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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 MARCH 31, 2005, OR
- TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM \_\_\_ TO \_\_\_

Commission file number 0-22025

**AASTROM BIOSCIENCES, INC.**

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(Exact name of registrant as specified in its charter)

Michigan

(State or other jurisdiction of  
incorporation or organization)

94-3096597

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

24 Frank Lloyd Wright Dr.  
P.O. Box 376

Ann Arbor, Michigan

(Address of principal executive offices)

48106

(Zip code)

(734) 930-5555

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(Registrant's telephone number, including area code)

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes —  No —

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

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

COMMON STOCK, NO PAR VALUE  
(Class)

101,782,296  
Outstanding at May 6, 2005

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AASTROM BIOSCIENCES, INC.  
Quarterly Report on Form 10-Q  
March 31, 2005

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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	March 31, 2005 <i>(Unaudited)</i>
<b>Assets</b>		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 16,926,000	\$ 13,494,000
Short-term investments	—	21,941,000
Receivables, net	246,000	259,000
Inventory	389,000	226,000
Other current assets	271,000	471,000
Total current assets	<u>17,832,000</u>	<u>36,391,000</u>
PROPERTY AND EQUIPMENT, NET	334,000	614,000
Total assets	<u>\$ 18,166,000</u>	<u>\$ 37,005,000</u>
<b>Liabilities and Shareholders' Equity</b>		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	\$ 382,000	\$ 614,000
Accrued employee benefits	176,000	187,000
Total current liabilities	<u>558,000</u>	<u>801,000</u>
SHAREHOLDERS' EQUITY:		
Common stock, no par value; shares authorized – 150,000,000; shares issued and outstanding – 81,373,191 and 101,780,930, respectively	131,472,000	158,519,000
Deficit accumulated during the development stage	<u>(113,864,000)</u>	<u>(122,315,000)</u>
Total shareholders' equity	17,608,000	36,204,000
Total liabilities and shareholders' equity	<u>\$ 18,166,000</u>	<u>\$ 37,005,000</u>

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,
	2004	2005	2004	2005	2005
<b>REVENUES:</b>					
Product sales and rentals	\$ 10,000	\$ 150,000	\$ 45,000	\$ 377,000	\$ 1,108,000
Grants	331,000	102,000	972,000	436,000	7,962,000
Research and development agreements	75,000	—	75,000	—	2,105,000
<b>Total revenues</b>	<b>416,000</b>	<b>252,000</b>	<b>1,092,000</b>	<b>813,000</b>	<b>11,175,000</b>
<b>COSTS AND EXPENSES:</b>					
Cost of product sales and rentals	5,000	77,000	22,000	131,000	546,000
Cost of product sales and rentals — provision for obsolete and excess inventory	—	9,000	253,000	9,000	2,239,000
Research and development	1,660,000	2,095,000	4,471,000	5,258,000	98,695,000
Selling, general and administrative	1,279,000	1,624,000	4,200,000	4,227,000	37,744,000
<b>Total costs and expenses</b>	<b>2,944,000</b>	<b>3,805,000</b>	<b>8,946,000</b>	<b>9,625,000</b>	<b>139,224,000</b>
<b>LOSS FROM OPERATIONS</b>	<b>(2,528,000)</b>	<b>(3,553,000)</b>	<b>(7,854,000)</b>	<b>(8,812,000)</b>	<b>(128,049,000)</b>
<b>OTHER INCOME (EXPENSE):</b>					
Other income	—	12,000	—	12,000	1,249,000
Interest income	28,000	192,000	113,000	349,000	5,720,000
Interest expense	—	—	—	—	(267,000)
<b>Other income</b>	<b>28,000</b>	<b>204,000</b>	<b>113,000</b>	<b>361,000</b>	<b>6,702,000</b>
<b>NET LOSS</b>	<b>\$ (2,500,000)</b>	<b>\$ (3,349,000)</b>	<b>\$ (7,741,000)</b>	<b>\$ (8,451,000)</b>	<b>\$ (121,347,000)</b>
<b>NET LOSS PER SHARE (Basic and Diluted)</b>	<b>\$ (.03)</b>	<b>\$ (.03)</b>	<b>\$ (.11)</b>	<b>\$ (.09)</b>	
Weighted average number of shares outstanding (Basic and Diluted)	72,204,000	100,140,000	71,384,000	90,719,000	

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,
	2004	2005	2005
<b>OPERATING ACTIVITIES:</b>			
Net loss	\$ (7,741,000)	\$ (8,451,000)	\$ (121,347,000)
Adjustments to reconcile net loss to net cash used for operating activities:			
Depreciation and amortization	91,000	110,000	3,681,000
Loss on property held for resale	—	—	110,000
Amortization of discounts and premiums on investments	—	—	(543,000)
Stock compensation expense	425,000	78,000	1,502,000
Inventory write downs and reserves	253,000	9,000	2,239,000
Stock issued pursuant to license agreement	—	—	3,300,000
Provision for losses on accounts receivable	—	—	156,000
Changes in assets and liabilities:			
Receivables	74,000	(13,000)	(439,000)
Inventory	(125,000)	154,000	(2,561,000)
Other current assets	(298,000)	(200,000)	(471,000)
Accounts payable and accrued expenses	(26,000)	232,000	614,000
Accrued employee benefits	(9,000)	11,000	187,000
Net cash used for operating activities	<u>(7,356,000)</u>	<u>(8,070,000)</u>	<u>(113,572,000)</u>
<b>INVESTING ACTIVITIES:</b>			
Organizational costs	—	—	(73,000)
Purchase of short-term investments	—	(25,941,000)	(88,065,000)
Maturities of short-term investments	—	4,000,000	66,667,000
Property and equipment purchases	(97,000)	(390,000)	(3,462,000)
Proceeds from sale of property held for resale	—	—	400,000
Net cash used for investing activities	<u>(97,000)</u>	<u>(22,331,000)</u>	<u>(24,533,000)</u>
<b>FINANCING ACTIVITIES:</b>			
Net proceeds from issuance of preferred stock	—	—	51,647,000
Net proceeds from issuance of common stock	7,367,000	26,969,000	97,644,000
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	<u>7,367,000</u>	<u>26,969,000</u>	<u>151,599,000</u>
<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	<u>(86,000)</u>	<u>(3,432,000)</u>	<u>13,494,000</u>
<b>CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD</b>	<u>10,512,000</u>	<u>16,926,000</u>	<u>—</u>
<b>CASH AND CASH EQUIVALENTS AT END OF PERIOD</b>	<u>\$ 10,426,000</u>	<u>\$ 13,494,000</u>	<u>\$ 13,494,000</u>

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**

Astrom 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 of proprietary cell-based therapeutics.

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 include: the rate and degree of progress for its product development, the rate of regulatory approval to proceed with 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 provide a fair statement of 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, 2005, 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 March 31,		For the Nine Months Ended March 31,	
	2004	2005	2004	2005
Reported net loss	\$ (2,500,000)	\$ (3,349,000)	\$ (7,741,000)	\$ (8,451,000)
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	(244,000)	(316,000)	(701,000)	(604,000)
Pro forma net loss	<u>\$ (2,744,000)</u>	<u>\$ (3,665,000)</u>	<u>\$ (8,070,000)</u>	<u>\$ (9,055,000)</u>
Net loss per common share:				
As reported	\$ (0.03)	\$ (0.03)	\$ (0.11)	\$ (0.09)
Pro forma	\$ (0.04)	\$ (0.04)	\$ (0.11)	\$ (0.10)



#### **4. Shareholders' Equity**

During the nine months ended March 31, 2005, the Company issued 17,294,874 shares of common stock to investors, 1,069,039 shares of common stock as part of the stock option plans, the Direct Stock Purchase Plan and the Employee Stock Purchase Plan and 2,043,826 shares of common stock in connection with the exercise of certain warrants previously issued to investors, for net cash proceeds of \$26,969,000.

#### **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 nine months ended March 31, 2004 and 2005 is approximately 5,922,000 and 10,092,000, 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 and recognized expense over the service period underlying the arrangement. Pursuant to Securities and Exchange Commission (SEC) rules, SFAS 123R is effective for all annual periods beginning after June 15, 2005 and, thus, will be effective for the Company beginning with the first quarter ending September 30, 2005 of 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.

In April 2005, the SEC adopted a final rule amending the compliance date for SFAS 123R. The effect of this ruling is to delay the effective date of SFAS 123R to the annual reporting period of the registrant's first fiscal year beginning on or after June 15, 2005. This rule does not change the effective date for the Company.

#### **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 nine months of fiscal year 2005, ended March 31, 2005, 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 March 31, 2005. The equipment will be depreciated over its useful life beginning when the equipment is placed into service.

## Overview of Aastrom

We are a late-stage development company focused on the development of 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 bone marrow-derived adult stem and progenitor cell mixtures being investigated for aiding in the growth of 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 of proprietary cell-based therapeutics.

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 adult stem and progenitor cells, produced outside of the body or “*ex vivo*” from a small amount of bone marrow taken from the patient. In clinical trials involving over 180 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 applied to the production of dendritic cells and dendritic cell vaccines for third parties 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 targeting developers of dendritic cells and dendritic cell vaccines 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 such as is needed 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, cardiac tissue regeneration, and dendritic cell based vaccines.

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 and, if necessary, to complete some pilot level of sales and marketing activity ourselves.

In the EU, our business development activities are aided through staff at Zellera AG, our small, 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 minimal and irregular revenue has been generated from this business and as a result, it is no longer a priority area 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, limited product sales of the AastromReplicell System 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 the necessary approvals to market our products. Through March 31,

2005, we have accumulated losses of approximately \$121 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 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 fracture trial is not yet complete, and may produce either similar or different outcomes. We cannot make any conclusions from the other sites at this time. However, the two patients at the Bochum site that were treated for difficult bone graft indication for a leg lengthening application (called failed osteogenic distractions), rather than a trauma fracture, did not experience new bone formation. These patients had failed multiple, previous standard of care treatments. 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 from the trials for fractures, we initiated the sinus lift bone generation clinical trial in Barcelona. This study has enrolled 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 revenue when 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 March 31, 2005, 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. AastromReplicell System 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 nine months ended March 31, 2005 were \$252,000 and \$813,000, respectively compared to \$416,000 and \$1,092,000 for the same periods in fiscal year 2004. Grant revenues decreased for the quarter and nine months ended March 31, 2005 to \$102,000 and \$436,000, respectively, from \$331,000 and \$972,000 for the same periods in fiscal year 2004. Grant revenues have decreased from the prior year as a result of reduced grant program activities; however, we continue to pursue grant-funded programs. Grant revenues accounted for 54% of total revenues for the nine months ended March 31, 2005 and 89% for the same period in fiscal year 2004 and are recorded on a cost-reimbursement basis. Grant revenues may vary in any period based on timing of grant awards, grant-funded activities, level of grant funding and number of grants awarded. Product sales and rentals increased to \$150,000 and \$377,000 for the quarter and nine months ended March 31, 2005, respectively, from \$10,000 and \$45,000 for the same periods in fiscal year 2004. The increase is due to increased volume of therapy kit sales for clinical trials and research by others and revenue from the sale of an AastromReplicell System that was delivered in the first quarter of fiscal year 2005, and recognized in this quarter. Revenues include rental revenue of \$10,000 and \$30,000 for the quarter and nine months ended March 31, 2004, respectively. This revenue was generated from an AastromReplicell System rental agreement that has been terminated. Based upon our current business strategy, we do not expect rental revenue in future periods. We plan to limit our marketing efforts promoting the AastromReplicell System as a stand-alone product; rather we are focusing on utilizing the AastromReplicell System technology to support our TRC development programs. At such time as we satisfy applicable regulatory approval requirements, we expect the sales of our TRCs and our related cell-based products will constitute nearly all of our product sales revenues.

Total costs and expenses for the quarter ended March 31, 2005 increased to \$3,805,000, compared to \$2,944,000 for the same quarter in fiscal year 2004. Costs and expenses during the third quarter of fiscal year 2005 included an increase in research and development expenses to \$2,095,000 from \$1,660,000 for the same quarter in fiscal year 2004. This increase reflects increased research activities to support regulatory submission approvals and anticipated product registrations, product development activities in the area of tissue regeneration, development of product distribution processes, and our on-going and planned bone grafting clinical trials in the United States and the European Union. Selling, general and administrative expenses increased in the second quarter of fiscal year 2005 to \$1,624,000 from \$1,279,000 for the same period in fiscal year 2004. This increase is due to additional consulting and pre-marketing activities in the United States and internationally, and increased costs required for financial internal controls compliance and certification. The cost of product sales and rentals

increased to \$77,000 in the third 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 nine months ended March 31, 2005 increased to \$9,625,000 compared to \$8,946,000 for the same period in fiscal year 2004. Costs and expenses during the period ended March 31, 2005 did require a provision for obsolete and excess AastromReplicell System inventory of \$9,000, due to a System that was under customer evaluation and that will not be purchased, versus the \$253,000 charge that was required in the comparable period of fiscal year 2004. The increase in costs and expenses also includes an increase in selling, general and administrative expenses to \$4,227,000 for the nine months ended March 31, 2005 from \$4,200,000 in the comparable period of fiscal year 2004. Research and development expenses for the nine months ended March 31, 2005 increased to \$5,258,000 from \$4,471,000 in the comparable period of fiscal year 2004, reflecting increased research and product development activities in the area of tissue regeneration and on-going and preparation for additional bone grafting clinical trials. Cost of product sales and rentals for the nine months ended March 31, 2005 increased to \$131,000 from \$22,000 for the same period in fiscal year 2004 due to increased volume of product sales.

Interest income increased to \$192,000 and \$349,000 for the quarter and nine months ended March 31, 2005, respectively, compared to \$28,000 and \$113,000 for the same periods in fiscal year 2004. The fluctuations in interest income are due primarily to an increased level of cash, cash equivalents and short-term investments during the periods and higher yields from our funds.

Our net loss increased to \$3,349,000 or \$.03 per common share for the quarter ended March 31, 2005, compared to a net loss of \$2,500,000, or \$.03 per common share for the same period in fiscal year 2004. For the nine months ended March 31, 2005, our net loss increased to \$8,451,000, or \$.09 per common share compared to a net loss of \$7,741,000, or \$.11 per common share for the same period in fiscal year 2004. The increase in net loss is primarily the result of increased costs and expenses. The decrease in the net loss per share for the nine months ended March 31, 2005, compared to the nine months ended March 31, 2004 is the result of the 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 March 31, 2005, have totaled approximately \$152 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 \$35,435,000 at March 31, 2005, an increase of \$18,509,000 from June 30, 2004. The primary uses of cash, cash equivalents and short-term investments during the nine months ended March 31, 2005 included \$8,070,000 to finance our operations and working capital requirements and \$390,000 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 \$26,969,000. 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.

In January 2005, we concluded our 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, previously issued warrants were exercised for the purchase of 1.8 million shares of common stock, generating 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 effect 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 and recognized expense over the service period underlying the arrangement. Pursuant to Securities and Exchange Commission (SEC) rules, 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 the first quarter ending September 30, 2005 of 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.

In April 2005, the SEC adopted a final rule amending the compliance date for SFAS 123R. The effect of this ruling is to delay the effective date of SFAS 123R to the first interim or annual reporting period of the registrant’s first fiscal year beginning on or after June 15, 2005. This rule does not change the effective date for the Company.

### **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, 2005, we have incurred cumulative net losses totaling approximately \$121 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 (such as the Tissue Repair Cells) 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 with Tissue Repair Cells 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 and cell manufacturing facilities. 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:

- 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. 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 \$0.65 and \$4.05 during the twelve month period ended March 31, 2005. 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
- changes in government sponsored funding
- 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
- 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 chemotherapy, 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 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 or the Tissue Repair Cells 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 controls over financial reporting 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 control over financial reporting. Additionally, our independent registered public accounting firm is 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 over financial reporting, 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 effective internal controls over financial reporting could result in an adverse report from our independent registered public accountants and 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:

- potential strategic collaborations with others
- future capital needs
- adequacy of existing capital to support operations for a specified time
- product development and marketing plans
- clinical trial plans and anticipated results
- anticipation of future losses
- replacement of manufacturing sources
- commercialization plans
- 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 on Form 10-K.

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

As of March 31, 2005, 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. However, several European Union clinical trial expenses are paid in euros. Our aggregate market risks from currency rate fluctuations are not expected to be significant. 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 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*

All required information was previously included in a Current Report on Form 8-K filed with the SEC on January 13, 2005.

### *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*

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: May 9, 2005

/s/ R. Douglas Armstrong

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

Date: May 9, 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
10.78	Employment Agreement with Robert J. Bard
31	Rules 13a-14(a) and 14(d)-14a Certifications
32	Section 1350 Certifications

\* 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.

EMPLOYMENT AGREEMENT

This Employment Agreement (the "Agreement") is entered into as of March 1, 2005, by and between AASTROM BIOSCIENCES, INC., a Michigan corporation ("Employer"), and Robert Bard ("Employee").

RECITALS

1. Employer desires to employ Employee on the terms and conditions set forth in this Agreement.
2. Employee desires to be employed by Employer on the terms and conditions set forth in this Agreement.

AGREEMENTS

1. DEFINITIONS. As used in this Agreement, the following terms shall have the following meanings:

"Acquiring Corporation" shall mean the surviving, successor or purchasing corporation or parent corporation thereof, in a Change in Control, as the case may be.

"Cause" means the occurrence of any of the following events, as determined by the Board of Directors of Employer, in good faith:

(i) Employee's theft, material act of dishonesty or fraud, or intentional falsification of any records of Employer;

(ii) Employee's breach of the Aastrom Biosciences, Inc. Employee Proprietary Information and Invention Agreement or any other agreement with the Employer covering the use or disclosure of confidential or proprietary information of Employer, the ownership of intellectual property or restrictions on competition;

(iii) Employee's gross negligence or willful misconduct in the performance of Employee's assigned duties (but not mere unsatisfactory performance); or

(iv) Employee's conviction (including any plea of guilty or nolo contendere) of a crime causing material harm to the reputation or standing of Employer or which materially impairs Employee's ability to perform his duties for Employer.

"Change in Control" shall mean the occurrence of any of the following:

(i) any "person" (as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act")), other than a trustee or other fiduciary holding securities of Employer under an employee benefit plan of Employer, becomes the "beneficial owner" (as defined in Rule 13d-3 promulgated under the Exchange Act), directly or indirectly, of securities of Employer representing 50% or more of (A) the outstanding



shares of common stock of Employer or (B) the combined voting power of Employer's then-outstanding securities;

(ii) Employer is party to a merger or consolidation which results in the holders of voting securities of Employer outstanding immediately prior thereto failing to continue to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity) at least 50% of the combined voting power of the voting securities of Employer or such surviving entity outstanding immediately after such merger or consolidation; or

(iii) the sale or disposition of all or substantially all of Employer's assets (or consummation of any transaction having similar effect).

"Disability" means that:

(i) Employee has been incapacitated by bodily injury, illness or disease so as to be prevented thereby from effectively performing Employee's duties;

(ii) Such incapacity shall have continued for a period of six (6) consecutive months; and

(iii) Such incapacity will, in the opinion of a qualified physician, be long-term, which shall mean a period exceeding twelve (12) months.

"Employee" means Robert Bard

"Employer" means Aastrom Biosciences, Inc., a Michigan corporation, and, following a Change in Control, any Successor that agrees to assume all of the terms and provisions of this Agreement, or a Successor which otherwise becomes bound by operation of law to this Agreement.

"Good Reason" means the occurrence of any of the following conditions following a Change in Control, without Employee's informed written consent, which condition(s) remain(s) in effect ten (10) days after written notice to Employer from Employee of such condition(s):

(i) assignment of Employee to responsibilities or duties that are not a Substantive Functional Equivalent of the position which Employee occupied prior to the Change in Control;

(ii) any decrease in Employee's base salary or target bonus amount (subject to applicable performance requirements with respect to the actual amount of bonus compensation earned by Employee);

(iii) any failure by Employer to (A) continue to provide Employee with the opportunity to participate, on terms no less favorable than those in effect for the benefit of any employee group which customarily includes a person holding the employment position or a comparable position with Employer then held by Employee, in any benefit or compensation plans and programs, including, but not limited to, Employer's life, disability, health, dental,

medical, savings, profit sharing, stock purchase and retirement plans, if any, in which Employee was participating immediately prior to the date of the Change in Control, or their equivalent, or (B) provide Employee with all other fringe benefits (or their equivalent) from time to time in effect for the benefit of any employee group which customarily includes a person holding the employment position or a comparable position with Employer then held by Employee;

(iv) the relocation of Employee's work place for Employer to a location more than 50 miles from the location of the work place prior to the Change in Control, or the imposition of travel requirements substantially more demanding of Employee than such travel requirements existing immediately prior to the Change in Control; or

(v) any material breach of this Agreement by Employer.

"Relocation Costs" shall mean the following actual out-of-pocket costs incurred by the Employee:

(i) Coach class airfare for Employee's family to move from Dana Point, California to Ann Arbor, Michigan, or, in the alternative, reimbursement of reasonable automobile operating costs (gas, tolls, etc.), not to exceed the current IRS permitted per mile allowances, for up to two automobiles required to move the Employee's family.

(ii) Cost for packing, shipping, and unloading personal household furnishings and belongings from Employee's prior residence to a new residence in Ann Arbor, Michigan, including temporary storage as needed.

(iii) Shipment of one personal vehicle from Dana Point, California to Ann Arbor, Michigan, via common carrier.

(iv) The aggregate of all of the above-described costs shall not exceed thirty thousand dollars (\$30,000) without prior written agreement of Employer.

"Substantive Functional Equivalent" means an employment position occupied by Employee after a Change in Control that:

(i) is in a substantive area of competence consistent with Employee's experience and not materially different from the position occupied by Employee prior to the Change in Control;

(ii) requires Employee to serve in a role and perform duties that are functionally equivalent to those performed prior to the Change in Control (such as, executive officer);

(iii) carries a title that does not connote a lesser rank or corporate role than the title held by Employee prior to the Change in Control; and

(iv) does not otherwise constitute a material, adverse change in Employee's responsibilities or duties, as measured against Employee's responsibilities or duties prior to the Change in Control, causing it to be of materially lesser rank or responsibility.

"Successor" means Employer and any successor or assign to substantially all of its business and/or assets.

2. EMPLOYMENT. Employer hereby engages Employee, and Employee hereby accepts such engagement, upon the terms and conditions set forth herein.

3. DUTIES. Employee is engaged as Vice President, Regulatory and Quality Systems. Employee shall perform faithfully and diligently the duties customarily performed by persons in the position for which employee is engaged, together with such other reasonable and appropriate duties as Employer shall designate from time to time. Employee shall devote Employee's full business time and efforts to the rendition of such services and to the performance of such duties. Employee shall not be entitled to provide consulting services or other business or scientific services to any other party, without the prior written consent of Employer.

4. COMPENSATION AND FRINGE BENEFITS.

4.1 BASE SALARY. During the term of this Agreement, as compensation for the proper and satisfactory performance of all duties to be performed by Employee hereunder, Employer shall pay to Employee a salary of two hundred three thousand dollars (\$203,000) per year ("Base Salary"), payable in arrears in equal semi-monthly installments, less required deductions for state and federal withholding tax, Social Security and all other employee taxes and payroll deductions. The Base Salary shall be subject to review and adjustment on an annual basis.

4.2 CUSTOMARY FRINGE BENEFITS. Employee shall be entitled to such fringe benefits as Employer customarily makes available to employees of Employer engaged in the same or similar position as Employee ("Fringe Benefits"). Such Fringe Benefits may include vacation leave, sick leave, and health insurance coverage. Employer reserves the right to change the Fringe Benefits on a prospective basis, at any time, effective upon delivery of written notice to Employee.

4.3 VACATION. Employee is entitled to twenty days of vacation in each calendar year.

4.4 ACCUMULATION. Employee shall earn and accumulate unused vacation and sick leave in accordance with the Company's policy in effect from time to time. Further, Employee shall not be entitled to receive payments in lieu of Fringe Benefits, other than for unused vacation leave earned and accumulated at the time the employment relationship terminates.

4.5 RELOCATION COSTS.

4.5.1 Temporary Living Allowance. Employee agrees to relocate Employee's principal domestic residence to within fifty (50) miles of Ann Arbor, Michigan, by December 31, 2005. For so long as Employee maintains Employee's principal domestic residence in Dana Point, California, but in no event later than August 31, 2005, Employer will reimburse Employee for the following costs:

(i) Employee's actual out-of-pocket housing and related costs (including rent, insurance, utilities, local telephone service, laundry) in Ann Arbor, Michigan, in an aggregate amount of not more than two thousand dollars (\$2,000) per calendar month.

(ii) Employee's actual out-of-pocket costs for round trip coach airfare travel from Ann Arbor, Michigan, to, Dana Point, California up to one such trip per calendar week. Employee shall use reasonable best efforts to obtain the most economical fares available for such trips.

4.5.2 Relocation Costs. Employer shall reimburse Employee for the Relocation Costs. The Employee shall be required to refund and pay to Employer 100% of the Relocation Costs that have been paid by the Employer on the following terms:

(i) If Employee's employment with Employer ceases within 24 months after Employee commences full-time employment with Employer (the "Commencement Date"), due to the Employee voluntarily electing to leave the employ of Employer, or Employer terminating the Employee for Cause, Employee hereby agrees to refund and pay to Employer 100% of the Relocation Costs that have been paid by Employer.

(ii) If Employer elects to terminate the employment of Employee without Cause, then Employee shall have no obligation to refund any of the Relocation Costs. If Employee's employment terminates due to Employee's death or disability, then Employee shall have no obligation to refund any of the Relocation Costs.

(iii) With respect to any of the Relocation Costs which Employee does become obligated to refund to Employer, as specified above, said refund shall be made within six months after the termination of employment. Any portion of the Relocation Costs which are obligated to be refunded by Employee, and which are not refunded within said six (6) months, shall thereafter bear a late payment charge of 10% per annum.

## 5. TERM.

5.1 COMMENCEMENT. The employment relationship pursuant to this Agreement shall commence at a date to be designated by mutual agreement of the Employer and Employee, but in any event such date shall not be later than April 1, 2005.

5.2 TERMINATION AT WILL. Employer and Employee acknowledge and agree that Employer's employment currently is "at will" and that their employment relationship may be terminated by either party at any time, with or without Cause.

## 6. PAYMENTS UPON TERMINATION.

6.1 PAYMENT OF COMPENSATION UPON TERMINATION. Upon termination of Employee's employment with the Company, Employee shall be entitled to be paid salary as provided in Section 4.1 through the effective date of such termination, as full compensation for any and all claims of Employee under this Agreement or otherwise, except as set forth in Section 6.2.

### 6.2 PAYMENT OF SEVERANCE UPON TERMINATION.

6.2.1 Severance. In the event Employee's employment is terminated by Employer without Cause, or in the event of Employee's termination of employment for Good Reason within twelve (12) months following a Change in Control, then Employer shall pay to

Employee severance payment equal to six months of Employee's then current annual salary rate, less customary payroll deductions. The severance payment shall be paid in equal installments over six months in accordance with the Employer's normal payroll periods, except that severance payments due following a Change in Control shall be paid in a lump sum immediately following the Change in Control.

6.2.2 Continued Medical Coverage. In the event Employee's employment is terminated, then Employee shall be entitled to elect continued medical insurance coverage in accordance with applicable provisions of the Consolidated Budget Reconciliation Act of 1985 ("COBRA").

6.2.3 Right to Terminate. Employer retains and reserves the right to terminate the employment of Employee at any time, with or without Cause. For avoidance of doubt, said severance payment shall not be owed if Employee's termination is for Cause, if Employee voluntarily terminates employment for reasons other than as specified in Section 6.2.1 hereof or if Employee's employment terminates as a result of Employee's death or disability.

6.2.4 No Liability. No director, officer or shareholder of Employer shall have any personal liability for the payment of any severance to Employee.

6.3 RESIGNATION. Employee's entitlement to any compensation or benefits under this Section 6 (other than compensation and benefits earned by Employee through the date of Employee's termination of employment) is conditioned upon Employee's resignation from all capacities in which Employee is then rendering services to Employer, including from the Board of Directors and any committees thereof on which Employee serves.

6.4 EXCLUSIVE REMEDY. The parties acknowledge and agree that the payments specified herein constitute Employee's sole and exclusive remedy for any alleged injury or other damages arising out of a termination of Employee's employment under circumstances described herein. Accordingly, as a condition to receipt of said payments, Employee shall sign a customary and reasonable release form, in the form attached hereto as Exhibit A, pursuant to which Employee acknowledges and agrees that Employee has no claims against Employer or any director, officer, shareholder or agent of Employer, or any successor in interest to Employer, with respect to any employment matters or termination of employment (excepting only for accrued salary, accrued vacation leave and reimbursement of customary business expenses incurred on behalf of Employer, all in the ordinary course of business, or any incentive sale bonus to which Employee may be entitled, if any).

## 7. GENERAL PROVISIONS.

7.1 ATTORNEYS' FEES. In the event of any dispute or breach arising with respect to this Agreement, the party prevailing in any negotiations or proceedings for the resolution or enforcement thereof shall be entitled to recover from the losing party reasonable expenses, attorneys' fees and costs incurred therein.

7.2 AMENDMENTS. No amendment or modification of the terms or conditions of this Agreement shall be valid unless in writing and signed by both parties hereto. There shall be no implied-in-fact contracts modifying the terms of this Agreement. However, the noncumulation

of benefits provision of Section 7.6 shall apply to any subsequent agreement, unless (i) such provision is explicitly disclaimed in the subsequent agreement, and (ii) the subsequent agreement has been authorized by the Board of Directors of the Employer or a committee thereof.

7.3 ENTIRE AGREEMENT. This Agreement constitutes the entire agreement between the parties with respect to the employment of Employee, other than relating to the Employer's stock option grants to Employee, the Employer's inventions, trade secrets, and proprietary and confidential information, competition with the Employer and solicitation of the Employer's employees. This Agreement supersedes all prior agreements, understandings, negotiations and representation with respect to the employment relationship.

7.4 SUCCESSORS AND ASSIGNS. This Agreement shall inure to the benefit of and be enforceable by the Employee's personal and legal representatives, executors, administrators, successors, heirs, distributees, devisees and legatees.

7.5 NO LIMITATION OF REGULAR BENEFIT PLANS. This Agreement is not intended to and shall not affect, limit or terminate any plans, programs, or arrangements of Employer that are regularly made available to a significant number of employees or officers of the Employer, including without limitation Employer's stock option plans.

7.6 NONCUMULATION OF BENEFITS. Employee may not cumulate cash severance payments under both this Agreement and another agreement. If Employee has any other binding written agreement with Employer which provides that, upon a Change in Control or termination of employment, Employee shall receive one or more of the benefits described in Sections 6 of this Agreement (i.e., the payment of cash compensation), then with respect to those benefits the aggregate amounts payable under this Agreement shall be reduced by the amounts paid or payable under such other agreements.

7.7 NO ASSIGNMENT OF BENEFITS. The rights of any person to payments or benefits under this Agreement shall not be made subject to option or assignment, either by voluntary or involuntary assignment or by operation of law, including (without limitation) bankruptcy, garnishment, attachment or other creditors process, and any action in violation of this Section 7.7 shall be void.

7.8 NOTICES. Notices and all other communications contemplated by this Agreement shall be in writing and shall be deemed to have been duly given when personally delivered, when mailed, if mailed by U.S. registered or certified mail, return receipt requested and postage prepaid, or when shipped, if shipped by nationally known reputable overnight delivery service and shipping charges prepaid. In the case of Employee, notices shall be addressed to Employee at the home address which he most recently communicated to the Employer, in writing. In the case of the Employer, notices shall be addressed to its corporate headquarters, and all notices shall be directed to the attention of its Secretary.

7.9 NO DUTY TO MITIGATE. Employee shall not be required to mitigate the amount of any payment contemplated by this Agreement (whether by seeking employment with a new employer or in any other manner), nor shall any such payment be reduced by any earnings that Employee may receive from any other source except as otherwise provided herein.

7.10 NO REPRESENTATIONS. Employee acknowledges that in entering into this Agreement Employee is not relying and has not relied on any promise, representation or statement made by or on behalf of the Employer which is not set forth in this Agreement.

7.11 CHOICE OF LAW. The validity, interpretation, construction and performance of this Agreement shall be governed by the laws of the State of Michigan, without regard to its choice of law rules.

7.12 WAIVER. Either party's failure to enforce any provision of this Agreement shall not in any way be construed as a waiver of any such provision, or prevent that party thereafter from enforcing each and every other provision of this Agreement.

7.13 SEVERABLE PROVISIONS. The provisions of this Agreement are severable, and if any one or more provisions may be determined to be judicially unenforceable, in whole or in part, the remaining provisions shall nevertheless be binding and enforceable.

7.14 TAX WITHHOLDING. The payments to be made pursuant to this Agreement will be subject to customary withholding of applicable income and employment taxes.

7.15 CONSULTATION. Employee acknowledges that this Agreement confers significant legal rights on Employee, and also involves Employee waiving other potential rights he might have under other agreements and laws. Employee acknowledges that Employer has encouraged Employee to consult with Employee's own legal, tax, and financial advisers before signing the Agreement; and that Employee has had adequate time to do so before signing this Agreement.

7.16 COUNTERPARTS. This Agreement may be executed in counterparts, and each of which shall be deemed an original, but all of which together will constitute one and the same instrument.

7.17 EXCESS PARACHUTE PAYMENT. In the event that any payment or benefit received or to be received by Employee pursuant to this Agreement or otherwise would subject Employee to any excise tax pursuant to Section 4999 of the Code due to the characterization of such payment or benefit as an excess parachute payment under Section 280G of the Code, Employee may elect in his sole discretion to reduce the amounts of any payments or benefits otherwise called for under this Agreement in order to avoid such characterization.

7.18 CLAIMS PROCEDURE FOR SEVERANCE PAYMENTS.

7.18.5 Administrator. The administrator for purposes of the severance payments provided by Section 6.2 of this Agreement shall be the Employer ("Administrator"), whose address is 24 Frank Lloyd Wright Dr., P.O. Box 376, Ann Arbor, Michigan 48106, and whose telephone number is 734-930-5555. The "Named Fiduciary" as defined in Section 402(a)(2) of ERISA, also shall be the Employer. The Employer shall have the right to designate one or more employees as the Administrator and the Named Fiduciary at any time, and to change the address and telephone number of the same. The Employer shall give the Employee written notice of any change in the Administrator and Named Fiduciary, or in the address or telephone number of the same.

7.18.6 Claims. The Administrator shall make all determinations as to the right of any person to receive benefits under this Agreement. Any denial by the Administrator of a claim for benefits by the Employee ("the claimant") shall be stated in writing by the Administrator and delivered or mailed to the claimant within ten (10) days after receipt of the claim, unless special circumstances require an extension of time for processing the claim. If such an extension is required, written notice of the extension shall be furnished to the claimant prior to the termination of the initial 10-day period. In no event shall such extension exceed a period of ten (10) days from the end of the initial period. Any notice of denial shall set forth the specific reasons for the denial, specific reference to pertinent provisions of this Agreement upon which the denial is based, a description of any additional material or information necessary for the claimant to perfect the claim, with an explanation of why such material or information is necessary, and any explanation of claim review procedures, and the time limits applicable to such procedures, including a statement of the claimant's right to bring a civil action under ERISA Section 502(a) after exhausting all levels of appeal provided herein, written to the best of the Administrator's ability in a manner that may be understood without legal or actuarial counsel.

7.18.7 Review of Claim Denial. A claimant whose claim for benefits has been wholly or partially denied by the Administrator may request, within sixty (60) days following the date of such denial, in a writing addressed to the Administrator, a review of such denial. The claimant shall be entitled to submit such issues or comments in writing or otherwise, as the claimant shall consider relevant to a determination of the claim, and the claimant may include a request for a hearing in person before the Administrator. Prior to submitting the request, the claimant shall be entitled to review such documents as are relevant to the claim. The claimant may, at all stages of review, be represented by counsel, legal or otherwise, of the claimant's choice. All requests for review shall be promptly resolved. The Administrator's decision with respect to any such review shall be set forth in writing and shall be mailed to the claimant not later than ten (10) days following receipt by the Administrator of the claimant's request unless special circumstances, such as the need to hold a hearing, require an extension of time for processing, in which case the Administrator's decision shall be so mailed not later than twenty (20) days after receipt of such request.

7.18.8 Arbitration. A claimant who has followed the procedure in paragraphs 7.18.2 and 7.18.3 of this Section, but who has not obtained full relief on the claim for benefits, may, within sixty (60) days following the claimant's receipt of the Administrator's written decision on review, apply in writing to the Administrator for arbitration of the claim as provided in Section 7.19.

#### 7.19 ARBITRATION.

(a) Either party to this Agreement, after complying with the requirements of Section 7.18, to the extent applicable, may submit any dispute under this Agreement for binding arbitration of the dispute before an arbitrator mutually acceptable to both parties, the arbitration to be held in Ann Arbor, Michigan, in accordance with the arbitration rules of the American Arbitration Association, as then in effect, and the rights of claimant under Section 7.18. If the parties are unable to mutually agree upon an arbitrator, then the arbitration proceedings shall be held before three arbitrators, one of which shall be designated by the Employer, one of which



shall be designated by the claimant and the third of which shall be designated mutually by the first two arbitrators in accordance with the arbitration rules referenced above. The arbitrator(s) sole authority shall be to interpret and apply the provisions of this Agreement; the arbitrator(s) shall not change, add to, or subtract from, any of the Agreement's provisions. The arbitrator(s) shall have the power to compel attendance of witnesses at the hearing. Any court having jurisdiction may enter a judgment based upon such arbitration. Except as set forth in Section 7.18, the decision of the arbitrator(s) shall be final and binding on the parties to this Agreement and without appeal to any court. Except as set forth in Section 7.18, upon execution of this Agreement, the Employee shall be deemed to have waived any right to commence litigation proceedings regarding this Agreement outside of arbitration without the express written consent of the Employer.

(b) In the case of a dispute relating to severance payments provided by Section 6.2, the decision of the arbitrator(s) shall be delivered or mailed to the claimant within sixty (60) days of the claimant's initial request for review of the denied claim under Section 7.18 unless special circumstances require an extension of time. If an extension is needed the arbitrator(s) shall, before the end of the sixty (60) day period, give to the claimant written notice of the special circumstances requiring the extension and the date by which the arbitrator(s) expect(s) to render a decision. The extension of time shall not exceed sixty (60) days from the end of the initial sixty (60) day period. Notwithstanding the provisions of Section 7.19(b), in the case of a dispute relating to severance payments provided by Section 6.2, the claimant shall not be precluded from challenging the arbitrator's decision under Section 502(a) of ERISA.

7.20 ERISA. The severance compensation provided by Section 6.2 of this Agreement constitutes an unfunded compensation arrangement for a member of a select group of the Employer's management and any exemptions under ERISA, as applicable to such an arrangement, shall be applicable to this Agreement. Section 7.18, Section 7.19(b) and Section 7.20 apply to the severance compensation provided by Section 6.2 of this Agreement.

7.21 REPORTING AND DISCLOSURE. The Employer, from time to time, shall provide government agencies with such reports concerning this Agreement as may be required by law, and the Employer shall provide the Employee with such disclosure concerning this Agreement as may be required by law or as the Employer may deem appropriate.

8. EMPLOYEE'S REPRESENTATIONS. Employee represents and warrants that Employee (i) is free to enter into this Agreement and to perform each of the terms and covenants contained herein, (ii) is not restricted or prohibited, contractually or otherwise, from entering into and performing this Agreement, and (iii) will not be in violation or breach of any other agreement by reason of Employee's execution and performance of this Agreement.

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date set forth above.

EMPLOYER:

Aastrom Biosciences, Inc.

By: \_\_\_\_\_

Its:

EMPLOYEE:

\_\_\_\_\_

Name: \_\_\_\_\_

Address: \_\_\_\_\_

\_\_\_\_\_

## 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 9, 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: May 9, 2005

/s/ Alan M. Wright

-----

Alan M. Wright  
Sr. Vice President Administrative & Financial  
Operations, Chief Financial Officer  
(Principal Financial and Accounting 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 March 31, 2005, 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.

May 9, 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 March 31, 2005, 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.

May 9, 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)