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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 DECEMBER 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 - ☑ No - o

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). Yes - ☑ No - o

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	100,989,193
(Class)	Outstanding at February 4, 2004

AASTROM BIOSCIENCES, INC.
Quarterly Report on Form 10-Q
December 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

	June 30, 2004	December 31, 2004 *(Unaudited)*
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	$ 16,926,000	$ 12,588,000
Short-term investments	—	10,000,000
Receivables, net	246,000	408,000
Inventory	389,000	361,000
Other current assets	271,000	716,000
Total current assets	17,832,000	24,073,000
PROPERTY AND EQUIPMENT, NET	334,000	466,000
Total assets	$ 18,166,000	$ 24,539,000
Liabilities and Shareholders' Equity		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	$ 382,000	$ 500,000
Accrued employee benefits	176,000	190,000
Total current liabilities	558,000	690,000
SHAREHOLDERS' EQUITY:		
Common stock, no par value; shares authorized – 150,000,000; shares issued and outstanding – 81,373,191 and 92,236,588, respectively	131,472,000	142,815,000
Deficit accumulated during the development stage	(113,864,000)	(118,966,000)
Total shareholders' equity	17,608,000	23,849,000
Total liabilities and shareholders' equity	$ 18,166,000	$ 24,539,000

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 December 31,		Six months ended December 31,		March 24, 1989 (Inception) to December 31,
	2003	2004	2003	2004	2004
REVENUES:					
Product sales and rentals	$ 10,000	$ 212,000	$ 35,000	$ 227,000	$ 958,000
Grants	366,000	162,000	641,000	334,000	7,860,000
Research and development agreements	—	—	—	—	2,105,000
Total revenues	376,000	374,000	676,000	561,000	10,923,000
COSTS AND EXPENSES:					
Cost of product sales and rentals	5,000	39,000	17,000	54,000	469,000
Cost of product sales and rentals - provision for obsolete and excess inventory	—	—	253,000	—	2,230,000
Research and development	1,455,000	1,596,000	2,811,000	3,163,000	96,600,000
Selling, general and administrative	1,356,000	1,289,000	2,921,000	2,603,000	36,120,000
Total costs and expenses	2,816,000	2,924,000	6,002,000	5,820,000	135,419,000
LOSS FROM OPERATIONS	(2,440,000)	(2,550,000)	(5,326,000)	(5,259,000)	(124,496,000)
OTHER INCOME (EXPENSE):					
Other income	—	—	—	—	1,237,000
Interest income	37,000	97,000	85,000	157,000	5,528,000
Interest expense	—	—	—	—	(267,000)
Other income	37,000	97,000	85,000	157,000	6,498,000
NET LOSS	$ (2,403,000)	$ (2,453,000)	$ (5,241,000)	$ (5,102,000)	$ (117,998,000)
NET LOSS PER SHARE (Basic and Diluted)	$ (.03)	$ (.03)	$ (.07)	$ (.06)	
Weighted average number of shares outstanding (Basic and Diluted)	71,294,000	89,485,000	70,978,000	86,112,000	

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)

	Six months ended December 31,		March 24, 1989 (Inception) to December 31,
	2003	2004	2004
OPERATING ACTIVITIES:			
Net loss	$ (5,241,000)	$ (5,102,000)	$ (117,998,000)
Adjustments to reconcile net loss to net cash used for operating activities:			
Depreciation and amortization	59,000	72,000	3,643,000
Loss on property held for resale	—	—	110,000
Amortization of discounts and premiums on investments	—	—	(543,000)
Stock compensation expense	425,000	—	1,424,000
Inventory write downs and reserves	253,000	—	2,230,000
Stock issued pursuant to license agreement	—	—	3,300,000
Provision for losses on accounts receivable	—	—	156,000
Changes in assets and liabilities:			
Receivables	40,000	(162,000)	(588,000)
Inventory	(75,000)	28,000	(2,687,000)
Other current assets	(304,000)	(445,000)	(716,000)
Accounts payable and accrued expenses	(39,000)	118,000	500,000
Accrued employee benefits	16,000	14,000	190,000
Net cash used for operating activities	(4,866,000)	(5,477,000)	(110,979,000)
INVESTING ACTIVITIES:			
Organizational costs	—	—	(73,000)
Purchase of short-term investments	—	(10,000,000)	(72,124,000)
Maturities of short-term investments	—	—	62,667,000
Property and equipment purchases	(48,000)	(204,000)	(3,276,000)
Proceeds from sale of property held for resale	—	—	400,000
Net cash used for investing activities	(48,000)	(10,204,000)	(12,406,000)
FINANCING ACTIVITIES:			
Net proceeds from issuance of preferred stock	—	—	51,647,000
Net proceeds from issuance of common stock	5,186,000	11,343,000	82,018,000
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	5,186,000	11,343,000	135,973,000
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	272,000	(4,338,000)	12,558,000
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	10,512,000	16,926,000	—
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 10,784,000	$ 12,588,000	$ 12,558,000

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. was incorporated in March 1989 (Inception), began employee-based operations in 1991, and is in the development stage. 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 the Company's products and the Company's continued ability to obtain future funding.

The Company is subject to certain risks related to the operation of its business and development of its products and product candidates. While management believes available cash, cash equivalents and short-term investments are adequate to finance currently planned activities through the end of fiscal year 2006 (ending June 30, 2006), the Company will need to raise additional funds in order to complete its product development programs, complete clinical trials needed to market its products and commercialize additional product candidates. The Company cannot be certain that such funding will be available on favorable terms, if at all. Some of the factors that will impact the Company's ability to raise additional capital and its overall success includes, the rate and degree of progress for its product development and clinical trial programs, the requirements for marketing authorization from regulatory bodies in the U.S., European Union and other countries, the liquidity and market volatility of the Company's equity securities, regulatory and manufacturing requirements and uncertainties, technological developments by competitors and other factors. If the Company cannot raise such funds, it may not be able to develop or enhance products, take advantage of future opportunities, or respond to competitive pressures or unanticipated requirements, which would negatively impact its business, financial condition and results of operations.

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 six months ended December 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 our 2004 Annual Report on Form 10-K for the year ended June 30, 2004, 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.

3. Stock-Based Employee Compensation

The Company has a 2004 Equity Incentive Plan that was adopted to provide an incentive program that would enable the Company to attract and retain employees, consultants, and directors. The 2004 Plan permits the grant of stock options, stock appreciation rights, restricted stock purchase rights, restricted stock awards, restricted stock units, and deferred stock units. At the time of stockholder approval of this plan in November 2004, this plan replaced the 2001 Stock Option Plan, which had been used for stock option grants since 2001. The Company accounts for these plans 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 the Three Months Ended December 31,		For the Six Months Ended December 31,	
	2003	2004	2003	2004
Reported net loss	$(2,403,000)	$(2,453,000)	$(5,241,000)	$(5,102,000)
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	(227,000)	(122,000)	(457,000)	(288,000)
Pro forma net loss	$(2,630,000)	$(2,575,000)	$(5,326,000)	$(5,390,000)
Net loss per common share:				
As reported	$ (0.03)	$ (0.03)	$ (0.07)	$ (0.06)
Pro forma	$ (0.04)	$ (0.03)	$ (0.08)	$ (0.06)

4. Shareholders' Equity

During the six months ended December 31, 2004, the Company issued 10,554,174 shares of common stock to investors, 102,067 shares of common stock as part of the stock option plans, the Direct Stock Purchase Plan and the Employee Stock Purchase Plan and 207,156 shares of common stock in connection with the exercise of certain warrants previously issued to investors, for net cash proceeds of $11,343,000.

5. Net Loss Per Common Share

Net loss per common share is computed using the weighted-average number of common shares outstanding during the period. Common equivalent shares, consisting of options and warrants for the purchase of common stock, 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 six months ended December 31, 2003 and 2004 is approximately 5,959,000 and 12,734,000, respectively.

6. Recent Accounting Pronouncements

In December 2004, the Financial Accounting Standards Board (FASB) issued Statements of Financial Accounting Standards No. 123R, "Share-Based Payment" (SFAS 123R), which requires companies to measure and recognize compensation expense for all employee stock-based payments at fair value over the service period underlying the arrangement. SFAS 123R is effective for all interim and annual periods beginning after June 15, 2005 and, thus, will be effective for the Company beginning with fiscal year 2006 (ending June 30, 2006). The Company is currently evaluating the impact of SFAS 123R on its financial statements. Management expects that SFAS 123R will result in an increase in operating expenses in future periods.

7. Short-term Investments

Short-term investments consist of highly rated corporate debt securities with original maturities of over three months and less than one year. Short-term investments are classified as available-for-sale, and are presented at market value, with unrealized gains and losses on investments reflected as a component of shareholders' equity. Interest earned on available-for-sale securities is included in interest income.

8. Property and Equipment

During the first six months of fiscal year 2005, ended December 31, 2004, the Company acquired equipment that it intends to use in the future in a specialized facility under the Company's control, for the production of human cells. The cost of this equipment is $111,000 and has been included in property and equipment at December 31, 2004. The equipment will be depreciated over its useful life beginning when the equipment is placed into service.

9. Subsequent Events

On January 10, 2005, the Company concluded its sale of common stock with Fusion Capital Fund II, LLC, pursuant to the common stock purchase agreement dated October 30, 2002. In this final tranche, Fusion purchased 4.8 million shares of common stock for gross proceeds of $12 million at an average price of $2.50 per share. As part of this transaction, the Company issued an additional 1,940,700 commitment shares to Fusion under the terms of the common stock purchase agreement, for which the Company received no additional proceeds. In addition, subsequent to the end of the quarter and through February 3, 2005, previously issued warrants were exercised for the purchase of 1.8 million shares of common stock for gross proceeds of $2.9 million.

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

Overview of Aastrom

We are a late-stage development company focused on the development of processes and products for the *ex vivo* production and sale of human cell products for use in cell therapy and tissue regeneration. Our pre-clinical and clinical product development programs utilize adult bone marrow stem and progenitor cell mixtures being investigated for aiding in the growth of solid tissues such as bone, vascular tissue and cartilage, as well as blood and immune system cells. 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.

While cell therapies are emerging as potential new treatment options for several diseases and medical disorders, the success of cellular therapy is based, in part, on the need for care providers to be able to access therapeutic quantities of biologically active cells necessary for patient treatment, cost-effectively and in compliance with regulatory requirements. Our patented AastromReplicell System and single-pass perfusion technology are intended to enable the manufacturing of patient specific cell products for clinical use.

In the expanding fields of cell therapy and tissue regeneration, we develop proprietary adult stem cell-based products for the regenerative repair of damaged human tissues and other medical disorders, several of which are now in the clinical stage. Our lead products contain Tissue Repair Cells (TRCs), which are a unique mixture of bone marrow-derived stem and progenitor cells, produced outside of the body or "*ex vivo*" from a small amount of bone marrow taken from the patient. In previous multi-center clinical trials involving over 175 patients, our TRCs have been demonstrated to be safe and reliable, and to regenerate certain normal healthy human tissues.

We have also developed our proprietary AastromReplicell System, which is a patented, integrated system of instrumentation and single-use consumable kits for the commercial production of human cells. The AastromReplicell System was developed to provide a manufacturing platform for our proprietary cell products, such as our TRCs. The AastromReplicell System technology has also been expanded for the production of dendritic cells and dendritic cell vaccines, by targeting academic and other third party therapeutic cell developers requiring automated cell production with GMP (Good Manufacturing Practice) compliance. Since this third-party development activity is minimal at present, active development and marketing activities have been halted.

Our commercial production pathway for our TRC products is in part 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 and progenitor cell

mixtures — cells required for forming tissues such as bone, vascular, cartilage, blood and immune system cells.

Our primary business model is to establish a core infrastructure for the manufacturing and distribution of TRC cell products for use in multiple medical indications. Initially, we intend to pursue TRC-based products for the following therapeutic areas:

- Local bone regeneration in fractures, spinal fusion and jaw bone reconstruction
- Vascular (blood vessel) regeneration in limb ischemia resulting from diabetes and other diseases

In the future, we may develop and/or support the development by third parties of TRC-based products for other areas such as cartilage regeneration and cardiac tissue regeneration.

We do not have the sales or marketing organization that would be needed to commercialize our therapeutic products. We intend to seek partnerships with other companies who have this capability, as well as to develop our own ability to either support these relationships or to complete some pilot level of sales and marketing ourselves.

In the EU, our business development activities are aided through Zellera AG, our wholly-owned subsidiary located in Berlin, Germany.

Since our inception, we have been in the development stage and engaged in research and product development, conducted principally on our own behalf, but also in connection with various collaborative research and development agreements with others. Our initial business plan was to pursue the bone marrow transplantation markets. At approximately the same time (late fiscal year 1999), that we intended to commence our initial pilot-scale product launch in the EU of the AastromReplicell System with the SC-I kit, data was released at international meetings that resulted in the majority of the patients who would otherwise have been candidates for the SC-I product, to no longer require the use of the product. This loss of market for the SC-I caused us to reorganize our operations and suspend all external activities in October 1999, pending the receipt of additional financing and the completion of the reorganization process. We expanded the capabilities of the AastromReplicell System to include dendritic cell production and initiated pilot marketing activities for the CE Marked DC-I, DCV-I and the DCV-II products. However, only very minor and irregular revenue has occurred from this business and as a result, it is not currently an active direction for us. Instead, our focus is on the development of our TRC-based products for tissue regeneration.

We do not expect to generate positive cash flows from our consolidated operations for at least the next several years and then only if more significant product sales commence. Until that time, we expect that our revenue sources will consist of only minor sales from our dendritic cell kits to academic and commercial research centers, grant revenue and research funding and potential licensing fees or other financial support from potential future corporate collaborators.

To date, we have financed our operations primarily through public and private sales of our equity securities and we expect to continue obtaining required capital in a similar manner. As a development-stage company, we have never been profitable and do not anticipate having net income unless and until significant product sales commence. This is not likely to occur until we obtain significant additional funding and complete the required clinical trials for regulatory approvals, and receive those approvals to market our products. Through December 31, 2004, we have accumulated losses of approximately $119 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, obtain the required regulatory approvals, or complete additional corporate partnering or acquisition transactions.

Recent Developments – Clinical Programs

We have initiated Phase I/II or “proof of concept” type clinical trials for use of TRCs in bone grafting of long bone non-union fractures as well as sinus lift bone generation (increasing bone thickness in the upper jaw bone). The trials for fractures are active at multiple sites in both the U.S. and the EU. The U.S. sites are performing the same protocol under an approved IND through the FDA. The site in Barcelona, Spain and the site in Bochum, Germany are performing under protocols specific to their individual sites, and these protocols have differences compared to the U.S. protocol. The differences generally relate to the type of carrier matrix, or material, that the TRCs are mixed with prior to the application at the bone repair site. There are also differences in the type of clinical injury being treated among the U.S., Barcelona, and Bochum trial sites.

The Barcelona study has included 6 patient treatments (5 patients, with one patient receiving treatment on two different fractured bones). Progress reports received from the lead investigator, along with x-rays received and evaluated by Aastrom have shown the TRC treatments to be safe, and the patients having some level of clinical progress, including varying levels of bone generation at the fracture sites. Although the results received were interim, since complete bone fusion typically can take many months, we believe the results were sufficient to expand this clinical program at the Barcelona site and at other U.S. locations. This decision was made even though the U.S. trial and the Bochum site trials are not yet completed, and may produce either similar or different outcomes. We cannot yet make any conclusions from the other sites, although we have been informed that not all patients have shown bone generation progress in all types of injuries at this time. We will continue to monitor the progressive bone regeneration in the Barcelona study patients, and expect to formally disclose the longer term results during 2005. We have added sites to the U.S. trial, and are active to expand the Barcelona trial with new patients.

With the safety and bone generation results obtained to date, we initiated the sinus lift clinical trials in Barcelona. This study is to include 5 patients and will evaluate bone generation resulting from TRCs compared with a standard bone grafting procedure (carried out in the same patient on a different location). This trial is underway.

We also have entered into a clinical trial agreement with the Heart & Diabetes Center located in Bad Oeynhausen, Germany to complete a pilot trial to evaluate the safety and potential beneficial effect of TRCs on the vasculature of diabetic patients with limb ischemia. The trial is expected to begin during 2005 after obtaining the needed cell manufacturing permits now required in Germany.

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 revenue recognition, accounts receivable, and inventory.

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. We recognize revenue from product sales when title to the product transfers and there are no remaining obligations that will affect the customer's final acceptance of the sale. If there are remaining obligations, including training and installation (which we believe to be significant), we do not recognize revenue until completion of these obligations. We recognize revenue from licensing fees under licensing agreements and rental revenuewhen there are no future performance obligations remaining with respect to such revenues. 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. As of December 31, 2004, our allowance for doubtful accounts was $7,000.

Inventory. We value our inventory that consists primarily of finished components of our lead product, the AastromReplicell System, and our disposable cell production cassettes, at the lower of cost (specific identification using first in, first out) or market. 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, AastromReplicell System 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 in equal amounts over a six-month period, until the items are either sold or fully reserved. We review cell production cassette inventory relative to its age and our expected sales and, where quantities exceed expected sales utilization, we reduce the recorded value of cell cassette inventory. 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 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.

These critical 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 2004 Annual Report on Form 10-K.

Results of Operations

Total revenues, consisting of grant funding and product sales and rentals, for the quarter and six months ended December 31, 2004 were $374,000 and $561,000, respectively compared to $376,000 and $676,000 for the same periods in fiscal year 2004. Grant revenues decreased for the quarter and six months ended December 31, 2004 to $162,000 and $334,000, respectively from $366,000 and $641,000 for the same periods in fiscal year 2004. Grant revenues have decreased from the prior year as a result of reduced grant program activities. Grant revenues accounted for 60% of total revenues for the six months ended December 31, 2004 and 95% for the same period in fiscal year 2004 and are recorded on a cost-reimbursement basis. Product sales and rentals increased to $212,000 and $227,000 for the quarter and six months ended December 31, 2004, respectively, from $10,000 and $35,000 for the same periods in fiscal year 2004. This increase is due to increased volume of therapy kit sales for clinical trials and research by others. We continue to pursue grant-funded programs as well as sales and marketing opportunities for our products.

Total costs and expenses for the quarter ended December 31, 2004 increased to $2,924,000, compared to $2,816,000 for the same quarter in fiscal year 2004. Costs and expenses during the second quarter of fiscal year 2005 included an increase in research and development expenses to $1,596,000 from $1,455,000 for the same quarter in fiscal year 2004. This increase reflects continued research and product development activities in the area of tissue regeneration and our on-going and planned bone grafting clinical trials in the United States and the European Union. Selling, general and administrative expenses decreased slightly in the second quarter of fiscal year 2005 to $1,289,000 from $1,356,000 for the same period in fiscal year 2004. Cost of product sales and rentals increased to $39,000 in the second quarter of fiscal year 2005 from $5,000 in the comparable period in fiscal year 2004 due to the increase in volume of product sales.

Total costs and expenses for the six months ended December 31, 2004 decreased to $5,820,000 compared to $6,002,000 for the same period in fiscal year 2004. Costs and expenses during the period ended December 31, 2004 did not require a provision for obsolete and excess AastromReplicell System inventory in fiscal year 2005 versus the $253,000 charge that was required in the comparable period of fiscal year 2004. The decrease in costs and expenses also includes selling, general and administrative expenses that decreased to $2,603,000 for the six months ended December 31, 2004 from $2,921,000 in the comparable period of fiscal year 2004. This decrease is primarily the result of a $372,000 non-cash charge related to an employee performance-based stock option that vested and the result of a non-cash

charge of $53,000 relating to certain warrants issued for public and investor relations services that were recorded in the first quarter of the prior fiscal year. Research and development expenses for the six months ended December 31, 2004 increased to $3,163,000 from $2,811,000 in the comparable period of fiscal year 2004, reflecting increased research and product development activities in the area of tissue regeneration. Cost of product sales and rentals for the six months ended December 31, 2004 increased slightly to $54,000 from $17,000 for the same period in fiscal year 2004 due to increased volume of product sales.

Interest income increased to $97,000 and $157,000 for the quarter and six months ended December 31, 2004, respectively, compared to $37,000 and $85,000 for the same periods in fiscal year 2004. 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 to a lesser extent in yields from our funds.

Our net loss increased slightly to $2,453,000 or $.03 per common share for the quarter ended December 31, 2004 compared to a net loss of $2,403,000, or $.03 per common share for the same period in fiscal year 2004. For the six months ended December 31, 2004, our net loss decreased to $5,102,000, or $.06 per common share compared to a net loss of $5,241,000, or $.07 per common share for the same period in fiscal year 2004. The decrease in net loss is primarily the result of decreased 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 described 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 December 31, 2004, have totaled approximately $144 million and, to a lesser degree, through grant funding, payments received under research agreements and collaborations, interest earned on cash, cash equivalents, and short-term investments and funding under equipment leasing agreements. These financing sources have generally allowed us to maintain adequate levels of cash and other liquid investments.

Our combined cash, cash equivalents and short-term investments totaled $22,588,000 at December 31, 2004, an increase of $5,662,000 from June 30, 2004. The primary uses of cash, cash equivalents and short-term investments during the six months ended December 31, 2004 included $5,477,000 to finance our operations and working capital requirements and $204,000 for capital equipment purchases. Included in our capital equipment purchases is $111,000 of equipment that we intend to use in the future in a specialized facility under our control for the production of human cells. The primary source of cash and cash equivalents was from equity financing transactions, with net proceeds of $11,343,000. This equity financing was obtained under multiple transactions in which we sold our common shares and warrants to purchase common shares to investors and common shares sold through our Employee Stock Purchase Plan, stock option plans and Direct Stock Purchase Plan.

On January 10, 2005, the Company concluded its sale of common stock with Fusion Capital Fund II, LLC, pursuant to the common stock purchase agreement dated October 30, 2002. In this final tranche, Fusion purchased 4.8 million shares of common stock for gross proceeds of $12 million at an average price of $2.50 per share. As part of this transaction, we issued an additional 1,940,700 commitment shares to Fusion under the terms of the common stock purchase agreement for which we received no additional proceeds. In addition, subsequent to the end of the quarter and through February 3, 2005, previously issued warrants were exercised for the purchase of 1.8 million shares of common stock for gross proceeds of $2.9 million.

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 agreements or grants, distribution and marketing agreements, 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 interest income, including that raised in the recent sale of common stock, described above, will be sufficient to finance currently planned activities through the end of fiscal year 2006 (ending June 30, 2006). These estimates are 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 2004 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, continued stock market listing and economic conditions affecting the public markets generally or some portion, or all, of the technology sector. If our common stock were to be delisted from the Nasdaq SmallCap Market, the liquidity of our common stock could be impaired, and prices for the shares of our common stock could be lower than might otherwise prevail.

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 2004 Annual Report on Form 10-K and “Notes to Consolidated Financial Statements” and “Certain Business Considerations” included herein.

New Accounting Standards

In December 2004, the Financial Accounting Standards Board (FASB) issued Statements of Financial Accounting Standards No. 123R, "Share-Based Payment" (SFAS 123R), which requires companies to measure and recognize compensation expense for all employee stock-based payments at fair value over the service period underlying the arrangement. SFAS 123R is effective for all interim and annual periods beginning after June 15, 2005 and, thus, will be effective for the Company beginning with fiscal year 2006 (ending June 30, 2006). We are currently evaluating the impact of SFAS 123R on its financial statements. We expect that SFAS 123R will result in an increase in operating expenses in future periods.

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 December 31, 2004, we have incurred cumulative net losses totaling approximately $119 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 ultimately be the largest market for our products. We will also be required to obtain additional approvals from foreign regulatory authorities for sales of our TRC-based products in those jurisdictions. If we cannot demonstrate the safety, reliability and efficacy of our product candidates, we may not be able to obtain required regulatory approvals. 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 currently 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 may, under current regulations be regulated as a biologic product, which requires a biologic license application (BLA).

New directives (laws) have recently become effective in the EU that affect the manufacturing of cell products and clinical trials. These changes have delayed or in some cases temporarily halted clinical trials of cellular products in the EU, 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, which will require license approvals in order to market and sell these products. These new laws may delay some of our current planned clinical trials in the EU, and will require clinical trials with data submission and review by European regulatory bodies. There is uncertainty as to the level of trials and data needed and because of the recent nature of these regulations; there is no established precedent to understand the timeline or other requirements for licensure.

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

Commercialization in the United States and Europe of our cell product candidates will require substantial clinical trials and requirements to meet new and changing regulations for licensure. 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 must successfully complete our clinical trials to be able to market certain of our products.

To be able to market cell-based products in the United States and Europe, 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, the eligibility criteria for the study, and the success of the investigator in enrolling patients. 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 will be seeking to obtain regulatory approvals to market our TRC-based tissue repair and regeneration 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.

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, which 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.

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

Some of the compounds we use in, and are critical to, our TRC manufacturing processes involve the use of animal-derived products. (However, such cells are not used as “feeder cells” in the growth of human TRCs). 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 or prevent manufacturing. 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 authorities 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. There are certain limitations in the supply of certain animal-derived materials, which may lead to delays in our ability to complete clinical trials or eventually to meet the anticipated market demand for our cell products.

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 previously commenced marketing on a very limited basis of the AastromReplicell System and SC-I, DC-I, DCV-I and DCV-II cell production kits in the EU and domestically for research and industrial use, we have only very limited internal or contracted 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. 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.

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. We expect that our available cash and interest income, including that raised in the

recent sale of common stock, described above, will be sufficient to finance currently planned activities through the end of fiscal year 2006 (ending June 30, 2006). 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:

Ÿ continued scientific progress in our research and development programs;

Ÿ costs and timing of conducting clinical trials and seeking regulatory approvals;

Ÿ competing technological and market developments;

Ÿ our ability to establish additional collaborative relationships; and

Ÿ 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. 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 such time, we may enter into financing transactions at prices, which are at a substantial discount to market. 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 $0.63 and $1.72 during the twelve month period ended December 31, 2004. The price of our common stock may continue to fluctuate in response to a number of events and factors, such as:

Ÿ clinical trial results

Ÿ the amount of our cash resources and our ability to obtain additional funding

Ÿ announcements of research activities, business developments, technological innovations, or new products by us or our competitors

Ÿ entering into or terminating strategic relationships

Ÿ changes in government regulation

Ÿ changes in government sponsored funding

Ÿ disputes concerning patents or proprietary rights

Ÿ changes in our revenues or expense levels

Ÿ public concern regarding the safety, efficacy or other aspects of the products or methodologies we are developing

Ÿ reports by securities analysts

Ÿ status of the investment markets

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

Our stock could be delisted from Nasdaq, which would 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. In May 2003, and July 2004, we received notification from Nasdaq of potential delisting as a result of our stock trading below $1.00 for more than thirty consecutive business days. While in each case our stock price recovered within the grace periods and Nasdaq notified us that we were again in full compliance, we cannot provide any assurance that our stock price would again recover within the specified times if future closing bid prices below $1.00 triggered another potential delisting. 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.

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 the AastromReplicell System instruments and consumable components, growth factors and other materials used in the cell manufacturing 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.

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 markets for our products are very competitive, subject to rapid technological changes, and vary for different 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 the practical elimination of this market for our cell-based product for this application.

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 could 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 previously needed to implement 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, Chief Executive Officer and Chairman of Aastrom. Our inability to replace any 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 may 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 has been or is being funded in part by government grants. As a result of such funding, the U.S. Government has established guidelines and have certain rights in the technology developed with the grant. 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.

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 (but not common stock above the shareholder approved maximum) 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.

Failure to achieve and maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act could have a material adverse effect on our business and.result in a negative market reaction.

We are in the process of documenting and testing our internal control procedures in order to satisfy the requirements of Section 404 of the Sarbanes-Oxley Act, which requires annual management assessments of the effectiveness of our internal controls over financial reporting. Additionally, our independent registered public accountants are required to audit both the design and operating effectiveness of our internal control over financial reporting and management's assessment of the design and the effectiveness of its internal control over financial reporting. Although no known material weaknesses exist at this time, this will be the first year that we have undergone an audit for our internal controls and procedures, and it is possible that material weaknesses could be found through the evaluation. If such weaknesses are found, we may not be able to remediate such weaknesses in time to meet the deadlines imposed by the Sarbanes-Oxley Act for compliance with requirements of Section 404. Failure to achieve and maintain an effective internal control environment could result in a negative market reaction.

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:

Ÿ potential strategic collaborations with others

Ÿ future capital needs

Ÿ adequacy of existing capital to support operations for a specified time

Ÿ product development and marketing plans

Ÿ clinical trial plans and anticipated results

Ÿ anticipation of future losses

Ÿ replacement of manufacturing sources

Ÿ commercialization plans

Ÿ 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 2004 Annual Report of Form 10-K.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

As of December 31, 2004, our cash, cash equivalents and short-term investments included money market securities and commercial paper. Due to the short duration of our investment portfolio and the high quality of our investments required by our investment policy, 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 instrument arrangements.

Item 4. Controls and Procedures

(a) Under the supervision and with the participation of our management, including our Chief Executive Officer 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 Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures are effective as of the end of the period covered by this quarterly report.

(b) During our last fiscal quarter, there have been no significant changes (including corrective actions with regard to significant deficiencies or material weaknesses) in our internal controls over financial reporting that have materially affected, or are reasonably likely to materially affect our internal controls over financial reporting.

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. Unregistered Sales of Equity Securities and Use of Proceeds

On October 19, 2004, we issued 187,156 shares of common stock upon net exercise of a warrant previously issued to a provider of public and investor relations' services. The shares were issued in a private transaction exempt from the registration requirements of the Securities Act pursuant to Section 4(2) thereof.

Item 3. Defaults Upon Senior Securities

None.

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

(a) The Annual Meeting of Shareholders of Aastrom Biosciences, Inc. was held on November 10, 2004.

(b) At the 2004 Annual Meeting of Shareholders, votes were cast on matters submitted to the shareholders, as follows:

Proposal 1: Election of two directors whose terms expire at the 2007 Annual Meeting of Shareholders.

NOMINEE	FOR	WITHHELD
Linda M. Fingerle	74,475,129	576,842
Susan L. Wyant	74,471,968	580,003

In addition to the election of the above referenced directors, the following individuals continue as directors; Arthur F. Staubitz, as a Class II Director, whose term expires at the 2005 Annual Meeting of Shareholders; R. Douglas Armstrong and Joseph A. Taylor as Class III Directors, whose terms expire at the 2006 Annual Meeting of Shareholders.

Proposal 2: Approve the 2004 Omnibus Equity Incentive Plan.

FOR	AGAINST	ABSTAIN	BROKER NON-VOTES
12,008,904	2,610,238	324,135	60,108,694

Proposal 3: Ratification of the selection of PricewaterhouseCoopers LLP as the Company's independent registered public accounting firm for the year ending June 30, 2005.

FOR	AGAINST	ABSTAIN
74,777,210	236,213	38,548

Item 5. Other Information

None.

Item 6. Exhibits

See Exhibit Index.

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: February 8, 2005

/s/ R. Douglas Armstrong

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

Date: February 8, 2005

/s/ Alan M. Wright

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

EXHIBIT INDEX

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

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* Incorporated by reference to the Company's Quarterly Report on 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: February 8, 2005

/s/ R. Douglas Armstrong
- ------------------------
R. Douglas Armstrong, Ph.D.
Chief Executive Officer and Chairman
(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: February 8, 2005

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

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 December 31, 2004, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, R. Douglas Armstrong, Chief Executive Officer and Chairman 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.

February 8, 2005

/s/ R. Douglas Armstrong
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R. Douglas Armstrong, Ph.D.
Chief Executive Officer and Chairman
(Principal Executive Officer)

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 December 31, 2004, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Alan M. Wright, Senior Vice President Administrative and Financial Operations 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.

February 8, 2005

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