and commercialization efforts.

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 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 and industrial 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 use for bone marrow transplantation, following marrow ablation due to chemo-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, the cost or process of treatment and other factors may cause researchers and practitioners to 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;
- replacement of manufacturing sources;
- commercialization plans; and
- revenue expectations and operating results.

These statements are subject to risks and uncertainties, including those set forth in this “Certain Business Considerations” section, and actual results could differ materially from those expressed or implied in these statements. 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 March 31, 2004, 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 significant 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 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

During the quarter ended March 31, 2004 we issued 80,000 shares of common stock upon exercise of previously issued warrants. The shares were sold for $0.50 per share. The shares of common stock 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 March 31, 2004 we submitted the following reports on Form 8-K:

(1) January 14, 2004 (Press Release relating to the initiation of a clinical trial, in collaboration with investigators at the Illinois Bone and Joint Foundation)

(2) January 22, 2004 (Press Release relating to the initiation of a clinical trial, in collaboration with investigators at the BG-Kliniken "Bergmannsheil" Ruhr-University)

(3) February 4, 2004 (2nd Quarter Earnings Release)

(4) February 19, 2004 (Slides used in presentations)

(5) March 30, 2004 (Press release relating to the initiation of a bone grafting clinical trial)

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: May 13, 2004 /s/ R. Douglas Armstrong

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

Date: May 13, 2004 /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 15d-14a Certifications
32	Section 1350 Certifications

* Incorporated by reference to the Company's Quarterly Report of Form 10-Q for the quarter ended September 30, 2003.

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

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: May 13, 2004

/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: May 13, 2004

/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 March 31, 2004, 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.

May 13, 2004

/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 March 31, 2004, 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.

May 13, 2004

/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.