

# Aastrom

2009 Annual Report

*A Year of  
Clinical Achievements*

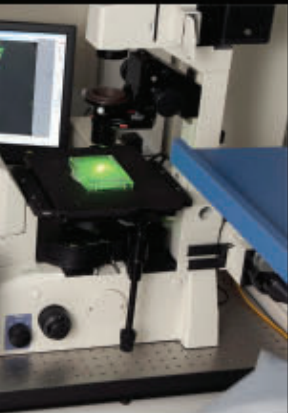
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## **AASTROM BIOSCIENCES, INC. (Nasdaq: ASTM)**

Aastrom is a leader in regenerative medicine developing autologous cell products for the treatment of chronic cardiovascular diseases. The Company's proprietary Tissue Repair Cell (TRC) technology expands the numbers of stem and early progenitor cells from a small amount of bone marrow collected from the patient. Bone marrow provides a rich source of diverse cell populations, is easily accessible and allows Aastrom to produce a personalized treatment for site-specific delivery to the patient's diseased tissues. Aastrom has treated more than 350 patients in various clinical trials over 10 years without any product safety issues. The Company is currently conducting a Phase II cardiac regeneration clinical trial (the IMPACT-DCM trial) in patients with dilated cardiomyopathy (DCM – severe chronic heart failure) and a Phase IIb vascular regeneration clinical trial (the RESTORE-CLI trial) in patients with critical limb ischemia (CLI – the most severe form of peripheral arterial disease).

### **OFFICERS and SENIOR MANAGEMENT TEAM**

**George W. Dunbar**

*President, Chief Executive Officer,  
Chief Financial Officer and Director*

**Peter C. Alain**

*Sr. Director, Quality Assurance*

**Ronnda L. Bartel, Ph.D.**

*Vice President, Technical Operations*

**Tod Borton**

*Sr. Director, Engineering and Development*

**Elmar R. Burchardt, M.D., Ph.D.**

*Vice President, Medical Affairs*

**Julie A. Caudill**

*Controller and Corporate Secretary*

**Frances J. Kivel**

*Sr. Director, Clinical Trials*

**Sherrill M. MacKay**

*Sr. Director, Manufacturing*

**Kristine M. Maly**

*Sr. Director, Communications & Administration*

**Sheldon A. Schaffer, Ph.D.**

*Vice President, Corporate Development &  
Intellectual Property*

**Francisco Vidal**

*Managing Director, Aastrom Biosciences, S.L.*

### **BOARD OF DIRECTORS**

**Nelson M. Sims**

*Chairman, Board of Directors  
Audit\* and Corporate Governance & Nominating Committees  
Former President and Chief Executive Officer  
Novavax, Inc.*

**George W. Dunbar**

*President, Chief Executive Officer,  
Chief Financial Officer and Director  
Aastrom Biosciences, Inc.*

**Timothy M. Mayleben**

*President  
EIMa Advisors, LLC*

**Alan L. Rubino**

*Compensation\* and Corporate Governance & Nominating  
Committees  
President and Chief Executive Officer  
Akrimax Pharmaceuticals, Inc.*

**Stephen G. Sudovar**

*Audit and Compensation Committees  
Chief Executive Officer, SGS Associates  
Former President and Chief Executive Officer  
Elusys Therapeutics, Inc.  
Former President  
Roche Laboratories, Inc.*

**Harold C. Urschel, Jr., M.D.**

*Chair, Cardiovascular & Thoracic Surgical Research,  
Education & Clinical Excellence  
Baylor University Medical Center*

**Robert L. Zerbe, M.D.**

*Audit, Compensation and Corporate Governance  
& Nominating\* Committees  
Chief Executive Officer  
QUATRx Pharmaceuticals Company*

\* Committee Chair

November 5, 2009

To Our Shareholders,

Our clinical progress at Aastrom is advancing at a steady pace and we are evolving organizationally to create a stronger company. As we announced in September, I am transitioning out of my day-to-day responsibilities as Chief Executive Officer and intend to assume my new role of Chairman of the Board of Directors effective at Aastrom's Annual Meeting of Shareholders in December. It has been an honor to serve as your CEO, and I look forward to remaining actively involved and supporting the Company in my new role.

My successor, Tim Mayleben, is a seasoned life sciences industry professional with extensive senior management leadership experience. He has a strong financial and operational background in the life sciences sector, and has been a strategic advisor to many companies and boards. Tim will provide the leadership Aastrom needs to continue to advance our products through the clinical development process toward commercialization. With the insight and knowledge acquired over the last four years as an Aastrom Board member, Tim has been working closely with the Aastrom team over the past few months to ensure a seamless transition takes place in December.

For most of my three years at Aastrom, we have faced significant challenges caused by the global economic downturn and the capital markets crisis in the U.S. Like most public companies, these factors have had an impact on our market value and our operations. Despite these challenges, I am pleased to recognize that both operationally and clinically we have achieved many important milestones over the past year. Foremost among them, we focused our business on developing cell-based therapeutics to support potentially life-saving cardiovascular applications. Over the past year, I have had the pleasure of meeting some of our cardiac patients and their families. It is inspiring and very gratifying to feel their enthusiasm about participating in our clinical trial. These people exemplify Aastrom's number one goal: improving lives through regenerative medicine.

We are approaching the one-year anniversary of the first patient enrolled and surgically treated in our U.S. Phase II IMPACT-DCM clinical trial for dilated cardiomyopathy (DCM), a form of severe chronic heart failure. Currently, heart transplant is the only long-term treatment option for these end-stage patients. However, access to heart transplants is often limited and typically available only to younger patients who then require life-long medications with potentially severe side effects to maintain their health. The hope for these patients is to use our Cardiac Repair Cells (CRCs) to halt or reverse cardiac disease progression and to improve quality of life. We anticipate that patient enrollment in the IMPACT-DCM trial will be completed by the end of calendar 2009 and that preliminary 6-month interim data on all 40 patients will be analyzed mid-2010.

With more than half of the patients enrolled in the surgical IMPACT-DCM clinical trial, we are expanding our ongoing clinical program evaluating CRCs in the treatment of patients suffering from DCM. We filed an Investigational New Drug (IND) application with the U.S. Food & Drug Administration (FDA) to initiate a second clinical trial designed to explore the benefits of a catheter-based approach for the delivery of CRCs to treat DCM patients. We look forward to initiating the clinical sites involved in this trial over the next few months, and commencing patient enrollment during 2010.

On the vascular regeneration front, as of the end of October we have enrolled 75 patients in our U.S. Phase IIb RESTORE-CLI clinical trial. In this trial we are evaluating our Vascular Repair Cells (VRCs) in the treatment of the most severe form of peripheral arterial disease, or PAD, a condition known as critical limb ischemia (CLI). Enrollment has now reached the halfway point in this 150-patient, prospective, controlled, randomized, double-blind, multi-center clinical trial. We will begin to analyze interim clinical data from RESTORE-CLI patients during the fourth quarter of 2009.

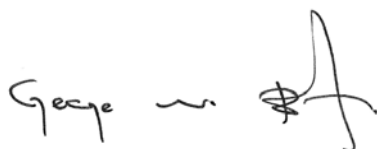
## Looking Forward

Aastrom continues to make significant strides toward its goal of being a leader in the development of regenerative therapies. Our CRCs and VRCs have already begun to benefit critically ill patients. We will maintain our focus on the cardiovascular space and will seek biologics license application (BLA) approvals from the FDA for the broadest-possible range of marketing options. As always, we will strive to build a financially viable enterprise to generate increasing shareholder value.

While we are mindful that there is still much to be done before we reach the goal of commercialization, your Company is energized by the progress we have made over the past three years. We remain continually inspired by the realization that every patient treated with our products brings us one step closer to achieving that goal.

On behalf of all our employees, directors, patients and their families, thank you for your continued support.

Sincerely,

A handwritten signature in black ink, appearing to read "George W. Dunbar". The signature is written in a cursive, flowing style with a prominent initial "G".

George W. Dunbar  
President and Chief Executive Officer

*This letter contains forward-looking statements, including without limitation, statements concerning clinical trial plans and expectations, clinical activity timing, intended product development and commercialization objectives, adequacy of existing capital to support operations for a specified time, future capital needs, and potential advantages and application of Tissue Repair Cell (TRC) technology, all of which involve certain risks and uncertainties. These statements are often, but are not always, made through the use of words or phrases such as "anticipates," "intends," "estimates," "plans," "expects," "we believe," "we intend," and similar words or phrases, or future or conditional verbs such as "will," "would," "should," "potential," "could," "may," or similar expressions. Actual results may differ significantly from the expectations contained in the forward-looking statements. Among the factors that may result in differences are the inherent uncertainties associated with clinical trial and product development activities, regulatory approval requirements, competitive developments, and the availability of resources and the allocation of resources among different potential uses. These and other significant factors are discussed in greater detail in Aastrom's Annual Report on Form 10-K and other filings with the Securities and Exchange Commission.*

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**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**Form 10-K**

- ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d)  
OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended June 30, 2009

or

- TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d)  
OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number 0-22025

**Aastrom Biosciences, Inc.**

*(Exact name of registrant as specified in its charter)*

**Michigan**

*(State or other jurisdiction of  
incorporation or organization)*

**94-3096597**

*(I.R.S. Employer  
Identification No.)*

**24 Frank Lloyd Wright Drive,  
P. O. Box 376,  
Ann Arbor, MI 48106**

*(Address of principal executive offices, including zip code)*

**Registrant's telephone number, including area code: (734) 930-5555**

**Securities registered pursuant to Section 12(b) of the Act:**

**Title of Class**

**Name of Each Exchange on Which Registered**

Common Stock (No par value)

The NASDAQ Stock Market, Inc.

**Securities registered pursuant to Section 12(g) of the Act:**

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  No

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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer -  Accelerated filer -  Non-accelerated filer -  Smaller reporting company -   
(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

The approximate aggregate market value of the registrant's Common Stock, no par value ("Common Stock"), held by non-affiliates of the registrant (based on the closing sales price of the Common Stock as reported on the NASDAQ Capital Market) on December 31, 2008 was approximately \$66 million. This computation excludes shares of Common Stock held by directors, officers and each person who holds 5% or more of the outstanding shares of Common Stock, since such persons may be deemed to be affiliates of the registrant. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of August 31, 2009, 168,327,577 shares of Common Stock, no par value, were outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

**Document**

**Form 10-K Reference**

Proxy Statement for the Annual Meeting of Shareholders  
scheduled for December 14, 2009

Items 10, 11, 12, 13 and 14 of  
Part III

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**AASTROM BIOSCIENCES, INC.**  
**ANNUAL REPORT ON FORM 10-K**  
**TABLE OF CONTENTS**

	<u>Page</u>
<b>PART I</b>	
Item 1. Business . . . . .	3
Item 1A. Risk Factors . . . . .	18
Item 1B. Unresolved Staff Comments . . . . .	27
Item 2. Properties . . . . .	27
Item 3. Legal Proceedings . . . . .	27
Item 4. Submission of Matters to a Vote of Security Holders . . . . .	27
<b>PART II</b>	
Item 5. Market for Registrant’s Common Equity, Related Shareholder Matters and Issuer Purchases of Equity Securities . . . . .	28
Item 6. Selected Financial Data . . . . .	31
Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations . . .	32
Item 7A. Quantitative and Qualitative Disclosures About Market Risk . . . . .	40
Item 8. Financial Statements and Supplementary Data . . . . .	41
Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure . . .	60
Item 9A. Controls and Procedures . . . . .	60
Item 9B. Other Information . . . . .	60
<b>PART III</b>	
Item 10. Directors, Executive Officers and Corporate Governance . . . . .	62
Item 11. Executive Compensation . . . . .	62
Item 12. Security Ownership of Certain Beneficial Owners and Management, and Related Shareholder Matters . . . . .	62
Item 13. Certain Relationships and Related Transactions, and Director Independence . . . . .	62
Item 14. Principal Accountant Fees and Services . . . . .	62
<b>PART IV</b>	
Item 15. Exhibits and Financial Statement Schedules . . . . .	63
Signatures . . . . .	64
Glossary . . . . .	67

*Except for the historical information presented, the matters discussed in this Report, including our product development and commercialization goals and expectations, our plans and anticipated timing and results of clinical development activities, potential market opportunities, revenue expectations and the potential advantages and applications of our products and product candidates under development, include forward-looking statements that involve risks and uncertainties. Our actual results may differ significantly from the results discussed in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed under the caption “Risk Factors.” Unless the context requires otherwise, references to “we,” “us,” “our” and “Aastrom” refer to Aastrom Biosciences, Inc.*

## PART I

### Item 1. *Business*

We are a regenerative medicine company (*a medical area that focuses on developing therapies that regenerate damaged or diseased tissues or organs*) that incorporated in 1989 and focuses on the clinical development of autologous cell products (*cells collected from a patient and returned to that same patient*) for the repair or regeneration of multiple human tissues, based on our proprietary Tissue Repair Cell (TRC) technology. Our preclinical and clinical product development programs utilize patient-derived bone marrow stem and early progenitor cell populations, and are being investigated for their ability to aid in the regeneration of tissues such as cardiac, vascular and bone. TRC-based products have been used in over 350 patients, and are currently in the following stages of development:

- Cardiac regeneration — Cardiac Repair Cells (CRCs):
  - Dilated cardiomyopathy (DCM) (severe heart failure):
    - U.S.: Phase II IMPACT-DCM clinical trial began treating patients in November 2008; to date, 21 patients enrolled in trial and all five clinical sites are open for patient enrollment (Methodist DeBakey Heart & Vascular Center, Houston, TX, Baylor University Medical Center, Dallas, TX, The University of Utah School of Medicine, Salt Lake City, UT, Cleveland Clinic Heart & Vascular Institute, Cleveland, OH, and Emory University Hospital Midtown, Atlanta, GA); Orphan Drug Designation from the FDA for use in treatment of DCM; all 40 patients expected to be enrolled by December 31, 2009, and a report of preliminary interim data expected once all patients have completed 6 month follow-up visits
    - Germany: Encouraging data reported April 2008 from compassionate use treatment in two patients which provided supporting information considered critical to success of U.S. Phase II IMPACT-DCM IND application.
- Vascular regeneration — Vascular Repair Cells (VRCs):
  - Critical limb ischemia (CLI):
    - U.S.: Phase IIb RESTORE-CLI clinical trial has enrolled 73 patients to date; interim analysis of clinical data expected to occur during the 4th quarter of calendar year 2009; patient enrollment continues
    - Germany: Phase I/II investigator-sponsored clinical trial completed enrollment and patient follow-up ongoing; positive interim data reported October 2007; investigator report of final data expected during the second half of calendar year 2009
    - Spain: 2 compassionate use cases have been treated with AEMPS (Spanish Drug Agency) approval to date

- Bone regeneration — Bone Repair Cells (BRCs):
  - Osteonecrosis of the femoral head:
    - U.S.: Phase III ON-CORE clinical trial active with 7 patients enrolled; no longer enrolling additional patients; Orphan Drug Designation from the FDA for use in treatment of osteonecrosis of the femoral head
    - Spain: Enrollment completed with 9 hips (7 patients treated); 24 month follow-up for all patients ongoing
    - Germany: Encouraging data reported October 2007 from compassionate use treatment cases; follow-up ongoing
  - Non-union fractures:
    - U.S.: Final Phase I/II clinical study report issued in December 2008; TRC product showed an excellent safety profile and the efficacy data indicated a high non-union healing rate, with bridging callus formation rates reported in over 90% of patients 12 months post-surgery compared to 50% historically
    - Spain: Final 24-month follow-up complete for 10-patient investigator-sponsored Phase II clinical trial; the final investigator report indicates that 7 of 10 cases resulted in healing at 24 months
    - Spain: 9 compassionate use cases of non-union long bone fracture have been treated; follow-up ongoing
  - Maxillofacial:
    - U.S.: Investigator-sponsored controlled study in the treatment of alveolar bone defects fully enrolled; follow-up ongoing
    - Spain: 3 patients with craniofacial defects have been treated under compassionate use; early bone formation resulted in healing, including peripheral nerve regeneration or repair, new skin formation and proliferation in blood vessels in ischemic areas

Our platform TRC technology is based on 1) autologous cell products, which are a unique cell mixture containing large numbers of stem and early progenitor cells produced outside of the body from a small amount of bone marrow taken from the patient, and 2) the ability to produce these products in an automated process that meets Good Manufacturing Practice (GMP) guidelines.

We have developed a manufacturing system to produce human cells for clinical use. This automated cell manufacturing system enables the “single-pass perfusion” cell culture process. Single-pass perfusion is our patented manufacturing technology for growing large numbers of human cells. The cellular components of TRC-based products include adult stem and early progenitor cell populations which are capable of forming tissues such as cardiac, vascular, bone, neural, and the hematopoietic and immune system.

All TRC-based products are produced using our cell manufacturing system in centralized manufacturing facilities. We have one manufacturing site in the U.S. located at our headquarters in Ann Arbor, MI, and two contract facilities in the EU located in Stuttgart, Germany (Fraunhofer Institute for Interfacial Engineering and Biotechnology) and Bad Oeynhausen, Germany (Institute of Laboratory and Transfusion Medicine at the Heart Center).

Since our inception, we have been in the development stage and engaged in research and product development, conducted principally on our own behalf. Our initial business plan was to pursue our targeted markets by commercializing our cell manufacturing system and supplies; however, since 2004 we have phased out our marketing efforts promoting the cell manufacturing system as a commercial product. Currently, we have minimal product sales consisting of manufacturing supplies to academic collaborators in the U.S. and cell-based products to EU-based physicians.

We are currently focused on utilizing our TRC technology to produce autologous cell-based products for use in regenerative medicine applications. At such time as we satisfy applicable regulatory approval requirements, we expect the sales of our TRC-based products to constitute nearly all of our product sales revenues.



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

In May 2008, we reprioritized our clinical development programs to focus primarily on cardiovascular applications, including dilated cardiomyopathy and critical limb ischemia. We have discontinued further patient enrollment into our Phase III ON-CORE (osteonecrosis) bone regeneration trial. We do not anticipate initiating new clinical bone activity, reactivating the Phase III ON-CORE trial or initiating formal clinical trials in the neural area without additional financial resources. While the decision to reprioritize was driven by economic factors, the clinical programs were prioritized based on anticipated time to market and the perceived relative clinical and market potential. We are also exploring the possibility of entering into complementary regenerative medicine business activities, whether through acquisition or otherwise. In addition to reprioritizing our development and clinical programs, we also made reductions in our staff and reduced our overhead expenses.

We expect that we will need to raise significant additional funds or pursue strategic transactions or other strategic alternatives in order to complete our product development programs, complete clinical trials needed to market our products, and commercialize our products. To date, we have financed our operations primarily through public and private sales of our equity securities, and we expect to continue to seek to obtain the 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. With respect to our current activities, this is not likely to occur until we obtain significant additional funding, complete the required clinical trials for regulatory approvals, and receive the necessary approvals to market our products. Through June 30, 2009, we have accumulated a net loss of approximately \$195 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.

We believe, based on our current projections of cash utilization (which is expected to average approximately \$1.4 million per month) available cash and cash equivalents on hand as of June 30, 2009 (which equaled approximately \$17 million) are adequate to finance our planned operations at least until June 30, 2010. However, we will need to raise a significant amount of additional funds in order to complete our product development programs, complete clinical trials needed to market our products, and commercialize these products. We cannot be certain that such funding will be available on favorable terms, if at all. Some of the factors that will impact our ability to raise additional capital and our overall success include: the rate and degree of progress of our product development, the rate of regulatory approval to proceed with clinical trial programs, the level of success achieved in clinical trials, fulfillment of the requirements for marketing authorization from regulatory bodies in the U.S., EU and other countries, the liquidity and market volatility of our equity securities, regulatory and manufacturing requirements and uncertainties, technological developments by competitors, the U.S. economic conditions regarding the availability of investment capital and other factors. If we cannot raise such funds, we may not be able to develop or enhance products, take advantage of future opportunities, or respond to competitive pressures or unanticipated requirements, which would likely have a material adverse impact on our business, financial condition and results of operations.

## **Clinical Development**

Currently, our clinical development programs are focused primarily on the utilization of our TRC technology for cardiac and vascular regeneration. An improved formulation for storage of our TRC-based cell product has been developed to extend the shelf-life of our product. The extended shelf-life provides additional flexibility in transport of the product and in scheduling of patient administration. The extended shelf-life product has been qualified and implemented at our centralized manufacturing sites in the U.S. and EU. It is used for all cardiac and vascular regeneration clinical trials in the U.S. and is available for supply to all active EU treatment sites.

In May 2008, we reprioritized our clinical development programs to focus on cardiovascular applications, including our Phase II IMPACT-DCM (dilated cardiomyopathy) trial and our Phase IIB RESTORE-CLI (critical

limb ischemia) trial. We have discontinued further patient enrollment into our Phase III ON-CORE (osteonecrosis) bone regeneration trial. We do not anticipate initiating new clinical bone activity, reactivating the Phase III ON-CORE trial or initiating formal clinical trials in the neural area without additional financial resources. While the decision to reprioritize was driven by economic factors, the clinical programs were prioritized based on anticipated time to market and the perceived relative clinical and market potential.

The preclinical data for our TRC-based products have shown that the large numbers of the stem and early progenitor cells obtained through application of our TRC technology can develop into a variety of tissues including blood, bone, vascular and fat, as well as the potential to form tissues characteristic of certain internal organs. We have demonstrated in the laboratory that TRC-based products can differentiate into both endothelial (blood vessel) and osteoblast (bone cell) lineages. Based on these preclinical observations, clinical trials have been initiated in the U.S. and European Union (EU) for cardiac tissue regeneration in patients with dilated cardiomyopathy, for vascular tissue regeneration in patients with critical limb ischemia and for bone regeneration in patients with osteonecrosis of the femoral head and severe long bone fractures.

The preliminary results of our current clinical trials may not be indicative of results that will be obtained from subsequent patients in those trials or from future clinical trials. Further, our future clinical trials may not be successful, and we may not be able to obtain the required Biologic License Application (BLA) registration in the U.S. or required foreign regulatory approvals for our TRC-based products in a timely fashion, or at all. See “Risk Factors.”

### ***Clinical Trials Summary***

#### ***Cardiac Regeneration***

##### ***Dilated Cardiomyopathy***

To date, 21 patients have been enrolled in our U.S. Phase II clinical trial (called IMPACT-DCM) and all five clinical sites are open for patient enrollment (Methodist DeBakey Heart & Vascular Center, Houston, TX, Baylor University Medical Center, Dallas, TX, The University of Utah School of Medicine, Salt Lake City, UT, Cleveland Clinic Heart & Vascular Institute, Cleveland, OH, and Emory University Hospital Midtown, Atlanta, GA). In November 2008, the first patient was treated in the 40-patient IMPACT-DCM trial to evaluate the use of Cardiac Repair Cells (CRCs), a mixture of stem and progenitor cells derived from a patient’s own bone marrow, for the treatment of dilated cardiomyopathy (DCM), a severe form of chronic heart failure. This randomized, controlled, prospective, open-label, Phase II study seeks to enroll 20 patients with ischemic DCM and 20 patients with non-ischemic DCM at up to 5 clinical sites in the U.S. CRCs, manufactured using Aastrom’s TRC technology, received an Orphan Drug Designation from the FDA for the treatment of DCM in February 2007. The U.S. Food & Drug Administration (FDA) approved our Investigational New Drug (IND) application for this clinical trial in May 2008.

We anticipate that all 40 patients will be enrolled into this trial by December 31, 2009, and that we will report preliminary interim data after all of the patients have completed their 6 month follow-up visits.

Participants in the IMPACT-DCM clinical trial must have a left ventricular ejection fraction (LVEF), the percentage of blood pumped out of the heart with each contraction, of less than or equal to 30% (60-75% is typical for a healthy person) and meet certain other eligibility criteria. All patients in each group will receive standard medical care and approximately 75% of the patients in each group will be treated with CRCs through direct injection into the heart muscle during open heart surgery. While the primary objective of this study is to assess the safety of CRCs in patients with DCM, efficacy measures including LVEF and other cardiac function parameters as well as heart failure stage will be monitored. Patients will be followed for 12 months post treatment.

In April 2008, we reported data from two compassionate use patients treated in Germany with our autologous stem cell therapy for DCM. A cardiothoracic surgeon experienced with cell therapy at the University Hospital in Dusseldorf, Germany performed the first human application of our CRC product through direct injection into the heart muscle during open heart surgery for these two patients in late 2007. The data from these two critically ill patients upon discharge from the surgical center was encouraging. Per typical treatment practices in Germany, once these patients were released from the surgical center, they were followed by regional rehabilitation hospitals or local physicians. Patient #1 had an LVEF of approximately 10% prior to the CRC treatment in November 2007. Over the

course of two months, this patient's LVEF improved to 25-30% and clinical improvement of his heart failure stage was noted. As reported to us by the surgeon, during his stay at a rehabilitation hospital, this critically ill patient refused all further medical treatment and discharged himself from the hospital against medical advice. This patient's subsequent death due to natural causes was unrelated to the cell therapy treatment. Patient #2 had an LVEF of 25-30% prior to being treated with CRCs in December 2007. Upon discharge from the surgical center in February 2008, her LVEF had improved to 45%. In September 2008, at a 7 month follow-up visit with the treating surgeon, this patient's LVEF was again measured at 45% and the patient reported further improvement in her heart failure symptoms. These EU compassionate use treatments provided supporting information considered critical to the success of the U.S. Phase II IMPACT-DCM IND application.

DCM is a chronic cardiac disease that leads to enlargement of the heart and is associated with reduced pump function to the point that blood circulation is impaired. Typically patients with DCM present with symptoms of congestive heart failure, including limitations in their physical activity and shortness of breath. DCM generally occurs in patients who have ischemic heart failure due to multiple heart attacks, though it can also be found in patients with non-ischemic heart failure caused by hypertension, viral infection or alcoholism. Patient prognosis depends on the stage of the disease but is typically characterized by a high mortality rate. Other than heart transplantation, there are currently no curative treatment options for end-stage patients with this disease. The New England Journal of Medicine estimates that in the U.S. alone 120,000 people currently suffer from this disease; other sources report estimates of up to 150,000.

### ***Vascular Tissue Regeneration***

#### ***Critical Limb Ischemia***

Based on our laboratory observations that TRC-based products have the ability to form small blood vessels *in vitro* and results from third party trials involving the use of bone marrow cells for peripheral vascular disease, we are conducting trials to evaluate the safety and efficacy of Vascular Repair Cells (VRCs) based on TRC technology in the treatment of diabetics with open foot wounds and patients diagnosed with critical limb ischemia (CLI), the end stage of peripheral arterial disease. These patients exhibit chronic rest pain, ulcers or gangrene in their limbs.

In October 2008, the first 30 patients (treatment and placebo control) completed enrollment in our RESTORE-CLI trial, a U.S. Phase IIb prospective, controlled, randomized, double-blind, multi-center clinical trial to treat patients suffering from CLI. This study is allowed to enroll up to 150 patients at up to 30 sites. Patients are randomized into two patient groups (treatment or placebo control), to evaluate the safety and efficacy of VRCs in the treatment of CLI. To date, 73 patients have been enrolled in the RESTORE-CLI trial and 21 clinical sites are open for patient enrollment. Please see our website for the most updated list of sites that are open for patient enrollment. Patients will be followed for a period of twelve months post-treatment. In addition to assessing the safety of the VRCs, secondary objectives include assessing major amputation rates, level of amputation, wound healing and blood flow in the affected limbs, patient quality of life, pain scores and analgesic use. During the 4th quarter of calendar year 2009, we expect to unblind and analyze interim clinical data from a subset of patients enrolled in the study that includes the first 30 patients who have completed their twelve month follow-up.

In October 2007, positive interim results from the first 13 patients treated in Germany in a 30-patient multi-arm Phase I/II single-center clinical trial to evaluate the safety of VRCs and unexpanded bone marrow cells in the treatment of chronic diabetic foot wounds associated with CLI were reported by an investigator from the Heart & Diabetes Center located in Bad Oeynhausen, Germany at the 2nd Congress of the German Society for Stem Cell Research in Würzburg, Germany. Results reflect treatment experience from: four diabetic patients with ischemia-related chronic tissue ulcers who were treated with our VRCs; seven patients who were treated with normal unexpanded marrow cells; and two standard of care patients who did not receive cells. All patients received standard wound care as described by the American Diabetes Association. Twelve months post-treatment, all patients in the interim analysis who were treated with VRCs reported no major amputations, no cell-related adverse events, and healing of all open wounds. Of the seven patients treated with unexpanded bone marrow cells, five reported results similar to the VRC-treated patients 12 months post-treatment, one reported similar results to the VRC-treated patients 18 months post-treatment, and one patient underwent a major amputation. For the two standard of care patients who only received wound care (no cells), one patient received a major amputation and one patient

experienced no improvement in wound healing after 12 months. Patient follow-up has been completed and final data is expected to be reported by the investigator during the second half of calendar year 2009.

### ***Bone Regeneration***

#### *Osteonecrosis of the Femoral Head*

In May 2008, we reprioritized our clinical development programs to primarily focus on cardiovascular applications. We have discontinued further patient enrollment into our U.S. Phase III ON-CORE (osteonecrosis) bone regeneration trial. We do not anticipate new clinical bone activity or reactivating the Phase III ON-CORE trial without additional financial resources.

In May 2007, the FDA approved our Investigational New Drug (IND) application which allowed us to proceed with our ON-CORE trial, a U.S. Phase III clinical trial, to use our Bone Repair Cells (BRCs) based on our TRC technology in the treatment of osteonecrosis (also known as avascular necrosis) of the femoral head. Osteonecrosis of the femoral head involves the death of cells in the bone and marrow within the femur head and in many cases leads to total hip replacement. While the 7 treated patients will continue to be monitored for the full 24-month follow-up period, no additional patients are being enrolled at this time. Our website will be updated if we resume patient enrollment in this trial. In March 2006, we received an Orphan Drug Designation from the FDA to use our BRCs in the treatment of osteonecrosis of the femoral head.

In October 2007, early clinical results from 4 compassionate use patients were presented by an investigator from the Orthopedic Institute, König-Ludwig-Haus, University of Würzburg, Germany, involving the first use of our Bone Repair Cells (BRCs) to treat patients suffering from osteonecrosis of the femoral head. After 6 months of follow-up all patients tolerated the procedure well. Three patients reported a reduction in hip pain, there were no signs of disease progression for any of the four patients (as determined by MRI and X-ray) and all were back to work within 6 months after treatment. In addition, no cell-related adverse events were reported and none of these patients have required hip replacement surgery. Follow-up for these compassionate use patients is ongoing.

In January 2007, we opened patient enrollment and treatment in a clinical trial in Spain utilizing BRCs for the treatment of osteonecrosis of the femoral head. The trial protocol was approved by the Spanish Drug Agency (AEMPS) and Centro Medico Teknon's (Teknon) Ethics Committee for our Investigational Medicinal Product Dossier (IMPD), and is being conducted at Teknon located in Barcelona, Spain. Patient recruitment is complete with 9 hips (7 patients) treated. All patients will be followed for 24 months post-treatment.

#### *Other Bone*

In December 2008, the final Aastrom clinical study report from our U.S. Phase I/II clinical trial for the treatment of severe long bone non-union fractures was completed. This trial demonstrated that the TRC product had an excellent safety profile. The overall number of adverse events reported was low in comparison to historical data, and no adverse events were considered related to the TRC product. The efficacy data indicated a high non-union fracture healing rate, with bridging callus formation rates in over 90% of patients 12 months post-surgery compared to 50% historically.

An initial 5 patient bone regeneration (post-fracture) study was conducted at three centers in Spain under Ethical Committee approval; positive results were disclosed in May 2005. Following this trial, a physician-sponsored 10 patient Phase II non-union fracture trial was initiated. The Phase II study has completed BRC treatment of all 10 patients. The final investigator report indicates that 7 of 10 cases resulted in healing at 24 months with no adverse events related to bone marrow aspiration or TRC administration.

The Phase I/II spine fusion clinical trial at William Beaumont Hospital, Royal Oak, MI has been closed and no further patients will be enrolled. While the 2 patients who were treated in this trial did not experience any cell-related adverse events and there were no safety issues, there was no conclusive evidence of efficacy with the current formulation for ectopic bone formation in this indication.

### ***Neural Regeneration***

In May 2008, we reprioritized our clinical development programs to primarily focus on cardiovascular applications. We do not anticipate initiating formal clinical trials in the neural area using our proprietary Neural Repair Cells (NRCs) without additional financial resources.

### ***Additional Activity***

In certain non-U.S. regions, autologous cells, such as our TRC-based products, do not require a marketing authorization for commercial distribution. This enables us to gain product use experience and refine our clinical development strategies through compassionate use and standard patient treatment in countries where it is allowed and where both the patient and the physician see a potential benefit from using TRC-based products.

Through limited commercial use of TRC-based products, we are also able to obtain a privileged regulatory position in some regions. In the EU, the Advanced Therapies and Medicinal Products (ATMP) regulation went into effect January 1, 2009 requiring cell products such as ours to obtain a marketing authorization from the European Medicines Agency (EMA) before they can be marketed in EU member states. However, the ATMP includes a grandfathering provision that allows products on the market in one or more EU member states on December 31, 2008 to remain on the market in those EU member states for a period of four years before EMA market authorization must be obtained. With the activities completed to date in Germany, we believe TRC-based products meet the requirements for the ATMP transition period in this member state.

In any event, we do not anticipate generating significant sales in any geographic region until we have sufficient evidence of clinical safety and efficacy to ensure marketplace acceptance and product reimbursement and to justify the investment in manufacturing, sales and marketing infrastructure. However, we are currently generating limited, nominal sales of TRC-based products and expect to continue this level of activity. As a result of these limited, commercial treatment activities, it is possible that we, or third parties, may make case studies and other data generated outside of a clinical trial program available on websites, in publications or in presentations. Such data should be considered anecdotal; it is not intended to represent evidence of clinical efficacy or to suggest that any future clinical trials will demonstrate that TRC-based products are effective in any specific medical application.

### **Product Development**

Our current product development efforts are focused on the development of our autologous TRC-based products for use in cardiac tissue regeneration (dilated cardiomyopathy) and vascular tissue regeneration (critical limb ischemia). Our TRC-based products have been used in over 350 human patients in several clinical trials. (See "Clinical Development.") We believe that TRC-based products can potentially be used in other clinical indications and that additional clinical trials will be required.

Our research programs are currently directed at improving TRC-based product functionality for certain clinical indications, improving product shelf life and decreasing the cost of manufacturing our TRC-based products. These production process changes may alter the functionality of our TRC-based products, and would require various levels of experimental and clinical testing and evaluation. Any such testing could lengthen the time before these products would be commercially available.

In addition, our proprietary cell manufacturing system has demonstrated the capability to produce other types of cells. Our cell manufacturing system is currently used at University of Pittsburgh to produce dendritic cells for investigator-sponsored clinical trials. When practical, we will continue to explore the application of our manufacturing technology for the production of non-TRC cell types where there are potential opportunities to collaborate in the development of new cell therapies.

Research and development expenses for the fiscal years ended June 30, 2007, 2008 and 2009 were \$11,443,000, \$15,249,000 and \$11,289,000, respectively.

## **Manufacturing**

### ***Cell Manufacturing***

Our TRC-based cell products will be regulated in the U.S., EU and other markets as somatic cell therapies/biologics/pharmaceuticals. With this classification, commercial manufacturing of TRC-based products will need to occur in registered/licensed facilities in compliance with Good Tissue Practice (GTP, U.S., FDA), Good Manufacturing Practice (GMP) for biologics (cellular products) or drugs, and the EU Tissue Procurement and GMP Directives.

In May 2006, we received a human pharmaceuticals manufacturing license from a regional regulatory authority in Germany for the production of TRC-based products at the Fraunhofer Institute for Interfacial Engineering and Biotechnology (Fraunhofer). This license allows us to produce our TRC-based products in compliance with EU regulations. The Fraunhofer facility and staff are under contract for the manufacturing of TRC-based products for both clinical trials and commercial activity under the license.

In the U.S. we have established and operate a pilot cell manufacturing facility in our Ann Arbor, Michigan location to support the current U.S. clinical trials. We intend to establish and operate our own larger commercial-scale cell manufacturing facilities for the EU and U.S. markets in the future to accommodate potential market growth.

An improved formulation for storage of our TRC-based cell product has been developed to extend the shelf-life of our product. The extended shelf-life provides additional flexibility in transport of the product and in scheduling of patient administration. The extended shelf-life product has been qualified and implemented at our centralized manufacturing sites in the U.S. and EU. It is used for all cardiac and vascular regeneration clinical trials in the U.S. and is available for supply to all active EU treatment sites.

### ***TRC-Based Cell Product Development***

We have established relationships with third parties such as BioLife and Invitrogen to manufacture and/or supply certain components, equipment, disposable devices and other materials used in our cell manufacturing process to develop our TRC-based cell products.

There can be no assurance that we will be able to continue our present arrangements with our suppliers, supplement existing relationships or establish new relationships or that we will be able to identify and obtain certain components, equipment, disposable devices and other materials used in our cell manufacturing process. Our dependence upon third parties for the supply and manufacture of such items could adversely affect our ability to develop and deliver commercially feasible TRC-based cell products on a timely and competitive basis. See "Risk Factors."

### ***Cell Manufacturing Platform Components***

We have established relationships with manufacturers that are FDA registered as suppliers of medical products to manufacture various components of our patented cell manufacturing system.

In March 2003, we signed a master supply agreement with Sparton Corporation formerly Astro Instrumentation, L.L.C., to manufacture our final assemblies, component parts, subassemblies and associated spare parts used in the instrumentation platform of our cell manufacturing system. This agreement automatically renews every 12 months unless canceled. We retain all proprietary rights to our intellectual property that is utilized by Sparton pursuant to this agreement.

In February 2004, we entered into a five-year agreement, with a one year automatic renewal, with Moll Industries as our supplier of the cell culture cassettes used in the production of TRC-based products. Under this agreement, Moll performs the manufacturing and assembly of the cassettes while we retain all rights to our intellectual property that is utilized by Moll pursuant to this agreement.

There can be no assurance that we will be able to continue our present arrangements with our suppliers, supplement existing relationships or establish new relationships or that we will 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 such items could adversely affect our ability to develop and deliver commercially feasible products on a timely and competitive basis. See “Risk Factors.”

### **Sales and Marketing**

We do not currently have the sales or marketing resources that will be needed to fully commercialize our therapeutic products. We intend to advance each target therapeutic area to a decision point where we can evaluate the options to seek a development and/or commercialization partnership, or to make the investment to complete development and commercialize a product alone. In some cases, we may undertake some pilot level of sales and marketing activity while seeking a commercial partnership.

Domestic product sales and rentals for the fiscal years ended June 30, 2007, 2008 and 2009 were \$44,000, \$78,000 and \$105,000, respectively. Foreign product sales and rentals for the fiscal years ended June 30, 2007, 2008 and 2009 were \$50,000, \$130,000 and \$77,000, respectively.

### **Patents and Proprietary Rights**

Our success depends in part on our ability, and the ability of our licensors, to obtain patent protection for our products and processes. We have exclusive rights to over 26 issued U.S. patents. These patents present various claims related to the following, as well as other, areas: (i) certain methods for enabling *ex vivo* stem cell division (for cells derived from bone marrow, peripheral blood, umbilical cord blood, or the spleen) or improving the *ex vivo* production of progenitor cells, and the therapeutic use of these cells where normal bone marrow has a therapeutic effect; (ii) certain apparatus for cell culturing, including a bioreactor suitable for culturing human stem cells or human hematopoietic cells; (iii) certain methods of infecting or transfecting target cells with vectors; and (iv) a cell composition containing human stem cells or progenitor cells, or genetically modified stem cells, when such cells are produced in an *ex vivo* medium exchange culture and have been originally derived from bone marrow, peripheral blood, umbilical cord blood, or the spleen. Certain patent equivalents to the U.S. patents have also been issued in other jurisdictions including Australia, Japan, the Republic of Korea and Canada and under the European Patent Convention. In addition, we have filed applications for patents in the U.S. and equivalent applications in certain other countries claiming other aspects of our products and processes, including U.S. patent applications and corresponding applications in other countries related to various components of our cell manufacturing system.

The validity and breadth of claims in medical technology patents involve complex legal and factual questions and, therefore, may be highly uncertain. No assurance can be given that any patents based on pending patent applications or any future patent applications by us, or our licensors, will be issued, that the scope of any patent protection will exclude competitors or provide competitive advantages to us, that any of the patents that have been or may be issued to us or our licensors will be held valid if subsequently challenged or that others will not claim rights in or ownership of the patents and other proprietary rights held or licensed by us. Furthermore, there can be no assurance that others have not developed or will not develop similar products, duplicate any of our products or design around any patents that have been or may be issued to us or our licensors. Since patent applications in the U.S. are maintained in secrecy until they are published 18 months after filing, we also cannot be certain that others did not first file applications for inventions covered by our and our licensors’ pending patent applications, nor can we be certain that we will not infringe any patents that may be issued to others on such applications.

We rely on certain licenses granted by the University of Michigan for certain patent rights. If we breach such agreements or otherwise fail to comply with such agreements, or if such agreements expire or are otherwise terminated, we may lose our rights in such patents, which would have a material adverse affect on our business, financial condition and results of operations. See “Research and License Agreements.”

We also rely on trade secrets and unpatentable know-how that we seek to protect, in part, by confidentiality agreements. It is our policy to require our employees, consultants, contractors, manufacturers, outside scientific collaborators and sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information developed or made known to the individual during the course of the individual’s relationship with us is to be kept confidential and not disclosed to third parties except in specific limited circumstances. We also require

signed confidentiality or material transfer agreements from any company that is to receive our confidential information. In the case of employees, consultants and contractors, the agreements generally provide that all inventions conceived by the individual while rendering services to us shall be assigned to us as the exclusive property of Aastrom. There can be no assurance, however, that these agreements will not be breached, that we would have adequate remedies for any breach, or that our trade secrets or unpatentable know-how will not otherwise become known or be independently developed by competitors.

Our success will also depend in part on our ability to develop commercially viable products without infringing the proprietary rights of others. We do not believe any of our currently contemplated products or processes infringe any existing valid issued patent. However, the results of patent litigation are unpredictable, and no assurance can be given that patents do not exist or could not be filed which would have an adverse affect on our ability to market our products or maintain our competitive position with respect to our products. If our technology components, designs, products, processes or other subject matter are claimed under other existing U.S. or foreign patents, or are otherwise protected by third party proprietary rights, we may be subject to infringement actions. In such event, we may challenge the validity of such patents or other proprietary rights or we may be required to obtain licenses from such companies in order to develop, manufacture or market our products. There can be no assurances that we would be able to obtain such licenses or that such licenses, if available, could be obtained on commercially reasonable terms. Furthermore, the failure to either develop a commercially viable alternative or obtain such licenses could result in delays in marketing our proposed products or the inability to proceed with the development, manufacture or sale of products requiring such licenses, which could have a material adverse affect on our business, financial condition and results of operations. If we are required to defend ourselves against charges of patent infringement or to protect our proprietary rights against third parties, substantial costs will be incurred regardless of whether we are successful. Such proceedings are typically protracted with no certainty of success. An adverse outcome could subject us to significant liabilities to third parties and force us to curtail or cease our development and sale of our products and processes.

Certain of our and our licensors' research has been or is being funded in part by the Department of Commerce and by a Small Business Innovation Research Grant obtained from the Department of Health and Human Services. As a result of such funding, the U.S. Government has certain rights in the technology developed with the funding. These rights include a non-exclusive, paid-up, worldwide license under such inventions for any governmental purpose. In addition, the government has the right to require us to grant an exclusive license under any of such inventions to a third party if the government determines that: (i) adequate steps have not been taken to commercialize such inventions, (ii) such action is necessary to meet public health or safety needs, or (iii) such action is necessary to meet requirements for public use under federal regulations. Additionally, under the federal Bayh Dole Act, a party which acquires an exclusive license for an invention that was partially funded by a federal research grant is subject to the following government rights: (i) products using the invention which are sold in the U.S. are to be manufactured substantially in the U.S., unless a waiver is obtained; (ii) the government may force the granting of a license to a third party who will make and sell the needed product if the licensee does not pursue reasonable commercialization of a needed product using the invention; and (iii) the U.S. Government may use the invention for its own needs.

### ***Research and License Agreements***

In March 1992, we entered into a License Agreement with the University of Michigan, as contemplated by a Research Agreement executed in August 1989 relating to the *ex vivo* production of human cells. Pursuant to this License Agreement, as amended: (i) we acquired exclusive worldwide license rights to the patents and know-how for the production of blood cells and bone marrow cells as described in the University of Michigan's research project or which resulted from certain further research conducted through December 1994; and (ii) we are obligated to pay to the University of Michigan a royalty equal to 2% of the net sales of products which are covered by the University of Michigan's patents. Unless it is terminated earlier at our option or due to a material breach by us, the License Agreement will continue in effect until the latest expiration date of the patents to which the License Agreement applies.

In December 2002, we entered into an agreement with Corning Incorporated that granted them an exclusive sublicense relating to our cell transfection technology for increased efficiency in loading genetic material into cells.



We own the intellectual property rights to methods, compositions and devices that increase the frequency and efficiency of depositing particles into cells to modify their genetic code. Under terms of the agreement, Corning's Life Sciences business will utilize our unique technology to enhance the development of their molecular and cell culture applications in areas that are not competitive to our core business interest. We retain exclusive rights to the applications of the technologies involving cells for therapeutic applications, and received an upfront payment in addition to future royalties we may receive from Corning.

## **Government Regulation**

Our research and development activities and the manufacturing and marketing of our products are subject to the laws and regulations of governmental authorities in the U.S. and other countries in which our products will be marketed. Specifically, in the U.S., the FDA, among other activities, regulates new product approvals to establish safety and efficacy of these products. Governments in other countries have similar requirements for testing and marketing. In the U.S., in addition to meeting FDA regulations, we are also subject to other federal laws, such as the Occupational Safety and Health Act and the Environmental Protection Act, as well as certain state laws.

### ***Regulatory Process in the United States***

Our products are subject to regulation as biological products under the Public Health Service Act and the Food, Drug and Cosmetic Act. Different regulatory requirements may apply to our products depending on how they are categorized by the FDA under these laws. The FDA has indicated that it intends to regulate products based on our TRC technology as licensed biologics through the Center for Biologics Evaluation and Research.

As current regulations exist, the FDA will require regulatory approval for certain human cellular- or tissue-based products, including our TRC-based cell products, through a BLA submission.

The FDA has published the GTP regulation which requires registration of facilities that manufacture or process cellular products and specific manufacturing practices to assure consistent finished cellular products. We believe that the automated platform manufacturing system we use will assist in meeting these requirements.

Approval of new biological products is a lengthy procedure leading from development of a new product through preclinical and clinical testing. This process takes a number of years and the expenditure of significant resources. There can be no assurance that our product candidates will ultimately receive regulatory approval.

Regardless of how our product candidates are regulated, the Federal Food, Drug, and Cosmetic Act and other Federal and State statutes and regulations govern or influence the research, testing, manufacture, safety, labeling, storage, record-keeping, approval, distribution, use, product reporting, advertising and promotion of such products. Noncompliance with applicable requirements can result in civil penalties, recall, injunction or seizure of products, refusal of the government to approve or clear product approval applications or to allow us to enter into government supply contracts, withdrawal of previously approved applications and criminal prosecution.

### ***Product Approval in the United States***

In order to obtain FDA approval of a new medical product, sponsors must submit proof of safety and efficacy. In most cases, such proof entails extensive preclinical and clinical studies. The testing, preparation of necessary applications and processing of those applications by the FDA is expensive and may take several years to complete. There can be no assurance that the FDA will act favorably or in a timely manner in reviewing submitted applications, and we may encounter significant difficulties or costs in our efforts to obtain FDA approvals, in turn, which could delay or preclude us from marketing any products we may develop. The FDA may also require post-marketing testing and surveillance of approved products, or place other conditions on the approvals. These requirements could cause it to be more difficult or expensive to sell the products, and could therefore restrict the commercial applications of such products. Product approvals may be withdrawn if compliance with applicable regulations is not maintained or if problems occur following commercialization. For patented technologies, delays imposed by the governmental approval process may materially reduce the period during which we will have the exclusive right to exploit such technologies.

If human clinical trials of a proposed medical product are required, the manufacturer or distributor of a drug or biologic will have to submit an IND application with the FDA prior to commencing human clinical trials. The submission must be supported by data, typically including the results of preclinical and laboratory testing. Following submission of the IND, the FDA has 30 days to review the application and raise safety and other clinical trial issues. If we are not notified of objections within that period, clinical trials may be initiated, and human clinical trials may commence at a specified number of investigational sites with the number of patients approved by the FDA. We have submitted several INDs for our TRC-based cell products, and we have conducted clinical studies under these INDs.

Our TRC-based products will be regulated by the FDA as a licensed biologic, although there can be no assurance that the FDA will not choose to regulate this product in a different manner in the future. The FDA categorizes human cell- or tissue-based products as either minimally manipulated or more than minimally manipulated, and has determined that more than minimally manipulated products require clinical trials to demonstrate product safety and efficacy and the submission of a BLA for marketing authorization. For products that may be regulated as biologics, the FDA requires: (i) preclinical laboratory and animal testing; (ii) submission to the FDA of an IND application, which must be approved prior to the initiation of human clinical studies; (iii) adequate and well-controlled clinical trials to establish the safety and efficacy of the product for its intended use; (iv) submission to the FDA of a BLA; and (v) review and approval of the BLA as well as inspections of the manufacturing facility by the FDA prior to commercial marketing of the product.

We conduct preclinical testing for internal use and as support for submissions to the FDA. Preclinical testing generally includes various types of in-vitro laboratory evaluations of TRC-based cell products as well as animal studies to assess the safety and the functionality of the product. Clinical trials are identified by phases (i.e., Phase I, Phase II, Phase III and Phase IV). Depending on the type of preclinical and/or clinical data available, the trial sponsor will submit a request to the FDA to initiate a specific phase study (e.g., a Phase I trial represents an initial study in a small group of patients to test for safety and other relevant factors; a Phase II trial represents a study in a larger number of patients to assess the safety and efficacy of a product; and, Phase III studies are initiated to establish safety and efficacy in an expanded patient population at multiple clinical study sites).

The results of the preclinical tests and clinical trials are submitted to the FDA in the form of a BLA for marketing approval. The testing, clinical trials and approval process are likely to require substantial time and effort and there can be no assurance that any approval will be granted on a timely basis, if at all. Additional animal studies or clinical trials may be requested during the FDA review period that may delay marketing approval. After FDA approval for the initial indications, further clinical trials may be necessary to gain approval for the use of the product for additional indications. The FDA requires that adverse effects be reported to the FDA and may also require post-marketing testing to monitor for adverse events, which can involve significant expense.

Under current requirements, facilities manufacturing biological products for commercial distribution must be licensed. To accomplish this, an establishment registration must be filed with the FDA. In addition to the preclinical and clinical studies, the BLA includes a description of the facilities, equipment and personnel involved in the manufacturing process. An establishment registration/license is granted on the basis of inspections of the applicant's facilities in which the primary focus is on compliance with GMPs/GTPs and the ability to consistently manufacture the product in the facility in accordance with the BLA. If the FDA finds the results of the inspection unsatisfactory, it may decline to approve the BLA, resulting in a delay in production of products.

As part of the approval process for human biological products, each manufacturing facility must be registered and inspected by the FDA prior to marketing approval. In addition, state agency inspections and approvals may also be required for a biological product to be shipped out of state.

### ***Regulatory Process in Europe***

The EU has approved a regulation specific to cell and tissue products and our products are regulated under this Advanced Therapy Medicinal Product (ATMP) regulation.

### *Clinical Trials in the European Union*

As provided for in the EU ATMP regulation, a Marketing Authorization (MA) is required for any cell-based medicinal product distributed in the EU. Sponsors must submit proof of safety and efficacy to the European Medicines Agency (EMA). In most cases, such proof entails extensive preclinical and clinical studies. The required testing and preparation for necessary applications and processing of those applications by the EMA is expensive and may take several years to complete. There can be no assurance that the EMA will act favorably or in a timely manner in reviewing submitted applications, and we may encounter significant difficulties or costs in our efforts to obtain EMA approvals. In turn, this could delay or preclude us from marketing any products we may develop. The EMA may also require post-marketing testing and surveillance of approved products, or place other conditions on the approvals. These requirements could cause it to be more difficult or expensive to sell the products, and could therefore restrict the commercial applications of such products. Product approvals may be withdrawn if compliance with applicable regulations is not maintained or if problems occur following commercialization.

If human clinical trials of a proposed medicinal product are required, the manufacturer or sponsor will have to file a Clinical Trial Application (CTA) with an IMPD with the Competent Authority of each EU Member State (MS) in which it intends to conduct human clinical trials. The submission must be supported by data, typically including the results of preclinical testing. Following submission of the CTA/IMPD, the MS Competent Authority has 90 days to review the application and raise safety and other clinical trial issues. The EU Clinical Directive allows the Competent Authority to extend this review period if it deems it necessary for the safety of the patient or it needs additional time to conduct a thorough review.

### *Product Approval in the European Union*

Under the current EU drug directive, our TRC-based cell products are regulated as an advanced therapy or medicinal product. For products that are regulated as an ATMP, the EU Directive requires: (i) preclinical laboratory and animal testing; (ii) submission of an IMPD to the Competent Authorities of the MS where the clinical trial will be conducted, which must be approved prior to the initiation of human clinical studies; (iii) adequate and well-controlled clinical trials to establish the safety and efficacy of the product for its intended use; (iv) submission to EMA for an MA; and, (v) review and approval of the MA. Under the newly approved ATMP regulation for cellular products only the EMA will be allowed to approve cell-based medicinal products (a “centralized” review of the submission) after December 31, 2008.

The regulatory requirements to market somatic cellular and ATMP products have changed significantly with the approval of the EU ATMP regulation. Beginning January 1, 2008, a one year transition time was put into effect. After December 31, 2008, any product that is considered “tissue engineered” under the definitions provided in the ATMP regulation was granted a four year “grandfather” marketing allowance if that product has been on the market on or before the end of the transition period.

Germany does not require marketing authorization to distribute cultured expanded autologous tissue products for tissue regeneration. When the newly revised law became effective, we had introduced a product into the German market, and we may fall under the “grandfathered” regulations for some period of time before we would need to apply for a centralized marketing authorization.

### **Recent Financing**

On June 12, 2009, we entered into a \$30.0 million common stock purchase agreement with Fusion Capital Fund II, LLC, (“Fusion Capital”) an Illinois limited liability company. Concurrently with entering into the common stock purchase agreement, we entered into a registration rights agreement with Fusion Capital. Under the registration rights agreement, we filed a registration statement related to the transaction with the U.S. Securities & Exchange Commission (“SEC”) covering the shares that have been issued or may be issued to Fusion Capital under the common stock purchase agreement. The SEC declared the registration statement effective on June 29, 2009.

On the commencement date, July 1, 2009, we have the right over a 25-month period to sell shares of our common stock to Fusion Capital from time to time in amounts between \$100,000 and \$4 million, depending on certain conditions as set forth in the agreement, up to an aggregate of \$30.0 million. The number of shares that could

be issued to Fusion Capital during each sale is determined based on a stock price (“Purchase Price”) that is the lower of the (a) the lowest sale price of common stock on the purchase date or (b) the arithmetic average of the three (3) lowest closing sale prices of common stock during the twelve (12) consecutive business days (ten (10) days in certain circumstances) ending on the business day immediately preceding the purchase date (to be appropriately adjusted for any reorganization, recapitalization, non-cash dividend, stock split or other similar transaction). We control the timing and amount of any sales of shares to Fusion Capital.

Pursuant to the common stock purchase agreement with Fusion Capital, there are certain events of default which, if such an event were to occur, would eliminate the obligation of Fusion Capital to purchase shares from us. Such events include, but are not limited to, (i) shares of our common stock not being listed on any one of several stock exchanges outlined in the agreement and (ii) a “material adverse change” in our business or operations. In addition, Fusion Capital shall not have the right or the obligation to purchase any shares of our common stock on any business day that the price of the common stock is below \$0.10. However, pursuant to the common stock purchase agreement, Fusion Capital may not purchase any shares of our stock on any business day that the price of the common stock is below \$0.36 without the approval of our shareholders. The common stock purchase agreement may be terminated by us at any time at our discretion without any cost to us. There are no negative covenants, restrictions on future fundings, penalties or liquidated damages in the agreement. The proceeds received by us under the common stock purchase agreement will be used to conduct operations and to continue to conduct our clinical development programs.

In consideration for entering into the agreement, upon execution of the common stock purchase agreement we issued 1,452,238 shares of our common stock to Fusion Capital as an initial commitment fee. We will also issue from time to time up to an additional 2,420,396 shares to Fusion Capital as a commitment fee pro rata as we receive the \$30.0 million of future funding.

Through September 9, 2009, 10,328,479 shares of our common stock (including 1,714,448 shares related to its commitment fee) were issued to Fusion Capital for net proceeds of \$3,250,000.

## **Competitive Environment**

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

Our potential commercial products address a broad range of existing and emerging therapeutic markets, in which cell-based therapy is a new and as of yet, unproven, commercial strategy. In a large part, we face primary competition from existing medical devices and drug products. Some of our competitors have longer operating histories and substantially greater resources. These include companies such as Baxter, Genzyme, Johnson & Johnson, Miltenyi Biotec and Medtronic.

In the general area of cell-based therapies, including tissue regeneration applications, we potentially compete with a variety of companies, most of whom are specialty medical products or biotechnology companies. Some of these, such as Baxter, Genzyme, Johnson & Johnson, Medtronic and Miltenyi Biotec are well-established and have substantial technical and financial resources compared to ours. However, as cell-based products are only just emerging as viable medical therapies, many of our most direct competitors are smaller biotechnology and specialty medical products companies. These include Advanced Cell Technology, Aldagen, Angioblast, Arterioocyte, Bioheart, Athersys, Cytori Therapeutics, Gamida Cell, Geron, Mesoblast, Osiris Therapeutics and StemCells.

## **General**

We cannot project when we will generate positive cash flows from our consolidated operations. In the next several years, we expect that our revenue sources will consist of modest sales of cell manufacturing supplies at irregular intervals to academic research centers, commercial evaluations, grant revenue, research funding, licensing fees from potential future corporate collaborators and interest income. To date, we have financed our operations primarily through public and private sales of our equity securities. As a clinical development-stage company, we have never been profitable and do not anticipate having net income unless and until significant product sales commence. Achieving this objective will require significant additional funding. Our ability to achieve profitability on a sustained basis, if at all, or to obtain the required funding to achieve our operating objectives, or complete additional corporate partnering transactions or acquisitions is subject to a number of risks and uncertainties. Please see the section entitled “Risk Factors”.

## **Employees**

As of September 1, 2009, we employed approximately 48 individuals on a full time equivalent basis. A significant number of our management and professional employees have had prior experience with pharmaceutical, biotechnology or medical product companies. None of our employees are covered by collective bargaining agreements, and management considers relations with our employees to be good.

## **Executive Officers**

*George W. Dunbar, Jr.*, 63, joined Aastrom as President, Chief Executive Officer and a member of the Company’s Board of Directors in July 2006, and has served as the Chief Financial Officer since July 2008. For 15 years prior to joining Aastrom, Mr. Dunbar served as Chief Executive Officer and Director of Quantum Dot Corporation, Targesome, Inc., and Epic Therapeutics; as Acting President and Chief Executive Officer of StemCells, Inc. (formerly CytoTherapeutics); and as President and Chief Executive Officer of Metra Biosystems, Inc. Prior to that time, Mr. Dunbar held senior positions in licensing, business development and marketing with The Ares-Serono Group and Amersham International. In addition to serving as a board member of companies where he also led the executive management team, Mr. Dunbar has other significant board experience serving both public and private companies. He currently serves as Chairman of Board for Accuri Cytometers, as well as the MBA Advisory Board of the College of Business at Auburn University. Previous boards of director appointments include: DepoTech, LJI Biosystems, Metrika, Molecular Probes, Quidel, Sonus Pharmaceuticals and The Valley Medical Center Foundation. Mr. Dunbar received a B.S. in Electrical Engineering and an MBA from Auburn University.

On September 3, 2009, we announced that our President, Chief Executive Officer and Chief Financial Officer, George W. Dunbar, Jr., will be stepping down from those positions immediately after our annual meeting in December 2009. At that time, Mr. Dunbar will be succeeded in those positions by Timothy Mayleben, currently a director of the Company.

## **Available Information**

Additional information about Aastrom is contained at our website, [www.aastrom.com](http://www.aastrom.com). Information on our website is not incorporated by reference into this report. We make available on our website our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K as soon as reasonably practicable after those reports are filed with the Securities and Exchange Commission. The following Corporate Governance documents are also posted on our website: Code of Business Conduct and Ethics, Code of Ethics for Senior Financial Officers, Board Member Attendance at Annual Meetings Policy, Director Nominations Policy, Shareholder Communications with Directors Policy and the Charters for each of the Committees of the Board of Directors.

## **Item 1A. Risk Factors**

*Our operations and financial results are subject to various risks and uncertainties, including those described below, that could adversely affect our business, financial condition, results of operations, cash flows, and trading price of our common stock. The risks and uncertainties described below are not the only ones we face. There may be additional risks and uncertainties that are not known to us or that we do not consider to be material at this time. If the events described in these risks occur, our business, financial condition, and results of operations would likely suffer.*

### **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 June 30, 2009, we have incurred a cumulative net loss totaling approximately \$195 million, and we have continued to incur losses since that date. These losses have resulted principally from costs incurred in the research and development (including clinical trials) of our cell culture technologies and our cell manufacturing system, general and administrative expenses, and the prosecution of patent applications. We expect to continue to incur significant operating losses over the next several years and at least until, and probably after, product sales increase, primarily owing to our research and development programs, including preclinical 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, timely initiation and completion of clinical trials, obtaining regulatory approvals, establishing manufacturing, sales and marketing arrangements with third parties, maintaining supplies of key manufacturing components, acquisition and development of complementary activities and raising sufficient cash to fund our operating activities. Therefore, we may not be able to achieve or sustain profitability.

The global economy and capital markets are challenging for the small cap biotech sector. This situation makes the timing and potential for future equity financings uncertain.

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

We are required to meet certain qualitative and financial tests (including a minimum bid price for our common stock of \$1.00 per share) to maintain the listing of our common stock on the NASDAQ Capital Market. On July 13, 2009, we received notification from the Listings Qualifications Department of NASDAQ that further suspended enforcement of the rules requiring a minimum \$1.00 per share closing bid price and a minimum market value of publicly held shares until July 31, 2009. As a result of NASDAQ further extending the suspension and the balance of 60 days remaining on our pending compliance period at the time of the initial suspension, we now have until October 1, 2009 to regain compliance with the \$1.00 minimum closing bid price rule in order to remain listed on the NASDAQ Capital Market. We can regain compliance with the minimum closing bid price rule if the bid price of our common stock closes at \$1.00 per share or higher for a minimum of ten consecutive business days during the 180-day compliance period, although NASDAQ may, in its discretion, require us to maintain a minimum closing bid price of at least \$1.00 per share for a period in excess of ten consecutive business days (but generally no more than 20 consecutive business days) before determining that we have demonstrated the ability to maintain long-term compliance. If we do not regain compliance during the further extended compliance period, NASDAQ will provide written notice that our securities will be delisted from the NASDAQ Capital Market. At such time, we would be able to appeal the determination to a NASDAQ Listing Qualifications Panel by requesting an oral hearing. A request for a hearing allows us to remain listed on the NASDAQ Capital Market pending the decision of the NASDAQ Hearing Panel.

In the event that our common stock is delisted from the NASDAQ Capital Market there are alternative listing options, as follows:

- We may be eligible for quotation on FINRA's Over-the-Counter Bulletin Board (OTCBB) if a market maker makes an application to register and quote our common stock in accordance with SEC Rule 15c2-11, and such application, Form 211, is cleared. Only a market maker is able to file Form 211.
- If we do not qualify for quotation on the OTCBB, we could apply to other unregulated markets.

We cannot provide any assurance that our stock price will recover within the permitted grace period. 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 may also impair our ability to raise capital.

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

In addition to our current financing with Fusion Capital, we will require substantial additional capital resources in order to conduct our operations and develop and commercialize our products and cell manufacturing facilities. In order to grow and expand our business, to introduce our new product candidates into the marketplace and to acquire or develop complementary business activities, we will need to raise a significant amount of additional funds. We will also need significant additional funds or a collaborative partner, or both, to finance the research and development activities of our cell product candidates for additional indications. 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, clinical 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;
- the effect of commercialization activities and facility expansions, if and as required; and
- complementary business acquisition or development opportunities.

Because of our long-term funding requirements, we intend to try to access the public or private equity markets if conditions are favorable to complete a financing, even if we do not have an immediate need for additional capital at that time, or whenever we require additional operating capital. 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 transaction with Fusion Capital, described above under “Recent Financing”, may provide us with some of the required capital to conduct our operations; however, we expect that we will need additional capital. In addition, under certain conditions, Fusion will not be required to purchase our shares, including if the market price of our common stock is less than \$0.10, if we are not listed on a national exchange or the OTC Bulletin Board or if there is a material adverse change to our business, properties, operations, financial condition or results of operations.

Additionally, in order to be in compliance with NASDAQ Capital Market rules, we cannot be required to sell, and Fusion Capital shall not have the right or the obligation to purchase, shares of our common stock at a price below \$0.36, which represents the greater of the book value per share of our common stock as of March 31, 2009 or the closing sale price per share of our common stock on June 11, 2009, the business day before we entered into the Purchase Agreement, plus \$0.01. If we elect to sell our shares of common stock to Fusion Capital at a price per share below \$0.36, we may be required to obtain shareholder approval in order to be in compliance with the NASDAQ Capital Market rules.

We only have the right to receive \$100,000 every other business day under the Purchase Agreement unless our stock price equals or exceeds \$0.25, in which case we can sell greater amounts to Fusion Capital as the price of our common stock increases. The extent to which we rely on Fusion Capital as a source of funding will depend on a number of factors including, the prevailing market price of our common stock and the extent to which we are able to secure working capital from other sources. Specifically, Fusion Capital shall not have the right nor the obligation to purchase any shares of our common stock on any business days that the market price of our common stock is less than \$0.10.

Even if we are able to access the full \$30.0 million under the Purchase Agreement with Fusion Capital, we will need additional capital to fully implement our business, operating and development plans. Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive when we require it, the consequences could have a material adverse effect on our business, operating results, financial condition and prospects.

**The sale of our common stock to Fusion Capital may cause dilution and the sale of the shares of common stock acquired by Fusion Capital could cause the price of our common stock to decline.**

In connection with entering into the Purchase Agreement, we authorized the sale to Fusion Capital of up to 36,000,000 shares of our common stock. The number of shares ultimately offered for sale by Fusion Capital is dependent upon the number of shares purchased by Fusion Capital under the Purchase Agreement. The purchase price for the common stock to be sold to Fusion Capital pursuant to the Purchase Agreement will fluctuate based on the price of our common stock. All 39,872,634 shares registered with the SEC are expected to be freely tradable. The registered shares may be sold over a period of up to 25 months from the commencement date of July 1, 2009. Depending upon market liquidity at the time, a sale of shares to Fusion Capital at any given time could cause the trading price of our common stock to decline. Fusion Capital may ultimately purchase all, or some of the 36,000,000 shares of common stock registered in the offering. After it has acquired such shares, it may sell all, some or none of such shares. Therefore, sales to Fusion Capital by us under the Purchase Agreement may result in substantial dilution to the interests of other holders of our common stock. The sale of a substantial number of shares of our common stock to Fusion Capital, or anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales. However, we have the right to control the timing and amount of any sales of our shares to Fusion Capital and the Purchase Agreement may be terminated by us at any time at our discretion without any cost to us.

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

Our success depends in large part upon our ability to attract and retain highly qualified scientific and management personnel. We face competition for such personnel from other companies, research and academic institutions and other entities. Further, in an effort to conserve financial resources, we have implemented reductions in our work force on three previous occasions. As a result of these and other factors, we may not be successful in hiring or retaining key personnel. Our inability to replace any key employee could harm our operations.

On September 3, 2009, we announced that our President, Chief Executive Officer and Chief Financial Officer, George W. Dunbar, Jr., will be stepping down from those positions immediately after our annual meeting in December 2009. At that time, Mr. Dunbar will be succeeded in those positions by Timothy Mayleben, currently a director of the Company. In addition, in the future, we expect to hire other key personnel as circumstances and our financial resources allow. If we are unable to fill these positions, at such time, our operations could be harmed.

**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 U.S., which we believe will ultimately be the largest market for our products. We will also be required to obtain additional approvals from various foreign regulatory authorities to initiate sales activities of cell products in those jurisdictions, including the EU under regulation of the EMEA. If we cannot demonstrate the safety and efficacy of our cell product candidates produced in our manufacturing system, we may not be able to obtain required regulatory approvals. If we cannot demonstrate the safety and efficacy of our product candidates produced in our manufacturing system, 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. Because our product development programs are designed to satisfy the standards applicable to 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. Each of these cell products (such as our TRC-based products) is, under current regulations, regulated as a biologic, which requires a Biologic License Application (BLA).

EU Directives and regulations (laws) have become effective, and have influenced the requirements for manufacturing cell products and the conduct of clinical trials. For products that are regulated as an ATMP, the EU Directive requires: (i) preclinical laboratory and animal testing; (ii) submission of an IMPD to the Competent Authorities of the MS where the clinical trial will be conducted, which must be approved prior to the initiation of human clinical studies; (iii) adequate and well-controlled clinical trials to establish the safety and efficacy of the product for its intended use; (iv) submission to EMEA for an MA; and, (v) review and approval of the MA. Under the newly approved ATMP regulation for cellular products only the EMEA will be allowed to approve cell-based medicinal products (a “centralized” review of the submission) after December 31, 2008.

The regulatory requirements to market somatic cellular and ATMP products have changed significantly with the approval of the EU ATMP regulation. Beginning January 1, 2008, a one year transition time was put into effect. After December 31, 2008, any product that is considered “tissue engineered” under the definitions provided in the ATMP regulation was granted a four year “grandfather” marketing allowance if that product has been on the market on or before the end of the transition period.

Germany had not required marketing authorization to distribute cultured expanded autologous tissue products for tissue regeneration when the newly revised law became effective. We had introduced a product into the German market by that time and we may fall under the “grandfathered” regulations for some period of time before we would need to apply for a centralized marketing authorization.

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

In order to commercialize our cell product candidates in the U.S. and the EU, we must complete substantial clinical trials, and obtain sufficient safety and efficacy results to support required registration approval and market acceptance of our cell product candidates. We may not be able to successfully complete the 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 cell 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 therapeutic cell products in the U.S. and across the EU, we must demonstrate, through extensive preclinical studies and clinical trials, the safety and efficacy of our processes and product candidates. If our clinical trials are not successful, our products may not be marketable.

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

Our research programs are currently directed at improving TRC-based product functionality for certain clinical indications, improving product shelf life, and decreasing the cost of manufacturing our TRC-based products. These production process changes may alter the functionality of our cells and require various additional levels of experimental and clinical testing and evaluation. Any such testing could lengthen the time before these products would be commercially available.

Even if successful clinical results are reported for a product from a completed clinical trial, this does not mean that the results will be sustained over time, or will be sufficient for a marketable or regulatory approvable product.

**Failure of third parties to manufacture or supply certain components, equipment, disposable devices and other materials used our cell manufacturing process, would impair our TRC-based cell product development.**

We rely solely on third parties such as BioLife and Invitrogen to manufacture and/or supply certain components, equipment, disposable devices and other materials used our cell manufacturing process to develop our TRC-based cell products.

It would be difficult to obtain alternate sources of supply for many of these items on a short-term basis. If any of our key manufacturers or suppliers fails to perform their respective obligations or if our supply of certain components, equipment, disposable devices and other materials is limited or interrupted, it would impair our ability to manufacture our TRC-based cell products which would delay our ability to conduct our clinical trials or market our product candidates on a timely and cost-competitive basis, if at all.

**Failure of third parties to manufacture component parts or provide limited source supplies, or the imposition of additional regulation, would impair our new product development.**

We rely solely on third parties such as Sparton (formerly Astro), Ethox, Moll, Lonza and Genpore to manufacture or supply certain of our devices/manufacturing equipment, as well as component parts and other materials used in the cell product 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 fails to perform their respective obligations or if our supply of 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.

**Manufacturing our cell products in centralized facilities may increase the risk that we will not have adequate quantities of our cell products for clinical programs.**

We rely on third party manufacturers, Fraunhofer Institute for Interfacial Engineering and Biotechnology in Stuttgart, Germany and the Institute of Laboratory and Transfusion Medicine at the Heart Center in Bad Oeynhausen, Germany to supply our TRC-based cell products for certain EU clinical activities. Reliance on third party manufacturers entails risks including regulatory compliance and quality assurance and the possible breach of the manufacturing agreement by the third party. We are subject to similar regulatory and compliance risks

at our site in Ann Arbor, Michigan. All sites could be subject to ongoing, periodic, unannounced inspection by regulatory agencies to ensure strict compliance with GMP regulations and other governmental regulations and corresponding foreign standards. Our present and future manufacturers might not be able to comply with these regulatory requirements. We do not have redundant cell manufacturing sites in the U.S. In the event our cell manufacturing facilities are damaged or destroyed or are subject to regulatory restrictions, our clinical trial programs and other business prospects would be adversely affected.

**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 cell products for tissue repair and regeneration treatments. Even if we obtain all required regulatory approvals, we cannot be certain that our products and processes will be accepted in the marketplace at a level that would allow us to operate profitably. Our products may be unable to achieve commercial acceptance for a number of reasons, such as the availability of alternatives that are less expensive, more effective, or easier to use; the perception of a low cost-benefit ratio for the product amongst physicians and hospitals; or an inadequate level of product support from ourselves or a commercial partner. 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 U.S. 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 from third party payors may reduce the demand for, or negatively affect the price of, our products. For example, in the past, published studies 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 has negatively affected the marketability of our products in this indication in the past.

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

Some of the manufacturing materials and/or components we use in, and are critical to, implementation of our TRC technology involve the use of animal-derived products, including fetal bovine serum. Suppliers or regulatory changes may limit or restrict the availability of such materials for clinical and commercial use. We currently purchase all of our fetal bovine sera from protected herds in Australia and New Zealand. These sources are considered to be the safest and raise the least amount of concern from the global regulatory agencies. If, for example, the so-called "mad cow disease" occurs in New Zealand or in Australia, it may lead to a restricted supply of the serum currently required for the TRC-based product manufacturing processes. Any restrictions on these materials would impose a potential competitive disadvantage for our products or prevent our ability to manufacture TRC-based cell products. Regulatory authorities in the EU are reviewing the safety issues related to the use of animal-derived materials, which we currently use in our production process. The FDA has issued draft regulations for controls over bovine materials. These proposed regulations do not appear to affect our ability to purchase the manufacturing materials we currently use. However, the FDA may issue final regulations that could affect our operations. We do not know 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 manufacturing, sales, marketing and distribution capabilities, we need to develop increased internal capability or collaborative relationships to manufacture, sell, market and distribute our products.**

We have only limited internal manufacturing, sales, marketing and distribution capabilities. As market needs develop, we intend to establish and operate commercial-scale manufacturing facilities, which will need to comply with all applicable regulatory requirements. We will also need to develop new configurations of our cell manufacturing system for these facilities to enable processes and cost efficiencies associated with large-scale manufacturing. Establishing these facilities will require significant capital and expertise. We may need to make such expenditures when there are significant uncertainties as to the market opportunity. Any delay in establishing, or difficulties in operating, these facilities will limit our ability to meet the anticipated market demand for our cell products. We intend to get assistance to market some of our future cell 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 market one or more of our TRC-based products through our own sales force. Our inability to develop and retain a qualified sales force could limit our ability to market, sell and distribute our cell products.

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

As noted above, we will need significant additional equity funding, in addition to the transactions with Fusion Capital, to provide us with the capital to reach our objectives. 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 \$0.16 and \$0.73 during the twelve month period ended June 30, 2009. The price of our common stock may continue to fluctuate in response to a number of events and factors, such as:

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

- concerns related to management transitions
- delisting from the NASDAQ Capital Market

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 recently 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.

**If we do not keep pace with our competitors and with technological and market changes, our products will 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 cell manufacturing system is 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. Finally, to the extent that others develop new technologies that address the targeted application for our products, our business will suffer.

**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. Certain patent equivalents to the U.S. patents have also been issued in other jurisdictions including Australia, Japan, the Republic of Korea, Canada and under the European Convention. Furthermore, we rely on 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, each of these licenses will terminate when the patent underlying the license expires. The first of these underlying patents will expire on March 21, 2012. We also rely on trade secrets and unpatentable know-how that we seek to protect, in part, by confidentiality agreements with our employees, consultants, suppliers and licensees. These agreements may be breached, and we might not have adequate remedies for any breach. If this were to occur, our business and competitive position would suffer.

**Intellectual property litigation could harm our business.**

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

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

Certain of our and our licensors' research have been or are being funded in part by government grants. As a result of such funding, the U.S. Government has 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 manufacture and/or use of TRC-based products during clinical trials, or after commercialization, results in adverse events. As a result, we may incur significant product liability exposure, which could exceed existing insurance coverage. We may not be able to maintain adequate levels of insurance at reasonable cost and/or reasonable terms. Excessive insurance costs or uninsured claims would increase our operating loss and affect our financial condition.

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

Our Board of Directors has the authority, without shareholder approval, to issue additional shares of preferred stock and to fix the rights, preferences, privileges and restrictions of these shares without any further vote or action by our shareholders. Michigan law contains a provision that makes it more difficult for a 10% shareholder, or its officers, to acquire a company. This authority, together with certain provisions of our charter documents, may have the effect 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 effect could occur even if our shareholders consider the change in control to be in their best interest.

**We are required to evaluate our internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act of 2002 and any adverse results from such evaluation could have a negative market reaction.**

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 (Section 404), we are required to furnish a report by our management on our internal control over financial reporting. That report must contain, among other matters, an assessment of the design and operating effectiveness of our internal controls over financial reporting as of the end of the fiscal year. This assessment must include disclosure of any material weaknesses in our internal control over financial reporting identified by management. That report must also contain a statement that our independent registered public accounting firm has issued an attestation report on the design and operating effectiveness of our system of internal accounting controls over financial reporting. If in the future we are unable to assert that our internal control over financial reporting is effective as of the end of the then current fiscal year (or, if our independent registered public accounting firm is unable to express an unqualified opinion on the design and operating effectiveness of our internal controls), we could lose investor confidence in the accuracy and completeness of our financial reports, which would have a negative effect on our stock price and our ability to raise capital.

**Forward-looking statements**

This report, including the documents that we incorporate by reference, contains forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act. Any statements about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and may be forward-looking. These statements are often, but are not always, made through the use of words or phrases such as "anticipates," "estimates," "plans," "projects," "trends," "opportunity," "comfortable," "current," "intention," "position," "assume," "potential," "outlook," "remain," "continue," "maintain," "sustain," "seek," "achieve," "continuing," "ongoing," "expects," "management believes," "we believe," "we intend" and similar words or phrases, or future or conditional verbs such as "will," "would," "should," "could," "may," or similar

expressions. Accordingly, these statements involve estimates, assumptions and uncertainties which could cause actual results to differ materially from those expressed in them. Any forward-looking statements are qualified in their entirety by reference to the factors discussed throughout this report, and in particular those factors listed under the section “Risk Factors.”

Because the factors referred to in the preceding paragraph could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements we make, you should not place undue reliance on any such forward-looking statements. Further, any forward-looking statement speaks only as of the date on which it is made, and we undertake no obligation to update any forward-looking statement or statements to reflect events or circumstances after the date on which such statement is made or to reflect the occurrence of unanticipated events. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. 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 plan
- clinical trial plans and anticipated results
- anticipation of future losses
- replacement of manufacturing sources
- commercialization plans
- revenue expectations and operating results

**Item 1B. *Unresolved Staff Comments***

None

**Item 2. *Properties***

We lease approximately 30,000 square feet of office, manufacturing and research and development space in Ann Arbor, Michigan under a lease agreement. This lease was entered into in January 2007 and covers a period of six years, beginning on the date we occupied the new space in May 2007. This lease also includes two five-year options to extend the term to 2018 and 2023, respectively. We believe that our facilities are adequate for our current needs. Additional facilities may be required to support expansion for research and development abilities or to assume manufacturing operations that are currently fulfilled through contract manufacturing relationships.

**Item 3. *Legal Proceedings***

We are currently not party to any material legal proceedings, although from time to time we may become involved in disputes in connection with the operation of our business.

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

None

**PART II**

**Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchase of Equity Securities**

Since February 4, 1997, our common stock has been quoted on the NASDAQ Capital Market under the symbol “ASTM”. The following table sets forth the high and low closing prices per share of common stock as reported on the NASDAQ Stock Market:

**Price Range of Common Stock**

	<u>High</u>	<u>Low</u>
Year ended June 30, 2008:		
1st Quarter . . . . .	\$1.34	\$1.10
2nd Quarter . . . . .	1.37	0.52
3rd Quarter . . . . .	0.76	0.38
4th Quarter . . . . .	0.47	0.35
Year ended June 30, 2009:		
1st Quarter . . . . .	0.40	0.22
2nd Quarter . . . . .	0.68	0.16
3rd Quarter . . . . .	0.73	0.33
4th Quarter . . . . .	0.46	0.32

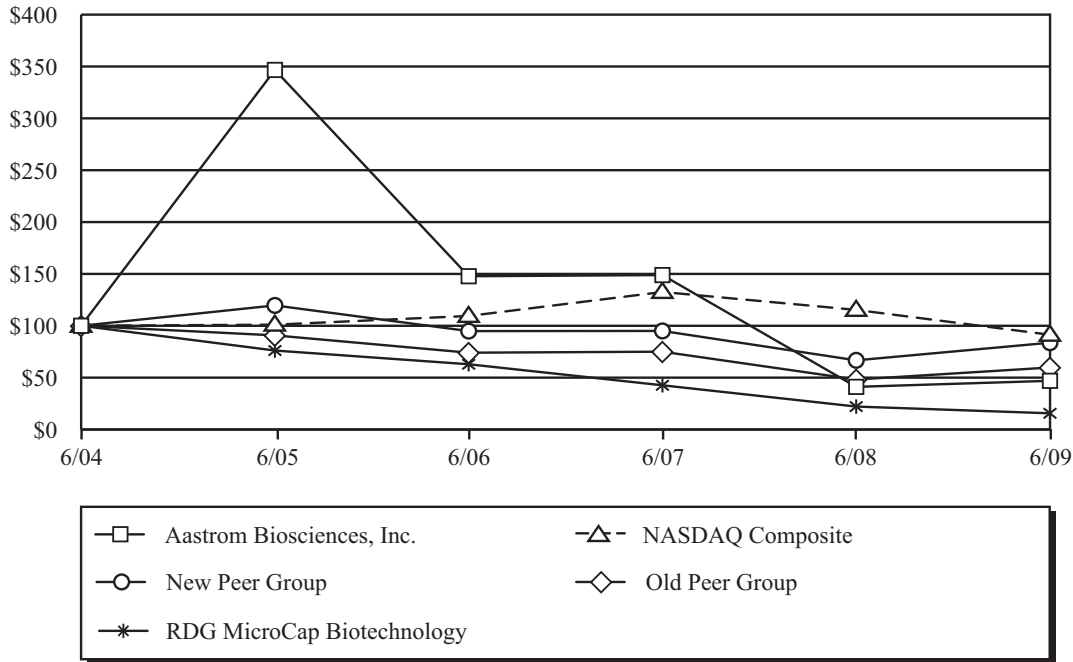
As of July 31, 2009, there were approximately 595 holders of record of the common stock. We have never paid any cash dividends on our common stock and we do not anticipate paying such cash dividends in the foreseeable future. We currently anticipate that we will retain all future earnings, if any, for use in the development of our business.



### Comparison of Shareholder Return

Set forth below is a line graph comparing changes in the cumulative total return on Aastrom’s common stock, a broad market index (the NASDAQ Composite Index), a peer group consisting of the following regenerative medicine companies: Advanced Cell Technology, Inc., Athersys, Inc., Bioheart, Cytori Therapeutics, Geron Corp., Isolagen, Inc., Osiris Therapeutics, Inc., and StemCells, Inc., for the period commencing on June 30, 2004 and ending on June 30, 2009<sup>1</sup>. The new peer group is the old peer group with the exclusion of Isolagen, Inc. as the company focuses on aesthetic cell therapies rather than regenerative medicine therapies.

**COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN\***  
**Among Aastrom Biosciences, Inc., The NASDAQ Composite Index,**  
**The RDG MicroCap Biotechnology Index,**  
**A New Peer Group And An Old Peer Group**



\* \$100 invested on 6/30/04 in stock or index, including reinvestment of dividends.  
 Fiscal year ending June 30.

Aastrom/Index	6/30/04	6/30/05	6/30/06	6/30/07	6/30/08	6/30/09
Aastrom Biosciences, Inc.	100.00	346.67	147.78	148.89	41.11	46.94
NASDAQ Composite	100.00	101.08	109.48	132.58	115.32	91.34
RDG MicroCap Biotechnology	100.00	76.14	62.90	42.63	22.12	15.62
Old Peer Group	100.00	90.75	74.05	75.02	48.19	59.77
New Peer Group	100.00	119.63	94.88	95.03	66.69	83.68

<sup>1</sup> Assumes that \$100.00 was invested on June 30, 2004 in Aastrom’s common stock and each index, and that all dividends were reinvested. No cash dividends have been declared on Aastrom’s common stock. Shareholder returns over the indicated period should not be considered indicative of future shareholder returns.

**Equity Compensation Plan Information as of June 30, 2009**

The following table sets forth information as of June 30, 2009 with respect to compensation plans (including individual compensation arrangements) under which equity securities are authorized for issuances:

	<u>Number of Securities to be Issued upon Exercise of Outstanding Options, Warrants and Rights</u>	<u>Weighted Average Exercise Price of Outstanding Options, Warrants and Rights</u>	<u>Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans</u>
Equity compensation plans approved by security holders (employees and directors)(1) . . . . .	<u>5,921,053</u>	\$1.59	<u>3,737,763(2)</u>

(1) The material features of these securities are described in Note 3 of the Consolidated Financial Statements.

(2) Includes shares issuable under the 2004 Equity Incentive Plan.

## Item 6. Selected Financial Data

The statement of operations data for the years ended June 30, 2007, 2008 and 2009 and for the period from March 24, 1989 (Inception) to June 30, 2009 and the balance sheet data at June 30, 2008 and 2009, are derived from, and are qualified by reference to, the audited consolidated financial statements included in this report on Form 10-K and should be read in conjunction with those financial statements and notes thereto. The statement of operations data for the years ended June 30, 2005 and 2006, and the balance sheet data at June 30, 2005, 2006 and 2007, are derived from audited consolidated financial statements not included herein. The data set forth below are qualified by reference to, and should be read in conjunction with, the consolidated financial statements and notes thereto and "Management's Discussion and Analysis of Financial Condition and Results of Operations."

	Year Ended June 30,					March 24, 1989
	2005	2006	2007	2008	2009	(Inception) to June 30, 2009
	(In thousands, except per share amounts)					
<b>Statement of Operations Data:</b>						
Revenues:						
Product sales and rentals . . . . .	\$ 387	\$ 159	\$ 94	\$ 208	\$ 182	\$ 1,761
Research and development agreements . . . . .	—	—	—	—	—	2,105
Grants . . . . .	522	704	591	314	—	9,657
Total revenues . . . . .	<u>909</u>	<u>863</u>	<u>685</u>	<u>522</u>	<u>182</u>	<u>13,523</u>
Costs and expenses:						
Cost of product sales and rentals(1) . . . . .	148	11	29	56	112	3,001
Research and development . . . . .	7,206	9,484	11,443	15,249	11,289	148,108
Selling, general and administrative . . . . .	5,972	9,101	8,682	6,436	4,950	68,658
Total costs and expenses . . . . .	<u>13,326</u>	<u>18,596</u>	<u>20,154</u>	<u>21,741</u>	<u>16,351</u>	<u>219,767</u>
Loss from operations . . . . .	(12,417)	(17,733)	(19,469)	(21,219)	(16,169)	(206,244)
Other income (expense):						
Other income . . . . .	12	—	—	—	—	1,249
Interest income . . . . .	594	1,258	1,875	1,170	296	10,564
Interest expense . . . . .	—	—	—	(84)	(73)	(424)
Net loss(2) . . . . .	<u>\$(11,811)</u>	<u>\$(16,475)</u>	<u>\$(17,594)</u>	<u>\$(20,133)</u>	<u>\$(15,946)</u>	<u>\$(194,855)</u>
Net loss applicable to common shares . . . . .	<u>\$(11,811)</u>	<u>\$(16,475)</u>	<u>\$(17,594)</u>	<u>\$(20,133)</u>	<u>\$(15,946)</u>	
Net loss per common share (basic and diluted) . . . . .	<u>\$ (.13)</u>	<u>\$ (.15)</u>	<u>\$ (.15)</u>	<u>\$ (.16)</u>	<u>\$ (.11)</u>	
Weighted average number of common shares outstanding (basic and diluted) . . . . .	<u>93,541</u>	<u>106,314</u>	<u>119,523</u>	<u>129,120</u>	<u>143,016</u>	

	June 30,				
	2005	2006	2007	2008	2009
	(In thousands)				
<b>Balance Sheet Data:</b>					
Cash, cash equivalents and short-term investments . . . . .	\$ 32,414	\$ 42,997	\$ 28,325	\$ 22,462	\$ 17,000
Working capital . . . . .	32,275	41,126	26,677	21,963	16,104
Total assets . . . . .	33,897	44,881	32,848	26,217	19,276
Long-term debt . . . . .	—	—	1,536	1,229	784
Deficit accumulated during the development stage . . . . .	(125,675)	(142,150)	(159,744)	(179,877)	(195,823)
Total shareholders' equity . . . . .	33,028	42,342	28,251	23,334	17,284

(1) Cost of product sales and rentals for the year ended June 30, 2005 and for the period from Inception to June 30, 2008 include a charge of \$9,000 and \$2,239,000 for excess inventories, respectively.

(2) Net loss for fiscal years ended June 30, 2006, 2007, 2008 and 2009 included stock-based compensation expense under Financial Accounting Standards Board Statement No. 123(R), "Share-Based Payment," ("SFAS 123(R)") of \$1.0, \$2.8, \$1.6 and \$1.4 million, respectively, related to employee and director stock-based awards. For the year ended June 30, 2005, we accounted for stock-based awards to employees and directors in accordance with Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB 25") and its related interpretations, accordingly, we recognized no compensation expense for stock-based awards because the awards had time-based vesting and the exercise price equaled the fair market value of the underlying common stock on the date of grant. See Note 3 to our consolidated financial statements.

## **Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations**

### **Overview**

We are a regenerative medicine company (*a medical area that focuses on developing therapies that regenerate damaged or diseased tissues or organs*) that incorporated in 1989 and focuses on the clinical development of autologous cell products (*cells collected from a patient and returned to that same patient*) for the repair or regeneration of multiple human tissues, based on our proprietary Tissue Repair Cell (TRC) technology. Our preclinical and clinical product development programs utilize patient-derived bone marrow stem and early progenitor cell populations, and are being investigated for their ability to aid in the regeneration of tissues such as cardiac, vascular and bone. TRC-based products have been used in over 350 patients, and are currently in the following stages of development:

- Cardiac regeneration — Cardiac Repair Cells (CRCs):
  - Dilated cardiomyopathy (DCM) (severe heart failure):
    - U.S.: Phase II IMPACT-DCM clinical trial began treating patients in November 2008; to date, 21 patients enrolled in trial and all five clinical sites are open for patient enrollment (Methodist DeBakey Heart & Vascular Center, Houston, TX, Baylor University Medical Center, Dallas, TX, The University of Utah School of Medicine, Salt Lake City, UT, Cleveland Clinic Heart & Vascular Institute, Cleveland, OH, and Emory University Hospital Midtown, Atlanta, GA); Orphan Drug Designation from the FDA for use in treatment of DCM; all 40 patients expected to be enrolled by December 31, 2009, and a report of preliminary interim data expected once all patients have completed 6 month follow-up visits
    - Germany: Encouraging data reported April 2008 from compassionate use treatment in two patients which provided supporting information considered critical to success of U.S. Phase II IMPACT-DCM IND application.
  - Vascular regeneration — Vascular Repair Cells (VRCs):
    - Critical limb ischemia (CLI):
      - U.S.: Phase IIb RESTORE-CLI clinical trial has enrolled 73 patients to date; interim analysis of clinical data expected to occur during the 4th quarter of calendar year 2009; patient enrollment continues
      - Germany: Phase I/II investigator-sponsored clinical trial completed enrollment and patient follow-up ongoing; positive interim data reported October 2007; investigator report of final data expected during the second half of calendar year 2009
      - Spain: 2 compassionate use cases have been treated with AEMPS (Spanish Drug Agency) approval to date
  - Bone regeneration — Bone Repair Cells (BRCs):
    - Osteonecrosis of the femoral head:
      - U.S.: Phase III ON-CORE clinical trial active with 7 patients enrolled; no longer enrolling additional patients; Orphan Drug Designation from the FDA for use in treatment of osteonecrosis of the femoral head
      - Spain: Enrollment completed with 9 hips (7 patients treated); 24 month follow-up for all patients ongoing
      - Germany: Encouraging data reported October 2007 from compassionate use treatment cases; follow-up ongoing

- Non-union fractures:
  - U.S.: Final Phase I/II clinical study report issued in December 2008; TRC product showed an excellent safety profile and the efficacy data indicated a high non-union healing rate, with bridging callus formation rates reported in over 90% of patients 12 months post-surgery compared to 50% historically
  - Spain: Final 24-month follow-up complete for 10-patient investigator-sponsored Phase II clinical trial; the final investigator report indicates that 7 of 10 cases resulted in healing at 24 months
  - Spain: 9 compassionate use cases of non-union long bone fracture have been treated; follow-up ongoing
- Maxillofacial:
  - U.S.: Investigator-sponsored controlled study in the treatment of alveolar bone defects fully enrolled; follow-up ongoing
  - Spain: 3 patients with craniofacial defects have been treated under compassionate use; early bone formation resulted in healing, including peripheral nerve regeneration or repair, new skin formation and proliferation in blood vessels in ischemic areas

Our platform TRC technology is based on 1) autologous cell products, which are a unique cell mixture containing large numbers of stem and early progenitor cells produced outside of the body from a small amount of bone marrow taken from the patient, and 2) the ability to produce these products in an automated process that meets Good Manufacturing Practice (GMP) guidelines.

We have developed a manufacturing system to produce human cells for clinical use. This automated cell manufacturing system enables the “single-pass perfusion” cell culture process. Single-pass perfusion is our patented manufacturing technology for growing large numbers of human cells. The cellular components of TRC-based products include adult stem and early progenitor cell populations which are capable of forming tissues such as cardiac, vascular, bone, neural, and the hematopoietic and immune system.

All TRC-based products are produced using our cell manufacturing system in centralized manufacturing facilities. We have one manufacturing site in the U.S. located at our headquarters in Ann Arbor, MI, and two contract facilities in the EU located in Stuttgart, Germany (Fraunhofer Institute for Interfacial Engineering and Biotechnology) and Bad Oeynhausen, Germany (Institute of Laboratory and Transfusion Medicine at the Heart Center).

Since our inception, we have been in the development stage and engaged in research and product development, conducted principally on our own behalf. Our initial business plan was to pursue our targeted markets by commercializing our cell manufacturing system and supplies; however, since 2004 we have phased out our marketing efforts promoting the cell manufacturing system as a commercial product. Currently, we have minimal product sales consisting of manufacturing supplies to academic collaborators in the U.S. and cell-based products to EU-based physicians.

We are currently focused on utilizing our TRC technology to produce autologous cell-based products for use in regenerative medicine applications. At such time as we satisfy applicable regulatory approval requirements, we expect the sales of our TRC-based products to constitute nearly all of our product sales revenues.

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

In May 2008, we reprioritized our clinical development programs to focus primarily on cardiovascular applications, including dilated cardiomyopathy and critical limb ischemia. We have discontinued further patient enrollment into our Phase III ON-CORE (osteonecrosis) bone regeneration trial. We do not anticipate initiating new clinical bone activity, reactivating the Phase III ON-CORE trial or initiating formal clinical trials in the neural area without additional financial resources. While the decision to reprioritize was driven by economic factors, the

clinical programs were prioritized based on anticipated time to market and the perceived relative clinical and market potential. We are also exploring the possibility of entering into complementary regenerative medicine business activities, whether through acquisition or otherwise. In addition to reprioritizing our development and clinical programs, we also made reductions in our staff and reduced our overhead expenses.

We expect that we will need to raise significant additional funds or pursue strategic transactions or other strategic alternatives in order to complete our product development programs, complete clinical trials needed to market our products, and commercialize our products. To date, we have financed our operations primarily through public and private sales of our equity securities, and we expect to continue to seek to obtain the 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. With respect to our current activities, this is not likely to occur until we obtain significant additional funding, complete the required clinical trials for regulatory approvals, and receive the necessary approvals to market our products. Through June 30, 2009, we have accumulated a net loss of approximately \$195 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.

On September 3, 2009, we announced that our President, Chief Executive Officer and Chief Financial Officer, George W. Dunbar, Jr., will be stepping down from those positions immediately after our annual meeting in December 2009. At that time, Mr. Dunbar will be succeeded in those positions by Timothy Mayleben, currently a director of the Company.

### **Critical Accounting Policies and Estimates**

The preparation of our consolidated financial statements in accordance with U.S. generally accepted accounting principles (“GAAP”) requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, net revenues and expenses, and related disclosures. We believe our estimates and assumptions are reasonable; however, actual results and the timing of the recognition of such amounts could differ from these estimates.

There are accounting policies that we believe are significant to the presentation of our consolidated financial statements. The most significant accounting policy relates to stock-based compensation expense.

*Stock-Based Compensation* — Effective July 1, 2005, we adopted SFAS 123(R) using the modified prospective method and therefore did not restate prior periods’ results. Under the fair value recognition provisions of SFAS 123(R), we recognize compensation, net of an estimated forfeiture rate, and therefore only recognize compensation cost for those option grants and restricted stock awards and units expected to vest over the service period. Prior to the adoption of SFAS 123(R), we accounted for stock-based payments under APB 25 and its interpretations.

Calculating stock-based compensation expense requires the input of highly subjective assumptions. We apply the Black-Scholes option-pricing model to determine the fair value of our stock options. Inherent in this model are assumptions related to expected stock-price volatility, option life, risk-free interest rate and dividend yield. We estimate the volatility of our common stock at the date of grant based on historical volatility. We estimate the expected life of options that vest solely on service, using the simplified method provided for in the Securities and Exchange Commission Staff Accounting Bulletin No. 107 for “plain vanilla options.” In December 2007, the SEC issued Staff Accounting Bulletin No. 110, (SAB 110). SAB 110 states that the SEC will continue to accept, under certain circumstances, when a company elects to use the “simplified” method after December 31, 2007 for determining the expected term for “plain vanilla” share option grants in accordance with SFAS 123(R) *Share-Based Payment*. SAB 110 updates guidance provided in SAB 107 *Share-Based Payment* that previously stated that the Staff would not expect a company to use the simplified method for share option grants after December 31, 2007. The Company implemented SAB 110 and has continued to use the “simplified” method for estimating the expected term of its “plain-vanilla” stock options as the Company concluded that its historical stock option exercise experience is likely not indicative of future exercise patterns. The risk-free interest rate is based on the U.S. Treasury zero-coupon yield curve on the grant date for a maturity similar to the expected life of the options. The dividend rate is based on our historical rate, which we anticipate to remain at zero. The assumptions used in calculating the fair

value of stock options represent our best estimates, but these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and different assumptions are used, the stock-based compensation expense could be materially different in the future. In addition, we are required to estimate the expected forfeiture rate and only recognize expense for those stock options and restricted stock awards and units expected to vest. We estimate the forfeiture rate based on historical experience of our stock-based awards. If the actual forfeiture rate is different from the estimate, we would report the effect of any change in estimated forfeiture rate in the period of change.

*Performance-Based Stock Options* — During the years ended June 30, 2007 and 2008, the Board of Directors granted performance-based stock options (performance options) to certain key employees. As of June 30, 2009, there were 881,334 performance-based stock options outstanding. These performance-based stock options have a 10-year life and exercise prices equal to the fair value of our stock at the grant date. The aggregate estimated fair value of the awards that are outstanding as of June 30, 2009 is approximately \$876,000. Vesting of these performance-based stock options is dependent on (i) the passage of time subsequent to the grant date and (ii) meeting certain performance conditions, which relate to our progress in our clinical trial programs, and which were established by the Board of Directors. The Board of Directors will determine if the performance conditions have been met. Stock-based compensation expense for these options will be recorded when we believe that the vesting of these options is probable based on the progress of its clinical trial programs and other relevant factors.

For the year ended June 30, 2009, management reviewed the progress toward the performance conditions necessary for these options to vest and concluded that it was not yet probable that the performance conditions of any of these options would be met and, accordingly, no compensation expense has been recorded.

The summary of significant accounting policies should be read in conjunction with our consolidated financial statements and related notes and this discussion of our results of operations.

## **Results of Operations**

Total revenues were \$182,000 in 2009, \$522,000 in 2008, and \$685,000 in 2007. Product sales and rental revenues decreased to \$182,000 in 2009 from \$208,000 in 2008 and increased from \$94,000 in 2007. The fluctuations in product sales and rental revenues is due to the changes in volume of cell production sales for investigator sponsored clinical trials in Spain and limited cell manufacturing supplies to a research institute in the U.S. At such time as we satisfy applicable regulatory approval requirements, we expect the sales of our TRC cell-based products will constitute nearly all of our product sales revenues.

No grant revenues were recorded for 2009 as there were no active grants with the National Institutes of Health. Grant revenues decreased to \$314,000 in 2008 from \$591,000 in 2007. Grant revenues decreased as the result of decreased activity on grants from the National Institutes of Health. Grant revenues accounted for 60% of total revenues for 2008 and 86% for 2007 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.

Total costs and expenses were \$16,351,000 in 2009, \$21,741,000 in 2008 and \$20,154,000 in 2007. The decrease in costs and expenses from 2008 to 2009 resulted from the reprioritization of our development and clinical programs to focus on cardiovascular applications and reductions in our staff and overhead expenses. The increase in costs and expenses from 2007 to 2008 reflected the continued expansion of our research and development and manufacturing activities to support regulatory submissions and on-going and planned tissue regeneration clinical trials in the U.S. and EU; and the costs associated with the reduction in staff in the fourth quarter of 2008.

Cost of product sales and rentals were \$112,000 in 2009, \$56,000 in 2008 and \$29,000 in 2007. The fluctuations in the cost of product sales and rentals are due to the changes in the volume of product sales.

Research and development expenses were \$11,289,000 in 2009, \$15,249,000 in 2008 and \$11,443,000 in 2007. The decrease from 2008 to 2009 reflects the changes we implemented in May 2008, when we reprioritized our clinical development programs to focus primarily on cardiovascular applications. The reprioritization reduced our overall research and development expenses, including salaries and benefits and other purchased services. The increase in research and development expenses from 2007 to 2008 reflected continued expansion of our research

and development activities to support regulatory submissions and on-going and planned tissue regeneration clinical trials in the U.S. and EU. Research and development expenses also include a non-cash charge of \$579,000 in 2009, \$515,000 in 2008 and \$702,000 in 2007 relating to stock compensation recognized following our adoption of SFAS 123(R) on July 1, 2005, which requires us to measure the fair value of all employee share-based payments and recognize that value as an operating expense.

Selling, general and administrative expenses decreased in 2009 to \$4,950,000 from \$6,436,000 in 2008 and \$8,682,000 in 2007. The decrease is due primarily to lower salaries and benefits that are the result of the reduction in force that was part of our reprioritization and management and employee changes in 2008; and the elimination of the management performance bonus plan and the associated costs for 2009 and 2008. Selling, general and administrative expenses also include a non-cash charge of \$783,000 in 2009, \$1,088,000 in 2008 and \$2,104,000 in 2007 relating to stock-based compensation recognized in accordance with SFAS 123(R). The increase in the 2007 non-cash charge includes a one-time charge of \$257,000 that relates to an amendment of our former CEO's stock options upon the termination of his service as a director.

Interest income was \$296,000 in 2009, \$1,170,000 in 2008 and \$1,875,000 in 2007. The fluctuations in interest income are due primarily to corresponding changes in the levels of cash, cash equivalents and short-term investments during the periods.

Our net loss was \$15,946,000, or \$.11 per common share in 2009, \$20,133,000, or \$.16 per common share in 2008, and \$17,594,000, or \$.15 per common share in 2007. The changes in net loss are primarily due to the fluctuations in spending of research and development expenses from year to year. We expect to report additional significant net losses until such time as substantial TRC-based product sales commence.

Our major ongoing research and development programs are focused on the clinical development of TRC-based products, bone marrow-derived adult stem and early progenitor cells, for use in cardiac regeneration, as well as vascular regeneration. We have reprioritized our clinical development programs to focus on cardiovascular applications including our Phase II IMPACT-DCM (dilated cardiomyopathy) trial and our Phase IIb RESTORE-CLI (critical limb ischemia) trial. We have discontinued further patient enrollment into our Phase III ON-CORE (osteonecrosis) bone regeneration trial. We do not anticipate initiating new clinical bone activity, reactivating the Phase III ON-CORE trial or initiating formal clinical trials in the neural area without additional financial resources. While the decision to reprioritize was driven by economic factors, the clinical programs were prioritized based on anticipated time to market and the relative clinical and market potential. Compassionate-use clinical activities were conducted in Europe to evaluate the treatment of dilated cardiomyopathy using our TRC-based product. All of these potential product applications use TRC technology, our proprietary cells and platform manufacturing technologies. We are also completing other research and development activities using our TRC-based products that are intended to improve the functionality for certain clinical indications, to improve shelf life, and to decrease the cost of manufacturing our TRC-based products. Research and development expenses outside of the TRC-based product development consist primarily of engineering and cell manufacturing.

The following table summarizes our research and development expenses for each of the fiscal years in the three year period ended June 30, 2009 (*in thousands*):

<u>R&amp;D Project</u>	<u>Year Ended June 30,</u>		
	<u>2007</u>	<u>2008</u>	<u>2009</u>
TRC-based products . . . . .	\$10,497	\$14,159	\$11,289
Other . . . . .	946	1,090	—
Total . . . . .	<u>\$11,443</u>	<u>\$15,249</u>	<u>\$11,289</u>

Because of the uncertainties of clinical trials and the evolving regulatory requirements applicable to TRC-based products, estimating the completion dates or cost to complete our major research and development program would be highly speculative and subjective. The risks and uncertainties associated with developing our products, including significant and changing governmental regulation and the uncertainty of future clinical study results, are discussed in greater detail in the "Any changes in the governmental regulatory classifications of our products could prevent, limit or delay our ability to market and develop our products," "Our inability to complete our product



development activities successfully would severely limit our ability to operate or finance operations,” and “We must successfully complete our clinical trials to be able to market certain of our products,” sections under the heading “Risk Factors” in Item 1a of this report. The lengthy process of seeking regulatory approvals for our product candidates, and the subsequent compliance with applicable regulations, will require the expenditure of substantial resources. Any failure by us to obtain, or any delay in obtaining, regulatory approvals could cause our research and development expenditures to increase and, in turn, have a material adverse effect on our results of operations. We cannot be certain when any net cash inflow from products validated under our major research and development project, if any, will commence.

We have not generated any net taxable income since our inception and therefore have not paid any federal income taxes since inception. We issued shares of common stock in prior years, which resulted in multiple ownership changes under relevant taxation rules (Section 382 of the Internal Revenue Code). Consequently, pursuant to these taxation rules, the utilization of net operating loss and tax credit loss and tax carryforwards will be significantly limited in future periods, even if we generate taxable income. Such limitations may result in our carryforwards expiring before we can utilize them. At June 30, 2009, we have generated cumulative Federal tax net operating loss and tax credit carryforwards of, \$111,238,000 and \$1,600,000, respectively, which will expire in various periods between 2009 and 2029, if not utilized. Our ability to utilize our net operating loss and tax credit carryforwards may become subject to further annual limitation in the event of future changes in ownership under the taxation rules.

### **Liquidity and Capital Resources**

We have financed our operations since inception primarily through public and private sales of our equity securities, which, from inception through June 30, 2009, have totaled approximately \$213 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 and cash equivalents totaled \$17,000,000 at June 30, 2009, a decrease of \$5,462,000 from June 30, 2008. During the year ended June 30, 2009, the primary source of cash and cash equivalents was from equity transactions, of which net proceeds of \$8,534,000 were raised principally through sales of our equity securities pursuant to the October 2008 agreement with Fusion Capital. The primary uses of cash, cash equivalents and short-term investments during the year ended June 30, 2009 included \$13,805,000 to finance our operations and working capital requirements, and \$35,000 in capital additions.

Our combined cash, cash equivalents and short-term investments totaled \$22,462,000 at June 30, 2008, a decrease of \$5,863,000 from June 30, 2007. During the year ended June 30, 2008, the primary source of cash, cash equivalents and short-term investments was from equity transactions from a registered direct placement of common stock to a select group of investors, from the employee stock option plans and Direct Stock Purchase Plan and the exercise of certain warrants previously issued to investors, with net proceeds of \$13,613,000. The primary uses of cash, cash equivalents and short-term investments during the year ended June 30, 2008 included \$19,527,000 to finance our operations and working capital requirements, and \$215,000 in capital additions for leasehold improvements and equipment.

Our cash and cash equivalents included money market securities, and short-term investments included short-term corporate debt securities (Standard & Poor’s Corporation: A1/A1+; Moody’s Investor Service, Inc.: P1) with original maturities of less than twelve months.

We expect our monthly cash utilization to average approximately \$1.4 million per month during fiscal year 2010.

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, costs of possible acquisition or development of complementary business activities 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 debt or equity financing transactions. Successful future operations are subject to several technical and risk factors, 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 expected interest income will be sufficient to finance current planned activities at least until June 30, 2010, in part due to the fact that many of our expenditures are discretionary in nature and could, if necessary, be delayed. These estimates are based on certain assumptions which could be negatively impacted by the matters discussed under this heading and under the caption "Risk Factors," in Item 1a of this report. In order to grow and expand our business, to introduce our product candidates into the marketplace and to possibly acquire or develop complementary business activities, we will need to raise additional funds. We will also need additional funds or a collaborative partner, or both, to finance the research and development activities of our product candidates for the expansion of additional cell types. We expect that our primary sources of capital for the foreseeable future will be through collaborative arrangements and through the public or private sale of our equity or debt 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 the entire technology sector. If our common stock is delisted from the NASDAQ Stock Market, the liquidity of our common stock could be impaired, and prices paid by investors to purchase our shares of our common stock could be lower than might otherwise prevail.

In October 2008, we entered into a common stock purchase agreement with Fusion Capital Fund II, LLC ("Fusion Capital"), an Illinois limited liability company for up to \$15 million. On April 29, 2009, we concluded the sales of the registered shares under this common stock purchase agreement. Under this purchase agreement we issued 22,692,664 shares of common stock for net proceeds of \$8.6 million.

In consideration for entering into the agreement, upon execution of the common stock purchase agreement in October 2008, we issued to Fusion Capital 1,936,317 shares of our common stock as a commitment fee. We also issued to Fusion Capital an additional 1,113,835 shares as a pro rata commitment fee.

On June 12, 2009, we entered into a \$30.0 million common stock purchase agreement with Fusion Capital Fund II, LLC, ("Fusion Capital") an Illinois limited liability company. Concurrently with entering into the common stock purchase agreement, we entered into a registration rights agreement with Fusion Capital. Under the registration rights agreement, we filed a registration statement related to the transaction with the U.S. Securities & Exchange Commission ("SEC") covering the shares that have been issued or may be issued to Fusion Capital under the common stock purchase agreement. The SEC declared the registration statement effective on June 29, 2009.

On the commencement date, July 1, 2009, we have the right over a 25-month period to sell shares of our common stock to Fusion Capital from time to time in amounts between \$100,000 and \$4 million, depending on certain conditions as set forth in the agreement, up to an aggregate of \$30.0 million. The number of shares that could be issued to Fusion Capital during each sale is determined based on a stock price ("Purchase Price") that is the lower of the (a) the lowest sale price of common stock on the purchase date or (b) the arithmetic average of the three (3) lowest closing sale prices of common stock during the twelve (12) consecutive business days (ten (10) days in certain circumstances) ending on the business day immediately preceding the purchase date (to be appropriately adjusted for any reorganization, recapitalization, non-cash dividend, stock split or other similar transaction). We control the timing and amount of any sales of shares to Fusion Capital.

Pursuant to the common stock purchase agreement with Fusion Capital, there are certain events of default which, if such an event were to occur, would eliminate the obligation of Fusion Capital to purchase shares from us. Such events include, but are not limited to, (i) shares of our common stock not being listed on any one of several stock exchanges outlined in the agreement and (ii) a "material adverse change" in our business or operations. In addition, Fusion Capital shall not have the right or the obligation to purchase any shares of our common stock on any business day that the price of the common stock is below \$0.36. The common stock purchase agreement may be terminated by us at any time at our discretion without any cost to us. There are no negative covenants, restrictions on

future fundings, penalties or liquidated damages in the agreement. The proceeds received by us under the common stock purchase agreement will be used to conduct operations and to continue to conduct our clinical development programs.

In consideration for entering into the agreement, upon execution of the common stock purchase agreement we issued 1,452,238 shares of our common stock to Fusion Capital as an initial commitment fee. We will also issue from time to time up to an additional 2,420,396 shares to Fusion Capital as a commitment fee pro rata as we receive the \$30.0 million of future funding.

Through September 9, 2009, 10,328,479 shares of our common stock (including 1,714,448 shares related to its commitment fee) were issued to Fusion Capital for net proceeds of \$3,250,000.

If we cannot raise such funds, we may not be able to develop or enhance products, take advantage of future opportunities, or respond to competitive pressures or unanticipated requirements, which would have a material adverse impact on our business, financial condition and results of operations. See “Risk Factors” and “Notes to Consolidated Financial Statements” included herein.

### Long-Term Contractual Obligations and Commitments

The following table sets forth our contractual obligations along with cash payments due each period, excluding interest payments (*in thousands*):

<u>Contractual Obligations</u>	<u>Total</u>	<u>Payments Due by Period</u>				<u>More than 5 Years</u>
		<u>2010</u>	<u>2011</u>	<u>2012</u>	<u>2013</u>	
Purchase order commitments . . . . .	\$ 184	\$ 184	\$ —	\$ —	\$ —	\$—
Operating leases . . . . .	4,360	1,102	1,126	1,153	979	—
Long-term debt . . . . .	783	479	225	79	—	—
Total . . . . .	<u>\$5,327</u>	<u>\$1,765</u>	<u>\$1,351</u>	<u>\$1,232</u>	<u>\$979</u>	<u>\$—</u>

In 2005, we entered into amended agreements with several employees that would result in a cash payment to these employees upon a change-in-control event. We do not believe a change-in-control event is probable at this time but if one were to take place, the maximum total cash payout would be \$1.5 million.

### New Accounting Standards

In June 2009, the FASB issued Statement No. 168, *The FASB Accounting Standards Codification™ (“Codification”) and the Hierarchy of Generally Accepted Accounting Principles — a replacement of FASB Statement 162* (SFAS No. 168). SFAS No. 168 establishes the Codification as the source of authoritative United States accounting and reporting standards for all non-governmental entities (other than guidance issued by the SEC). The Codification is a reorganization of current GAAP into a topical format that eliminates the current GAAP hierarchy and establishes two levels of guidance - authoritative and nonauthoritative. According to the FASB, all “non-grandfathered, non-SEC accounting literature” that is not included in the Codification would be considered nonauthoritative. The FASB has indicated that the Codification does not change current GAAP. Instead, the changes aim to (1) reduce the time and effort it takes for users to research accounting questions and (2) improve the usability of current accounting standards. The Codification is effective for interim and annual periods ending on or after September 15, 2009. The Company will apply the Codification to its disclosures beginning with the first quarter ended September 30, 2009. As the Codification is not intended to change the existing accounting guidance, its adoption will not have an impact on the Company’s results of operations and financial condition.

In May 2009, the FASB issued Statement No. 165, *Subsequent Events* (SFAS No. 165). SFAS No. 165 provides guidance on management’s assessment of subsequent events. The new standard clarifies that management must evaluate, as of each reporting period, events or transactions that occur after the balance sheet date “through the date that the financial statements are issued or are available to be issued.” Management must perform its assessment for both interim and annual financial reporting periods. SFAS No. 165 does not significantly change the Company’s practice for evaluating such events. SFAS No. 165 is effective prospectively for interim and annual periods ending

after June 15, 2009 and requires disclosure of the date subsequent events are evaluated through. The Company adopted SFAS No. 165 for the fiscal year ended June 30, 2009. The adoption of SFAS No. 165 did not have any impact on the Company's results of operations and financial condition. For information regarding the evaluation and disclosure of subsequent events as of June 30, 2009, see Footnote 1.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements*. SFAS No. 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. It emphasizes that fair value is a market-based measurement, not an entity-specific measurement. Fair value measurements should be determined based on the assumptions that market participants would use in pricing an asset or liability. Effective July 1, 2008, the Company adopted SFAS No. 157. As permitted by FASB issued Staff Position (FSP) No. FAS 157-2, *Effective Date of FASB Statement No. 157*, issued February 12, 2008, the Company elected to defer the effective date of SFAS No. 157 as it pertains to measurement and disclosures about the fair value of non-financial assets and liabilities made on a nonrecurring basis. The Company will be required to adopt the recognition provisions for non-financial assets and liabilities for interim and annual periods as of July 1, 2009.

**Item 7A. *Quantitative and Qualitative Disclosures About Market Risk***

As of June 30, 2009, our cash and cash equivalents included money market securities, 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 or credit conditions on our securities portfolio.

Our sales to customers in foreign countries are denominated in U.S. dollars or Euros. Our vendors, employees and clinical sites in countries outside the U.S. are typically paid in Euros. However, such expenditures have not been significant to date. Accordingly, we are not directly exposed to significant market risks from currency exchange rate fluctuations. We believe that the interest rate risk related to our accounts receivable is not significant. We manage the risk associated with these accounts through periodic reviews of the carrying value for non-collectibility and establishment of appropriate allowances. We do not enter into hedging transactions and do not purchase derivative instruments.

**Item 8. *Financial Statements and Supplementary Data***

	<u>Page</u>
Report of Independent Registered Public Accounting Firm . . . . .	42
Consolidated Balance Sheets as of June 30, 2008 and 2009 . . . . .	43
Consolidated Statements of Operations for the years ended June 30, 2007, 2008 and 2009 and for the Period from March 24, 1989 (Inception) to June 30, 2009 . . . . .	44
Consolidated Statements of Shareholders' Equity and Comprehensive Loss from March 24, 1989 (Inception) to June 30, 2009 . . . . .	45
Consolidated Statements of Cash Flows for the years ended June 30, 2007, 2008 and 2009 and for the Period from March 24, 1989 (Inception) to June 30, 2009 . . . . .	46
Notes to Consolidated Financial Statements . . . . .	47

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders  
of Aastrom Biosciences, Inc.:

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, shareholders' equity and comprehensive loss and cash flows present fairly, in all material respects, the financial position of Aastrom Biosciences, Inc. and its subsidiaries (a development stage company) at June 30, 2009 and 2008, and the results of their operations and their cash flows for each of the three years in the period ended June 30, 2009, and for the period from March 24, 1989 (Inception) to June 30, 2009, in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of June 30, 2009, based on criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control over Financial Reporting, appearing under Item 9A of this Annual Report on Form 10-K. Our responsibility is to express opinions on these financial statements and on the Company's internal control over financial reporting based on our integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ PRICEWATERHOUSECOOPERS LLP  
PricewaterhouseCoopers LLP  
Detroit, Michigan  
September 14, 2009

**AASTROM BIOSCIENCES, INC.**  
**(a clinical development stage company)**  
**CONSOLIDATED BALANCE SHEETS**

	June 30,	
	2008	2009
	(In thousands, except share data)	
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents . . . . .	\$ 16,492	\$ 17,000
Short-term investments . . . . .	5,970	—
Receivables, net . . . . .	18	58
Inventories . . . . .	—	1
Other current assets . . . . .	1,583	732
Total current assets . . . . .	24,063	17,791
<b>PROPERTY AND EQUIPMENT, NET . . . . .</b>	<b>2,154</b>	<b>1,485</b>
Total assets . . . . .	<b>\$ 26,217</b>	<b>\$ 19,276</b>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable and accrued expenses . . . . .	\$ 907	\$ 853
Accrued employee benefits . . . . .	747	355
Current portion of long-term debt . . . . .	446	479
Total current liabilities . . . . .	2,100	1,687
<b>LONG-TERM DEBT . . . . .</b>	<b>783</b>	<b>305</b>
<b>COMMITMENTS AND CONTINGENCIES (Notes 6 and 7)</b>		
<b>SHAREHOLDERS' EQUITY:</b>		
Common Stock, no par value; shares authorized — 250,000,000; shares issued and outstanding — 132,858,736 and 160,222,644, respectively . . . . .	203,211	213,107
Deficit accumulated during the development stage . . . . .	(179,877)	(195,823)
Total shareholders' equity . . . . .	23,334	17,284
Total liabilities and shareholders' equity . . . . .	<b>\$ 26,217</b>	<b>\$ 19,276</b>

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

**AASTROM BIOSCIENCES, INC.**  
**(a clinical development stage company)**

**CONSOLIDATED STATEMENTS OF OPERATIONS**

	Year Ended June 30,			March 24, 1989
	2007	2008	2009	(Inception) to June 30, 2009
	(In thousands, except per share amounts)			
<b>REVENUES:</b>				
Product sales and rentals . . . . .	\$ 94	\$ 208	\$ 182	\$ 1,761
Research and development agreements . . . . .	—	—	—	2,105
Grants . . . . .	591	314	—	9,657
Total revenues . . . . .	685	522	182	13,523
<b>COSTS AND EXPENSES:</b>				
Cost of product sales and rentals . . . . .	29	56	112	762
Cost of product sales and rentals — provision for excess inventories. . . . .	—	—	—	2,239
Research and development . . . . .	11,443	15,249	11,289	148,108
Selling, general and administrative . . . . .	8,682	6,436	4,950	68,658
Total costs and expenses . . . . .	20,154	21,741	16,351	219,767
<b>LOSS FROM OPERATIONS . . . . .</b>	<b>(19,469)</b>	<b>(21,219)</b>	<b>(16,169)</b>	<b>(206,244)</b>
<b>OTHER INCOME (EXPENSE):</b>				
Other income . . . . .	—	—	—	1,249
Interest income . . . . .	1,875	1,170	296	10,564
Interest expense . . . . .	—	(84)	(73)	(424)
Total other income . . . . .	1,875	1,086	223	11,389
<b>NET LOSS . . . . .</b>	<b>\$(17,594)</b>	<b>\$(20,133)</b>	<b>\$(15,946)</b>	<b>\$(194,855)</b>
<b>NET LOSS PER SHARE (Basic and Diluted) . . . . .</b>	<b>\$ (.15)</b>	<b>\$ (.16)</b>	<b>\$ (.11)</b>	
Weighted average number of common shares outstanding (Basic and Diluted) . . . . .	119,523	129,120	143,016	

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



**AASTROM BIOSCIENCES, INC.**  
(a clinical development stage company)

**CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY AND COMPREHENSIVE LOSS**

	Preferred Stock		Common Stock		Deficit Accumulated During the Development Stage	Total Shareholders' Equity
	Shares	Amount	Shares	Amount		
(In thousands, except share and per share data)						
BALANCE, MARCH 24, 1989 (Inception)	—	\$ —	—	\$ —	\$ —	\$ —
Net loss and comprehensive loss					(141,182)	(141,182)
Issuance of common stock for cash, services and license rights			1,195,124	2,336		2,336
Issuance of Series A through Series E Preferred Stock for cash, net of issuance costs of \$342	9,451,766	34,218				34,218
Issuance of Series E Preferred Stock at \$17.00 per Share	205,882	3,500		(3,500)		—
Exercise of stock options and stock purchase warrants, and issuance of stock under Employee Stock Purchase Plan			7,681,670	5,583		5,583
Issuance of Stock Purchase Rights for cash in September 1995 and March 1996				3,500		3,500
Principal payment received under shareholder note Receivable				31		31
Initial public offering of common stock at \$7.00 per share, net of issuance costs of \$2,865			3,250,000	19,885		19,885
Conversion of preferred stock	(11,865,648)	(55,374)	21,753,709	55,374		—
Compensation expense related to stock options and warrants granted				2,608		2,608
Issuance of 5.5% Convertible Preferred Stock at \$5.00 per share, net of issuance costs of \$1,070	2,200,000	9,930				9,930
Issuance of 1998 Series I Convertible Preferred Stock at \$1,000 per share, net of issuance costs of \$460	5,000	4,540	40,404	149		4,689
Issuance of 1999 Series III Convertible Preferred Stock at \$1,000 per share, net of issuance costs of \$280	3,000	2,720	49,994	90		2,810
Issuance of common stock, net of issuance costs of \$9,147			84,890,298	97,821		97,821
Issuance of restricted stock			342,817	—		—
Issuance of stock under Direct Stock Purchase Plan			119,199	186		186
Dividends and yields on preferred stock		466	148,568	502	(968)	—
Repurchase and retirement of Common Shares Outstanding			(32,171)	(73)		(73)
BALANCE, JUNE 30, 2006	—	—	119,439,612	184,492	(142,150)	42,342
Net loss and comprehensive loss					(17,594)	(17,594)
Exercise of stock options			176,484	133		133
Issuance of restricted stock			39,675	—		—
Cancellation of restricted stock			(69,425)	—		—
Issuance of stock under Direct Stock Purchase Plan			426,523	564		564
Compensation expense related to stock options and restricted stock awards and units granted			—	2,806		2,806
BALANCE, JUNE 30, 2007	—	—	120,012,869	187,995	(159,744)	28,251
Net loss and comprehensive loss					(20,133)	(20,133)
Exercise of stock options and stock purchase warrants			846,392	995		995
Issuance of restricted stock			64,300	—		—
Cancellation of restricted stock			(88,058)	—		—
Issuance of stock under Direct Stock Purchase Plan			181,128	186		186
Compensation expense related to stock options and restricted stock awards and units granted			—	1,603		1,603
Issuance of common stock, net of issuance costs of \$1,068			11,842,105	12,432		12,432
BALANCE, JUNE 30, 2008	—	—	132,858,736	203,211	(179,877)	23,334
Net loss and comprehensive loss					(15,946)	(15,946)
Issuance of restricted stock and units			155,775	—		—
Cancellation of restricted stock			(7,050)	—		—
Issuance of stock under Direct Stock Purchase Plan			20,128	7		7
Compensation expense related to stock options and restricted stock awards and units granted			—	1,362		1,362
Issuance of common stock, net of issuance costs of \$1,682			27,195,055	8,527		8,527
BALANCE, JUNE 30, 2009	—	\$ —	160,222,644	\$213,107	\$(195,823)	\$ 17,284

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

**AASTROM BIOSCIENCES, INC.**  
(a clinical development stage company)

**CONSOLIDATED STATEMENTS OF CASH FLOWS**

	Year Ended June 30,			March 24, 1989
	2007	2008	2009	(Inception) to June 30, 2009
	(In thousands)			
<b>OPERATING ACTIVITIES:</b>				
Net loss	\$(17,594)	\$(20,133)	\$(15,946)	\$(194,855)
Adjustments to reconcile net loss to net cash used for operating activities:				
Depreciation and amortization	500	732	704	6,000
Loss on property held for resale	—	—	—	110
Amortization of discounts and premiums on Investments	(547)	(381)	(30)	(1,704)
Stock compensation expense	2,806	1,603	1,362	8,389
Inventories write downs and reserves	—	—	—	2,239
Stock issued pursuant to license agreement	—	—	—	3,300
Provision for losses on accounts receivable	—	—	—	204
Changes in assets and liabilities:				
Receivables	61	60	(40)	(307)
Inventories	(7)	8	(1)	(2,336)
Other current assets	(461)	(58)	592	(434)
Accounts payable and accrued expenses	633	(867)	(54)	796
Accrued employee benefits	(217)	(491)	(392)	355
Net cash used for operating activities	(14,826)	(19,527)	(13,805)	(178,243)
<b>INVESTING ACTIVITIES:</b>				
Organizational costs	—	—	—	(73)
Purchase of short-term investments	(49,376)	(30,703)	—	(212,041)
Maturities of short-term investments	69,000	40,000	6,000	213,745
Property and equipment purchases	(1,064)	(215)	(35)	(5,761)
Proceeds from sale of property held for resale	—	—	—	400
Net cash provided by (used for) investing activities	18,560	9,082	5,965	(3,730)
<b>FINANCING ACTIVITIES:</b>				
Net proceeds from issuance of preferred stock	—	—	—	51,647
Net proceeds from issuance of common stock	697	13,613	8,534	145,345
Repurchase of common stock	—	—	—	(49)
Payments received for stock purchase rights	—	—	—	3,500
Payments received under shareholder notes	—	—	—	31
Restricted cash used as compensating balance	(777)	241	259	(277)
Proceeds from long-term debt	751	—	—	751
Principal payments under long-term debt	—	(356)	(445)	(1,975)
Net cash provided by financing activities	671	13,498	8,348	198,973
<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>				
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	9,034	13,439	16,492	—
CASH AND CASH EQUIVALENTS AT END OF PERIOD	\$ 13,439	\$ 16,492	\$ 17,000	\$ 17,000
<b>SUPPLEMENTAL CASH FLOW INFORMATION:</b>				
Interest paid	\$ —	\$ 84	\$ 73	\$ 424
Equipment acquired under capital lease obligations	\$ —	\$ —	\$ —	\$ 1,174

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

**AASTROM BIOSCIENCES, INC.**  
**(a clinical development stage company)**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1. Organization and Summary of Significant Accounting Policies**

Aastrom Biosciences, Inc. was incorporated in March 1989 (Inception), began employee-based operations in 1991, and is in the development stage. The Company operates its business in one reportable segment — research and product development involving the development of autologous cell products for use in regenerative medicine.

Successful future operations are subject to several technical hurdles and risk factors, including satisfactory product development, timely initiation and completion of clinical trials, regulatory approval and market acceptance of 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 its operations at least until the end of fiscal year 2010 (ending June 30, 2010), in part due to the fact that many of the Company's expenditures are discretionary in nature and could, if necessary, be delayed, 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 these products. 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 level of success achieved in clinical trials, the requirements for marketing authorization from regulatory bodies in the U.S., EU 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 likely have a material adverse impact on the Company's business, financial condition and results of operations.

*Suppliers* — Some of the key components used to manufacture the Company's TRC-based products come from single or limited sources of supply.

*Principles of Consolidation* — The consolidated financial statements include the accounts of Aastrom and its wholly-owned subsidiaries, Aastrom Biosciences GmbH, located in Berlin, Germany, Aastrom Biosciences, SL, located in Barcelona, Spain, and Aastrom Biosciences, Ltd. located in Dublin, Ireland (collectively, the Company). All significant inter-company transactions and accounts have been eliminated in consolidation. As of June 30, 2009, all subsidiaries had limited operations and are not currently a significant component of the consolidated financial statements.

*Cash and Cash Equivalents* — Cash and cash equivalents include cash and highly liquid short-term investments with original maturities of three months or less.

*Fair Value Measurements* — Effective July 1, 2008, the Company adopted Statement of Financial Accounting Standards No. 157, "Fair Value Measurements" (SFAS 157) for financial assets and liabilities measured at fair value on a recurring basis. As permitted by FASB Staff Position (FSP) No. FAS 157-2, *Effective Date of FASB Statement No. 157*, issued February 12, 2008, the Company elected to defer the effective date of SFAS No. 157 as it pertains to measurement and disclosures about the fair value of non-financial assets and liabilities made on a nonrecurring basis. The Company will be required to adopt the recognition provisions for non-financial assets and liabilities for interim and annual periods as of July 1, 2009. In addition to expanding the disclosures surrounding fair value measurements, SFAS 157 indicates that fair value represents the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is determined based upon assumptions that market participants would use in pricing an asset or liability. As a basis for considering

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

such assumptions, SFAS 157 establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

- Level 1 inputs: Quoted prices (unadjusted) for identical assets or liabilities in active markets
- Level 2 inputs: Inputs, other than quoted prices included in Level 1 that are observable either directly or indirectly; and
- Level 3 inputs: Unobservable inputs for which there is little or no market data, which require the reporting entity to develop its own assumptions.

In many cases, a valuation technique used to measure fair value includes inputs from multiple levels of the fair value hierarchy described above. The lowest level of significant input determines the placement of the entire fair value measurement in the hierarchy.

At June 30, 2009, the Company had \$17 million invested in two money market funds, which is included within the “Cash and cash equivalents” line on the balance sheet. Because there are quoted prices in an active market for shares of this money market fund, the Company considers its fair value measure of this investment to be based on Level 1 inputs. The adoption of SFAS 157 did not change the way in which the Company records this investment at fair value.

*Short-Term Investments* — Short-term investments consisted of highly rated corporate debt securities with original maturities of over three months and less than one year. Short-term investments were classified as available-for-sale, and were presented at market value, with unrealized gains and losses on investments, if any, reflected as a component of accumulated other comprehensive income within shareholders’ equity. The Company had no short-term investments at June 30, 2009.

*Diversity of Credit Risk* — The Company has established guidelines relative to diversification and maturities of its investments in an effort to limit risk. These guidelines are periodically reviewed and modified to take advantage of trends in yields and interest rates. The Company has not experienced any losses on its cash equivalents or short-term investments.

*Property and Equipment* — Property and equipment is recorded at cost and depreciated or amortized using the straight-line method over the estimated useful life of the asset (primarily three to five years) or the underlying lease term for leasehold improvements, whichever is shorter. Depreciation expense was \$500,000, \$732,000, \$704,000 and \$6,000,000 for the years ended June 30, 2007, 2008, 2009 and for the period from Inception to June 30, 2009, respectively. When assets are disposed of, the cost and accumulated depreciation are removed from the accounts. Repairs and maintenance are charged to expense as incurred.

*Revenue Recognition* — The Company’s revenue can be generated from grants and research agreements, collaborative agreements, product sales. Revenue from grants and research agreements is recognized on a cost reimbursement basis consistent with the performance requirements of the related agreement. Revenue from collaborative agreements is recognized when the scientific or clinical results stipulated in the agreement have been met and there are no ongoing obligations on the Company’s part. Revenue from product sales is recognized when title to the product transfers and there are no remaining obligations that will affect the customer’s final acceptance of the sale. Revenue from licensing fees under licensing agreements is recognized 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.

*Research and Development Costs* — Research and development costs are expensed as incurred.

*Stock-Based Compensation* — Effective July 1, 2005, the Company adopted SFAS 123(R) using the modified prospective method and therefore did not restate prior periods’ results. Under the fair value recognition provisions of SFAS 123(R), the Company recognizes compensation, net of an estimated forfeiture rate, and therefore only

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

recognizes compensation cost for those option grants and restricted stock awards and units expected to vest over the service period.

*Income Taxes* — Income taxes are accounted for in accordance with SFAS No. 109, “Accounting for Income Taxes.” Deferred tax assets are recognized for deductible temporary differences and tax credit carryforwards and deferred tax liabilities are recognized for taxable temporary differences. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized.

*Net Loss Per Share* — Net loss per common share is computed using the weighted-average number of common shares outstanding during the period. Common equivalent shares are not included in the diluted per share calculation where the effect of their inclusion would be anti-dilutive. The aggregate number of common equivalent shares (primarily options and warrants) that have been excluded from the computations of diluted net loss per common share for the periods ended June 30, 2007, 2008 and 2009 is approximately 16,106,000, 20,072,000 and 17,825,596, respectively.

*Use of Estimates* — The preparation of financial statements in accordance with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reported period. Actual results could differ from those estimates.

*Financial Instruments* — The Company’s financial instruments include cash equivalents, short-term investments and accounts receivable for which the current carrying amounts approximate market value based upon their short-term nature.

*Long-Lived Assets* — The Company reviews its long-lived assets for impairment whenever an event or change in circumstances indicates that the carrying values of an asset may not be recoverable. If such an event or change in circumstances occurs and potential impairment is indicated because the carrying values exceed the estimated future undiscounted cash flows of the asset, the Company would measure the impairment loss as the amount by which the carrying value of the asset exceeds its fair value. No significant impairment losses have been identified by the Company for any of the periods presented in the accompanying financial statements.

*New Accounting Standards* — In June 2009, the FASB issued Statement No. 168, *The FASB Accounting Standards Codification*<sup>™</sup> (“Codification”) and the *Hierarchy of Generally Accepted Accounting Principles — a replacement of FASB Statement 162* (SFAS No. 168). SFAS No. 168 establishes the Codification as the source of authoritative United States accounting and reporting standards for all non-governmental entities (other than guidance issued by the SEC). The Codification is a reorganization of current GAAP into a topical format that eliminates the current GAAP hierarchy and establishes two levels of guidance — authoritative and nonauthoritative. According to the FASB, all “non-grandfathered, non-SEC accounting literature” that is not included in the Codification would be considered nonauthoritative. The FASB has indicated that the Codification does not change current GAAP. Instead, the changes aim to (1) reduce the time and effort it takes for users to research accounting questions and (2) improve the usability of current accounting standards. The Codification is effective for interim and annual periods ending on or after September 15, 2009. The Company will apply the Codification to its disclosures beginning with the first quarter ended September 30, 2009. As the Codification is not intended to change the existing accounting guidance, its adoption will not have an impact on the Company’s results of operations and financial condition.

In May 2009, the FASB issued Statement No. 165, *Subsequent Events* (SFAS No. 165). SFAS No. 165 provides guidance on management’s assessment of subsequent events. The new standard clarifies that management must evaluate, as of each reporting period, events or transactions that occur after the balance sheet date “through the date that the financial statements are issued or are available to be issued.” Management must perform its assessment for

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

both interim and annual financial reporting periods. SFAS No. 165 does not significantly change the Company's practice for evaluating such events. SFAS No. 165 is effective prospectively for interim and annual periods ending after June 15, 2009 and requires disclosure of the date subsequent events are evaluated through. The Company adopted SFAS No. 165 for the fiscal year ended June 30, 2009. The adoption of SFAS No. 165 did not have any impact on the Company's results of operations and financial condition.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements*. SFAS No. 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. It emphasizes that fair value is a market-based measurement, not an entity-specific measurement. Fair value measurements should be determined based on the assumptions that market participants would use in pricing an asset or liability. Effective July 1, 2008, the Company adopted SFAS No. 157. As permitted by FASB issued Staff Position (FSP) No. FAS 157-2, *Effective Date of FASB Statement No. 157*, issued February 12, 2008, the Company elected to defer the effective date of SFAS No. 157 as it pertains to measurement and disclosures about the fair value of non-financial assets and liabilities made on a nonrecurring basis. The Company will be required to adopt the recognition provisions for non-financial assets and liabilities for interim and annual periods as of July 1, 2009.

*Subsequent Events* — The Company has evaluated subsequent events through September 14, 2009, the date that these financial statements were issued.

**2. Selected Balance Sheet Information**

*Property and Equipment* — Property and equipment consists of the following (*in thousands*):

	June 30,	
	2008	2009
Machinery and equipment . . . . .	\$ 2,649	\$ 2,493
Furniture and fixtures . . . . .	469	469
Computer software . . . . .	397	410
Computer equipment . . . . .	300	262
Office equipment . . . . .	92	75
Leasehold improvements . . . . .	891	891
	4,798	4,600
Less accumulated depreciation and amortization . . . . .	(2,644)	(3,115)
	\$ 2,154	\$ 1,485

*Accounts Payable and Accrued Expenses* — Accounts payable and accrued expenses consist of the following (*in thousands*):

	June 30,	
	2008	2009
Accounts payable . . . . .	\$344	\$248
Accrued expenses:		
Professional services . . . . .	146	205
Clinical studies . . . . .	154	184
Manufacturing and engineering . . . . .	99	79
Other . . . . .	164	137
	\$907	\$853

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

*Accrued Employee Benefits* — Accrued employee benefits consists of the following (in thousands):

	June 30,	
	2008	2009
Accrued vacation pay . . . . .	\$373	\$352
Severance payments . . . . .	366	—
Other . . . . .	8	3
	\$747	\$355

**3. Stock-Based Compensation**

*Stock Option and Equity Incentive Plans*

The Company has various stock incentive plans and agreements (Option Plans) that provide for the issuance of nonqualified and incentive stock options as well as other equity awards. Such awards may be granted by the Company’s Board of Directors to certain of the Company’s employees, directors and consultants. Options granted under these plans expire no later than ten years from the date of grant, and other than those granted to non-employee directors, generally become exercisable over a four-year period (other than 3,545,000 of options granted in October 2008 that vest over 3 years), under a graded-vesting methodology, following the date of grant.

Following shareholder approval of the 2001 Stock Option Plan, the Company agreed that it would not grant additional options under the 1992 Stock Option Plan or the 1996 Outside Director Stock Option Plan. The expiration or cancellation of options previously granted under the 1992 Stock Option Plan or the 1996 Outside Director Stock Option Plan will not increase the awards available for issuance under the Option Plans.

In November 2004, the shareholders approved the 2004 Equity Incentive Plan (the “2004 Plan”). The 2004 Plan provides incentives through the grant of stock options (including indexed options), stock appreciation rights, restricted stock purchase rights, restricted stock awards, restricted stock units and deferred stock units. The exercise price of stock options granted under the 2004 Plan shall not be less than the fair market value of the Company’s common stock on the date of grant. The 2004 Plan replaced the 2001 Stock Option Plan and no new awards will be granted under the 2001 Stock Option Plan. However, the expiration or cancellation of options previously granted under the 2001 Stock Option Plan will increase the awards available or issuance under the 2004 Plan.

In November 2006, the shareholders approved the Company’s Amended and Restated 2004 Plan. The material amendment to the 2004 Plan included the addition of 8,000,000 awards available for issuance under the 2004 Plan.

In February 2008, a new compensation program for outside directors was approved. Each nonemployee director who continues to serve beyond an Annual Shareholder Meeting will also receive a stock option to purchase 55,000 shares granted on the date of each Annual Meeting, with an exercise price equal to the fair value of the common stock on the date of grant, and will vest in equal quarterly increments over a period of one year. In addition, the Chairman of the Board of Directors will be granted restricted stock equal to \$45,000 on the date of each Annual Meeting. Newly elected directors joining the board during the period between shareholder meetings will receive a grant for a pro rata amount of the 55,000 shares subject to option (reflecting the period of time until the next annual meeting).

As of June 30, 2009, there were 3,737,763 of awards available for future grant under the Option Plans.

*Service-Based Stock Options*

During the year ended June 30, 2009, the Company granted 3,990,000 service-based options to purchase common stock. These were granted with exercise prices equal to the fair value of the Company’s stock at the grant date, vest over four years (other than 3,545,000 of options granted in October 2008 that vest over 3 years and non-

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

employee director options which vest over one year) and have lives of ten years. The weighted average grant-date fair value of service-based options granted under the Company's Option Plans during the years ended June 30, 2007, 2008 and 2009 was \$0.88, \$0.67 and \$0.26, respectively.

The net compensation costs recorded for the service-based stock options related to employees and directors (including the impact of the forfeitures) were approximately \$2,598,000, \$1,597,000 and \$1,292,000 for the years ended June 30, 2007, 2008 and 2009, respectively.

The fair value of each service-based stock option grant for the reported periods is estimated on the date of the grant using the Black-Scholes option-pricing model using the weighted average assumptions noted in the following table.

	<u>Year Ended June 30,</u>		
	<u>2007</u>	<u>2008</u>	<u>2009</u>
Stock Option Plans:			
Expected dividend rate . . . . .	0%	0%	0%
Expected stock price volatility . . . . .	67%	61%	70%
Risk free interest rate . . . . .	4.9%	4.2%	3.2%
Estimated forfeiture rate . . . . .	10%	10%	10%
Expected life (years) . . . . .	6.6	6.6	6.6

The following table summarizes the activity for service-based stock options for the indicated periods:

	<u>Options</u>	<u>Weighted Average Exercise Price</u>	<u>Weighted Average Remaining Contractual Term</u>	<u>Aggregate Intrinsic Value</u>
Outstanding at June 30, 2006 . . . . .	3,524,553	\$ 1.67	<u>6.5</u>	<u>\$ 860,000</u>
Granted . . . . .	5,326,200	\$ 1.29		
Exercised . . . . .	(176,484)	\$0 .75		<u>\$ 83,000</u>
Forfeited or expired . . . . .	<u>(316,733)</u>	\$1 .27		
Outstanding at June 30, 2007 . . . . .	8,357,536	\$ 1.46	<u>7.8</u>	<u>\$1,093,000</u>
Granted . . . . .	2,690,900	\$ 1.05		
Exercised . . . . .	(18,518)	\$0 .38		<u>\$ 3,000</u>
Forfeited or expired . . . . .	<u>(2,494,737)</u>	\$1 .53		
Outstanding at June 30, 2008 . . . . .	8,535,181	\$ 1.31	<u>7.8</u>	<u>\$ 1,000</u>
Granted . . . . .	3,990,000	\$ 0.39		
Exercised . . . . .	—	—		
Forfeited or expired . . . . .	<u>(1,602,122)</u>	\$ 1.36		
Outstanding at June 30, 2009 . . . . .	<u>10,923,059</u>	<u>\$ 0.97</u>	<u>7.9</u>	<u>\$ 114,000</u>
Exercisable at June 30, 2009 . . . . .	<u>5,188,778</u>	<u>\$ 1.27</u>	<u>6.9</u>	<u>\$ 28,000</u>

As of June 30, 2009 there was approximately \$861,000 of total unrecognized compensation cost related to non-vested service-based stock options granted under the Option Plan. That cost is expected to be recognized over a weighted-average period of 1.2 years.



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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

In July 2009, the Company granted 2,905,000 service-based options to employees under the Option Plans. These options were granted with an exercise price equal to the fair value of the Company's stock at the grant date and fully vest four years from the grant date.

***Performance-Based Stock Options***

During the years ended June 30, 2007 and 2008 the Board of Directors granted 2,800,400 and 69,400, respectively, performance-based stock options to key employees in three equal tranches. The weighted average grant-date fair value of performance-based options granted under the Company's Option Plans during the years ended June 30, 2007 and 2008 was \$0.95 and \$0.67, respectively. These performance options have a 10 year life and exercise prices equal to the fair value of the Company's stock at the grant date. Vesting of these performance options is dependent on (i) the passage of time subsequent to the grant date and (ii) meeting certain performance conditions, which relate to our progress in our clinical trial programs, which were established by the Board of Directors. The Board of Directors will determine if the performance conditions have been met. Stock-based compensation expense for these options will be recorded when the Company believes that the vesting of these options is probable based on the progress of its clinical trial programs and other relevant factors.

There are three tranches of performance-based options that vest upon the satisfaction of performance conditions, all of which vest based on progress toward clinical trial or product successes within a certain timeframe.

The first tranche expired on March 31, 2008 unvested; the second tranche would vest if performance conditions are met by June 2011; and, the third tranche would vest if performance conditions are met by June 2012. Each tranche of options is forfeited if its performance conditions are not met by the required timeframe, and vesting for any tranche of options is not dependent on the vesting of the other tranches of options.

For the years ended June 30, 2007, 2008 and 2009, management reviewed the progress toward the performance conditions necessary for these options to vest and concluded that it was not yet probable that the performance conditions of any of the tranches of options would be met and, accordingly, no compensation expense has been recorded.

The fair value of the performance-based stock option grants for the reported periods is estimated on the date of the grant using the Black-Scholes option-pricing model using the assumptions noted in the following table.

	<u>June 30, 2007</u>	<u>June 30, 2008</u>
Stock Option Plans:		
Expected dividend rate . . . . .	0%	0%
Expected stock price volatility . . . . .	66%	66%
Risk free interest rate . . . . .	4.7%	4.7%
Estimated forfeiture rate . . . . .	0%	0%
Expected life (years). . . . .	6.8	6.9

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

The following table summarizes the activity for performance-based stock options for the indicated periods:

<u>Options</u>	<u>Shares</u>	<u>Weighted Average Exercise Price</u>	<u>Weighted Average Remaining Contractual Term</u>	<u>Aggregate Intrinsic Value</u>
Outstanding at June 30, 2006 . . . . .	—	—		
Granted . . . . .	2,800,400	\$1.50		
Exercised . . . . .	—	—		
Forfeited or expired . . . . .	<u>(320,000)</u>	\$1.53		
Outstanding at June 30, 2007 . . . . .	2,480,400	<u>\$1.50</u>	<u>9.3</u>	<u>\$0</u>
Granted . . . . .	69,400	\$1.53		
Exercised . . . . .	—	—		
Forfeited or expired . . . . .	<u>(1,261,932)</u>	\$1.51		
Outstanding at June 30, 2008 . . . . .	1,287,868	<u>\$1.49</u>	<u>8.5</u>	<u>\$0</u>
Granted . . . . .	—	—		
Exercised . . . . .	—	—		
Forfeited or expired . . . . .	<u>(406,534)</u>	\$1.53		
Outstanding at June 30, 2009 . . . . .	<u>881,334</u>	<u>\$1.47</u>	<u>7.2</u>	<u>\$0</u>

The aggregate estimated fair value of awards that are outstanding as of June 30, 2009 is approximately \$876,000.

***Restricted Stock Awards***

Restricted stock awards, other than those granted to non-employee directors, generally vest over a four year period and entitle the recipient to receive common stock. The net compensation costs charged as operating expenses for restricted stock for the years ended June 30, 2007, 2008 and 2009 were \$208,000, \$6,000 and \$69,000, respectively.

The following table summarizes the activity for restricted stock awards for the indicated periods:

<u>Non-Vested Restricted Shares</u>	<u>Shares</u>	<u>Weighted Average Grant Date Fair Value</u>
Non-vested at June 30, 2006 . . . . .	367,117	\$2.35
Granted . . . . .	39,400	\$1.17
Vested . . . . .	(116,204)	\$2.31
Forfeited . . . . .	<u>(70,250)</u>	\$2.26
Non-vested at June 30, 2007 . . . . .	220,063	\$2.19
Granted . . . . .	64,300	\$0.70
Vested . . . . .	(107,480)	\$1.75
Forfeited . . . . .	<u>(88,058)</u>	\$2.15
Non-vested at June 30, 2008 . . . . .	88,825	\$1.68
Granted . . . . .	155,200	\$0.29
Vested . . . . .	(133,825)	\$0.76
Forfeited . . . . .	<u>(10,050)</u>	\$1.85
Non-vested at June 30, 2009 . . . . .	<u>100,150</u>	\$0.74

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

The total market value (at the vesting date) of restricted stock award shares that vested during the year ended June 30, 2007, 2008 and 2009 was \$93,000, \$63,000 and \$9,000, respectively.

As of June 30, 2009 there was approximately \$5,000 of total unrecognized compensation cost related to non-vested restricted stock awards granted under the Option Plan. That cost is expected to be recognized over a weighted-average period of 0.6 years.

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

In October 2008, the Company entered into a common stock purchase agreement with Fusion Capital Fund II, LLC ("Fusion Capital"), an Illinois limited liability company for up to \$15 million. On April 29, 2009, the Company concluded the sales of the registered shares under this common stock purchase agreement. Under this purchase agreement the Company issued 22,692,664 shares of common stock for net proceeds of \$8.6 million.

In consideration for entering into the agreement, upon execution of the common stock purchase agreement in October 2008, Aastrom issued to Fusion Capital 1,936,317 shares of the Company's common stock as a commitment fee. Aastrom also issued to Fusion Capital an additional 1,113,835 shares as a pro rata commitment fee.

On June 12, 2009, the Company entered into a \$30.0 million common stock purchase agreement with Fusion Capital Fund II, LLC, ("Fusion Capital") an Illinois limited liability company. Concurrently with entering into the common stock purchase agreement, the Company entered into a registration rights agreement with Fusion Capital. Under the registration rights agreement, the Company filed a registration statement related to the transaction with the U.S. Securities & Exchange Commission ("SEC") covering the shares that have been issued or may be issued to Fusion Capital under the common stock purchase agreement. The SEC declared the registration statement effective on June 29, 2009.

On the commencement date, July 1, 2009, the Company has the right over a 25-month period to sell shares of its common stock to Fusion Capital from time to time in amounts between \$100,000 and \$4 million, depending on certain conditions as set forth in the agreement, up to an aggregate of \$30.0 million. The number of shares that could be issued to Fusion Capital during each sale is determined based on a stock price ("Purchase Price") that is the lower of the (a) the lowest sale price of common stock on the purchase date or (b) the arithmetic average of the three (3) lowest closing sale prices of common stock during the twelve (12) consecutive business days (ten (10) days in certain circumstances) ending on the business day immediately preceding the purchase date (to be appropriately adjusted for any reorganization, recapitalization, non-cash dividend, stock split or other similar transaction). The Company controls the timing and amount of any sales of shares to Fusion Capital.

Pursuant to the common stock purchase agreement with Fusion Capital, there are certain events of default which, if such an event were to occur, would eliminate the obligation of Fusion Capital to purchase shares from the Company. Such events include, but are not limited to, (i) shares of the Company's common stock not being listed on any one of several stock exchanges outlined in the agreement and (ii) a "material adverse change" in the Company's business or operations. In addition, Fusion Capital shall not have the right or the obligation to purchase any shares of the Company's common stock on any business day that the price of the common stock is below \$0.10. However, pursuant to the common stock purchase agreement, Fusion Capital may not purchase any shares of the Company's stock on any business day that the price of the common stock is below \$0.36 without the approval of the Company's shareholders. The common stock purchase agreement may be terminated by the Company at any time at its discretion without any cost to the Company. There are no negative covenants, restrictions on future fundings, penalties or liquidated damages in the agreement. The proceeds received by the Company under the common stock purchase agreement will be used to conduct operations and to continue to conduct the Company's clinical development programs.

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

In consideration for entering into the agreement, upon execution of the common stock purchase agreement the Company issued 1,452,238 shares of its common stock to Fusion Capital as an initial commitment fee. The Company will also issue from time to time up to an additional 2,420,396 shares to Fusion Capital as a commitment fee pro rata as it receive the \$30.0 million of future funding.

Through September 9, 2009, 10,328,479 shares of the Company's common stock (including 1,714,448 shares related to its commitment fee) were issued to Fusion Capital for net proceeds of \$3,250,000.

***Stock Purchase Warrants***

In October 2007, the Company issued 11,842,105 shares of common stock through a registered direct offering to institutional investors. As part of this transaction, the Company issued warrants to the institutional investors and placement agent, exercisable from April 27, 2008 through April 17, 2013, to purchase up to 5,921,053 shares of common stock at an exercise price of \$1.59 per share. At June 30, 2009, all of these warrants remained outstanding.

In October 2008, warrants to purchase up to 1,838,843 shares of common stock pursuant to previous warrant agreements expired unexercised.

On April 5, 2009, warrants to purchase up to 2,400,000 shares of common stock pursuant to previous warrant agreements expired unexercised.

No cash dividends have been declared or paid by the Company since its Inception.

**5. Income Taxes**

A reconciliation of income taxes computed using the federal statutory rate to the taxes reported in our consolidated statements of operations is as follows (*in thousands*):

	<u>Year Ended June 30,</u>		
	<u>2007</u>	<u>2008</u>	<u>2009</u>
Loss before income taxes . . . . .	\$13,450	\$20,130	\$15,946
Federal statutory rate . . . . .	34%	34%	34%
Taxes computed at federal statutory rate . . . . .	(4,570)	(6,845)	(5,420)
State taxes, net of federal taxes . . . . .	—	—	—
Increase (decrease) in taxes from:			
Stock compensation . . . . .	950	175	79
Other, net . . . . .	(270)	(250)	—
Loss attributable to foreign operations . . . . .	—	630	437
Valuation allowance . . . . .	<u>3,890</u>	<u>6,290</u>	<u>4,904</u>
Reported income taxes . . . . .	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

Deferred tax assets consist of the following (*in thousands*):

	June 30,	
	2008	2009
Net operating loss carryforwards . . . . .	\$ 36,400	\$ 38,265
Research and development credit carryforwards . . . . .	1,600	1,600
Inventories . . . . .	—	—
Property and equipment . . . . .	104	33
Employee benefits . . . . .	276	131
Other, net . . . . .	280	257
Total deferred tax assets . . . . .	38,660	40,286
Valuation allowance . . . . .	(38,660)	(40,286)
Net deferred tax assets . . . . .	\$ —	\$ —

Due to the historical losses incurred by the Company, a full valuation allowance for deferred tax assets has been provided. If the Company achieves profitability, these deferred tax assets may be available to offset future income taxes.

The Company has issued shares of common stock in prior years, which resulted in multiple ownership changes under Section 382 of the Internal Revenue Code. Consequently, the utilization of net operating loss and tax credit carryforwards is significantly limited. Such limitations may result in these carryforwards expiring before the Company utilizes them. At June 30, 2009 the Company estimates the maximum Federal tax net operating loss and tax credit carryforwards, which could be utilized, were \$111,238,000 and \$1,600,000, respectively. If this Federal tax net operating loss carryforward is not utilized, the following amounts will expire: \$5,400,000 by 2012, \$9,000,000 between 2013 and 2018, and \$96,838,000 thereafter. The Company's ability to utilize its net operating loss and tax credit carryforwards may become subject to further annual limitation in the event of future change in ownership events.

The Company has adopted FASB Interpretation No. 48 (FIN 48), "Accounting for Uncertainty for Income Taxes — an interpretation of FASB Statement No. 109." FIN 48 prescribes a recognition threshold and measurement methodology for recording within the financial statements uncertain tax positions taken, or expected to be taken, in tax returns. It also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods and disclosure related to uncertain tax positions. As of June 30, 2009, the Company has no unrecognized tax benefits as defined in FIN 48.

The Company files U.S. Federal and State income tax returns. Due to the Company's net operating loss carryforwards, Federal income tax returns from incorporation are still subject to examination. In addition, open tax years related to state jurisdictions remain subject to examination.

The Company is also subject to the rules governing the limitation on net operating loss carryforwards. The Company has not conducted a detailed analysis of the application of these rules to the existing net operating losses but has estimated the impact of these rules in determining the Company's available net operating losses. The losses have been fully reserved along with all deferred tax assets as the Company does not believe that it is more likely than not that it will be able to utilize these attributes.

**6. Licenses, Royalties and Collaborative Agreements and Commitments**

*University of Michigan* — In August 1989, the Company entered into a research agreement with the University of Michigan (the University). In March 1992, and as provided for under the research agreement, the Company also entered into a license agreement for the technology developed under the research agreement. The

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

license agreement, as amended, provides for a royalty to be paid to the University equal to 2% of net sales of products containing the licensed technology sold by the Company. Such royalties have been nominal since Inception.

*Corning Incorporated* — In December 2002, the Company entered into an agreement with Corning Incorporated that granted them an exclusive sublicense relating to the Company’s cell transfection technology. Under the terms of the agreement, the Company retains exclusive rights to the applications of the technologies involving cells for therapeutic applications. In addition, the agreement provides for future royalty payments on net sales of licensed products sold under the sublicense amounting to 5% of such sales up to \$50 million. However, the Company does not expect to receive material revenue from this source for several years, if ever.

*Manufacture, Supply and Other Agreements* — The Company has entered into various agreements relating to the manufacture of its products and the supply of certain components. If the manufacturing or supply agreements expire or are otherwise terminated, the Company may not be able to identify and obtain ancillary materials that are necessary to develop its product and such expiration and termination could have a material affect on the Company’s business.

**7. Commitments, Contingencies and Debt**

During 2007 the Company entered into a new lease with Domino’s Farms Office Park, LLC, for approximately 30,000 square feet. This lease has a noncancelable term of six years, beginning on May 14, 2007, and has two five-year market value renewals that the Company, at its option, can exercise six months prior to May 14, 2018 and May 14, 2023. The Company’s leased facility includes a Class 100,000 modular manufacturing clean room, laboratories and office space. The Company obtained seller-financing from the landlord in the amount of \$834,000 for the purchase of leasehold improvements. This debt obligation to the landlord is payable over a four-year period at a 7.0% rate of interest. The lease also provides the Company the right of first refusal on certain additional space.

In June 2007, the Company entered into a loan with Key Equipment Finance Inc. in the amount of \$751,000, payable over 36 months at a 7.24% fixed interest rate. The proceeds of the loan were used to purchase property and equipment. This loan is collateralized by manufacturing equipment, laboratory equipment and furniture acquired for the Company’s new leased facility and by a restricted compensating cash balance held by the lender. The compensating balance that we are required to maintain declines ratably over the term of the loan and equaled approximately \$278,000 at June 30, 2009, which is recorded as a component of other current assets.

As of June 30, 2009, future minimum payments related to our operating leases and long-term debt is as follows (*in thousands*):

<u>Year Ending June 30,</u>	<u>Operating Leases</u>	<u>Debt</u>
2010 .....	\$1,102	\$479
2011 .....	1,126	225
2012 .....	1,153	79
2013 .....	<u>979</u>	<u>—</u>
Total .....	<u>\$4,360</u>	<u>\$783</u>

Rent expense for the years ended June 30, 2007, 2008 and 2009, was \$679,000, \$1,107,000 and \$1,153,000, respectively, and \$9,270,000 for the period from Inception to June 30, 2008.

In 2005, the Company entered into amended agreements with several employees that would result in a cash payment to these employees upon a change-in-control event. The Company does not believe a change-in-control event is probable at this time but if one were to take place, the maximum total cash payout would be \$1.5 million.

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

**8. Employee Savings Plan**

The Company has a 401(k) savings plan that allows participating employees to contribute up to 15% of their salary, subject to annual limits and minimum qualifications. The Board may, at its sole discretion, approve Company matching contributions to the plan. The Company has made contributions of \$172,000, \$217,000 and \$195,000 for the years ended June 30, 2007, 2008 and 2009, respectively and \$1,257,000 for the period from Inception to June 30, 2009.

**9. Quarterly Financial Data (Unaudited) (In thousands, except per share data):**

<u>Year Ended June 30, 2009</u>	<u>First Quarter</u>	<u>Second Quarter</u>	<u>Third Quarter</u>	<u>Fourth Quarter</u>	<u>Fiscal Year</u>
Revenues . . . . .	\$ 27	\$ 28	\$ 58	\$ 69	\$ 182
Loss from operations . . . . .	(4,019)	(4,152)	(4,012)	(3,986)	(16,169)
Net loss . . . . .	(3,913)	(4,103)	(3,972)	(3,958)	(15,946)
Net loss per common share . . . . .	(.03)	(.03)	(.03)	(.03)	(.11)
<u>Year Ended June 30, 2008</u>	<u>First Quarter</u>	<u>Second Quarter</u>	<u>Third Quarter</u>	<u>Fourth Quarter</u>	<u>Fiscal Year</u>
Revenues . . . . .	\$ 87	\$ 84	\$ 202	\$ 149	\$ 522
Loss from operations . . . . .	(5,400)	(5,537)	(5,289)	(4,993)	(21,219)
Net loss . . . . .	(5,050)	(5,172)	(5,048)	(4,863)	(20,133)
Net loss per common share . . . . .	(.04)	(.04)	(.04)	(.04)	(.16)

The summation of quarterly earnings per share computations may not equate to the year-end computation as the quarterly computations are performed on a discrete basis.

## **Item 9. *Changes in and Disagreements with Accountants on Accounting and Financial Disclosure***

There are none to report.

### **Item 9A. *Controls and Procedures***

#### **Disclosure Controls and Procedures**

The Company conducted an evaluation, under the supervision and with the participation of management, including the Chief Executive Officer/Chief Financial Officer (“CEO/CFO”), who currently is the same individual, of the effectiveness of the design and operation of the Company’s disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Securities and Exchange Act of 1934, as amended (the “Exchange Act”). Based on that evaluation, the CEO/CFO has concluded that the Company’s disclosure controls and procedures were effective as of June 30, 2009, to ensure that information related to the Company required to be disclosed in reports the Company files or submits under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms, and (ii) accumulated and communicated to the Company’s management, including the CEO/CFO, to allow timely decisions regarding required disclosure. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that the Company’s disclosure controls and procedures will detect or uncover every situation involving the failure of persons within the Company to disclose material information otherwise required to be set forth in the Company’s periodic reports; however, the Company’s disclosure controls are designed to provide reasonable assurance that they will achieve their objective of timely alerting the CEO/CFO to the information relating to the Company required to be disclosed in the Company’s periodic reports required to be filed with the SEC.

#### **Management’s Report on Internal Control over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a — 15(f) under the Exchange Act). Our internal control over financial reporting is a process designed under the supervision of our CEO/CFO to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America. Management evaluated the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control — Integrated Framework. Management, under the supervision and with the participation of the Company’s CEO/CFO, assessed the effectiveness of our internal control over financial reporting as of June 30, 2009 and concluded that it was effective.

Our independent registered public accounting firm, PricewaterhouseCoopers LLP, has audited the effectiveness of our internal control over financial reporting as of June 30, 2009, and has expressed an unqualified opinion thereon in their report which appears under Item 8.

#### **Changes in Internal Control over Financial Reporting**

During our fourth quarter of fiscal 2009, there were no changes made in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) occurred that have materially affected, or are reasonably likely to materially affect, the Company’s internal control over financial reporting.

### **Item 9B. *Other Information***

#### **Shareholder Proposals to be Presented at Next Annual Meeting**

Under the Company’s bylaws, in order for business to be properly brought before a meeting by a shareholder, such shareholder must have given timely notice thereof in writing to the Corporate Secretary of Aastrom. To be timely, such notice must be received at Aastrom’s principal executive offices not less than 120 calendar days in



advance of the one year anniversary of the date Aastrom's proxy statement was released to shareholders in connection with the previous year's Annual Meeting of Shareholders, except that (i) if no Annual Meeting was held in the previous year, (ii) if the date of the annual meeting has been changed by more than thirty calendar days from the date contemplated at the time of the previous year's proxy statement or (iii) in the event of a special meeting, then notice must be received not later than the close of business on the tenth day following the day on which notice of the date of the meeting was mailed or public disclosure of the meeting date was made.

Proposals of shareholders intended to be presented at the next annual meeting of the shareholders of Aastrom must be received by Aastrom at its offices at 24 Frank Lloyd Wright Drive, Lobby K, Ann Arbor, Michigan 48105, no later than September 14, 2009. Such shareholder proposals may also be included in Aastrom's proxy statement if they also satisfy the conditions established by the Securities and Exchange Commission for such inclusion.

### **PART III**

Certain information required by Part III is omitted from this Report, and is incorporated by reference to our definitive Proxy Statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A in connection with our 2009 Annual Meeting of Shareholders scheduled for December 14, 2009.

#### **Item 10. *Directors, Executive Officers and Corporate Governance***

The information relating to our directors is incorporated by reference to the Proxy Statement as set forth under the caption "Election of Directors." Information relating to our executive officers is set forth in Part I of this Report under the caption "Executive Officers of Aastrom."

Information with respect to delinquent filings pursuant to Item 405 of Regulation S-K is incorporated by reference to the Proxy Statement as set forth under the caption "Section 16(a) Beneficial Ownership Reporting Compliance."

#### **Item 11. *Executive Compensation***

The information relating to executive compensation is incorporated by reference to the Proxy Statement under the caption "Executive Compensation and Other Matters."

#### **Item 12. *Security Ownership of Certain Beneficial Owners and Management, and Related Shareholder Matters***

The information relating to ownership of our equity securities by certain beneficial owners and management is incorporated by reference to the Proxy Statement as set forth under the caption "Stock Ownership of Certain Beneficial Owners and Management."

#### **Item 13. *Certain Relationships and Related Transactions, and Director Independence***

The information relating to certain relationships and related person transactions is incorporated by reference to the Proxy Statement under the captions "Certain Transactions" and "Compensation Committee Interlocks and Insider Participation in Compensation Decisions."

#### **Item 14. *Principal Accountant Fees and Services***

The information relating to principal accountant fees and services is incorporated by reference to the Proxy Statement under the caption "Ratification of Appointment of Independent Registered Public Accounting Firm."

## PART IV

### **Item 15. *Exhibits and Financial Statement Schedules***

(a) The following documents are filed as part of this Report:

1. Financial Statements (see Item 8).
2. All information is included in the Financial Statements or Notes thereto.
3. Exhibits:

See Exhibit Index.

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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.

/s/ GEORGE W. DUNBAR, JR.

George W. Dunbar, Jr.  
*President and Chief Executive Officer*  
*(Principal Executive Officer)*  
*Chief Financial Officer*  
*(Principal Financial and Accounting Officer)*

Date: September 14, 2009

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below on September 14, 2009 by the following persons in the capacities indicated.

<u>Signature</u>	<u>Title</u>
<u>/s/ GEORGE W. DUNBAR, JR.</u> George W. Dunbar, Jr.	<i>President and Chief Executive Officer</i> <i>(Principal Executive Officer)</i> <i>Chief Financial Officer</i> <i>(Principal Financial and Accounting Officer)</i>
<u>/s/ NELSON M. SIMS</u> Nelson M. Sims	Chairman
<u>/s/ TIMOTHY M. MAYLEBEN</u> Timothy M. Mayleben	Director
<u>/s/ ALAN L. RUBINO</u> Alan L. Rubino	Director
<u>/s/ STEPHEN G. SUDOVAR</u> Stephen G. Sudovar	Director
<u>/s/ ROBERT L. ZERBE, M.D.</u> Robert L. Zerbe, M.D.	Director

## **EXHIBIT INDEX**

<u>Exhibit No.</u>	<u>Description</u>
3.1	Restated Articles of Incorporation of Aastrom, as amended, attached as Exhibit 4.1 to Aastrom's Current Report on Form 8-K filed on October 23, 2008, incorporated herein by reference.
3.2	Bylaws, as amended, attached as Exhibit 4.2 to Aastrom's Current Report on Form 8-K filed on October 23, 2008, incorporated herein by reference
10.1#	Form of Indemnification Agreement, attached as Exhibit 10.1 to Aastrom's Registration Statement on Form S-1 (No. 333-15415), filed on November 1, 1996, incorporated herein by reference.
10.2#	Amended and Restated 1992 Incentive and Non-Qualified Stock Option Plan and forms of agreements thereunder, attached as Exhibit 10.5 to Aastrom's Registration Statement on Form S-1 (No. 333-15415), filed on November 1, 1996, incorporated herein by reference.
10.3#	Form of Employment Agreement, attached as Exhibit 10.8 to Aastrom's Registration Statement on Form S-1 (No. 333-15415), filed on November 1, 1996, incorporated herein by reference.
10.4	License Agreement, dated July 17, 1992, between J.G. Cremonese and Aastrom and related addenda thereto dated July 14, 1992 and July 7, 1993, attached as Exhibit 10.11 to Aastrom's Registration Statement on Form S-1 (No. 333-15415), filed on November 1, 1996, incorporated herein by reference.
10.5	License Agreement, dated March 13, 1992, between Aastrom and the University of Michigan and amendments thereto dated March 13, 1992, October 8, 1993 and June 21, 1995, attached as Exhibit 10.17 to Aastrom's Registration Statement on Form S-1 (No. 333-15415), filed on November 1, 1996, incorporated herein by reference.
10.6#	Aastrom Biosciences 2001 Stock Option Plan, attached as Exhibit 10.72 to Aastrom's Annual Report on Form 10-K for the year ended June 30, 2002, incorporated herein by reference.
10.7	Master Supply Agreement with Spartan Corporation (formerly Astro Instrumentation, LLC), attached as Exhibit 10.76 to Aastrom's Annual Report on Form 10-K for the year ended June 30, 2003, incorporated herein by reference.
10.8	Supply Agreement between Aastrom and Moll Industries, Inc., dated December 16, 2003, attached as Exhibit 10.77 to Aastrom's Annual Report on Form 10-K for the year ended June 30, 2004, incorporated herein by reference.
10.9#	2004 Equity Incentive Plan, attached as Exhibit 10.82 to Amendment No. 1 to Aastrom's Quarterly Report on Form 10-Q/A for the quarter ended September 30, 2004, incorporated herein by reference.
10.10#	Form of Option and Restricted Stock Award Agreements for Grants under 2004 Equity Incentive Plan, attached as Exhibit 10.84 to Aastrom's Annual Report on Form 10-K for the year ended June 30, 2005, incorporated herein by reference.
10.11#	Employee Compensation Guidelines, attached as Exhibit 10.85 to Aastrom's Annual Report on Form 10-K for the year ended June 20, 2005, incorporated herein by reference.
10.12	Amendment dated December 5, 2002 to License Agreement with the University of Michigan, attached as Exhibit 10.87 to Aastrom's Annual Report on Form 10-K for the year ended June 30, 2005, incorporated herein by reference.
10.13#	Employment Agreement with George W. Dunbar dated July 17, 2006, attached as Exhibit 99.1 to Aastrom's Current Report on Form 8-K filed on July 18, 2006, incorporated herein by reference.
10.14#	Summary of Changes to Employee Compensation Guidelines, attached as Exhibit 10.94 to Aastrom's Quarterly Report on Form 10-Q for the quarter ended December 31, 2006, incorporated herein by reference.
10.15#	2004 Equity Incentive Plan, as amended, attached as Exhibit 99.1 to Aastrom's Current Report on Form 8-K filed on November 8, 2006, incorporated herein by reference.
10.16#	Forms of Grant Notice and Stock Option Agreement for Grants under 2004 Equity Incentive Plan, as amended, attached as Exhibit 99.2 to Aastrom's Current Report on Form 8-K filed on November 8, 2006, incorporated herein by reference.
10.17	Placement Agency Agreement, dated October 15, 2007, by and between the Company and BMO Capital Markets Corp., attached as Exhibit 10.1 to Aastrom's Current Report on Form 8-K filed on October 16, 2007, incorporated herein by reference.

<u>Exhibit No.</u>	<u>Description</u>
10.18	Escrow Agreement, dated as of October 15, 2007, among the Company, BMO Capital Markets Corp. and The Bank of New York, attached as Exhibit 10.2 to Aastrom's Current Report on Form 8-K filed on October 16, 2007, incorporated herein by reference.
10.19	Form of Purchase Agreement, attached as Exhibit 10.3 to Aastrom's Current Report on Form 8-K filed on October 16, 2007, incorporated herein by reference.
10.20	Form of Warrant, attached as Exhibit 10.2 to Aastrom's Current Report on Form 8-K filed on October 16, 2007, incorporated herein by reference.
10.21	Standard Lease between Aastrom and Domino's Farms Office Park, L.L.C. dated January 31, 2007., attached as Exhibit 10.96 to Amendment No. 1 to Aastrom's Annual Report on Form 10-K for the year ended June 30, 2007, incorporated herein by reference.
10.22#	Nonemployee Director Compensation Guidelines, attached as Exhibit 10.98 to Aastrom's Quarterly Report on Form 10-Q for the quarter ended March 31, 2008, incorporated herein by reference.
10.23#	Amendment to Employment Agreement, dated March 10, 2008, between Aastrom Biosciences, Inc. and Gerald D. Brennan, Jr., attached as Exhibit 10.99 to Aastrom's Quarterly Report on Form 10-Q for the quarter ended March 31, 2008, incorporated herein by reference.
10.24	Common Stock Purchase Agreement, dated October 27, 2008, between Aastrom Biosciences, Inc. and Fusion Capital Fund II, LLC, attached as Exhibit 10.1 to Aastrom's Current Report on Form 8-K filed on October 29, 2008, incorporated herein by reference.
10.25	Registration Rights Agreement, dated October 27, 2008, between Aastrom Biosciences, Inc. and Fusion Capital Fund II, LLC, attached as Exhibit 10.2 to Aastrom's Current Report on Form 8-K filed on October 29, 2008, incorporated herein by reference.
10.26	Common Stock Purchase Agreement, dated June 12, 2009, between Aastrom Biosciences, Inc. and Fusion Capital Fund II, LLC, attached as Exhibit 10.1 to Aastrom's Current Report on Form 8-K filed on June 12, 2009, incorporated herein by reference.
10.27	Registration Rights Agreement, dated June 12, 2009, between Aastrom Biosciences, Inc. and Fusion Capital Fund II, LLC, attached as Exhibit 10.2 to Aastrom's Current Report on Form 8-K filed on June 12, 2009, incorporated herein by reference.
21	Subsidiaries of Registrant.
23.1	Consent of Independent Registered Public Accounting Firm.
31.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

# Management contract or compensatory plan or arrangement covering executive officers or directors of Aastrom.

## GLOSSARY

<u>Term</u>	<u>Definition</u>
Adult Stem Cell . . . . .	A cell present in adults that can generate a limited range of cell types as well as renew itself.
Adverse Event . . . . .	Any adverse change in health or “side-effect” that occurs in a person participating in a clinical trial, from the time they consent to joining the trial until a pre-specified period of time after their treatment has been completed.
AEMPS — Agencia Española de Medicamentos y Productos Sanitarios . . . . .	Spanish Drug Agency
Allogeneic . . . . .	Originating from someone other than the patient receiving treatment. (Aastrom does NOT use allogeneic cells)
ATMP — Advanced Therapy Medicinal Product . . . . .	New medical products in the European Union based on genes (gene therapy), cells (cell therapy) and tissues (tissue engineering).
Autologous . . . . .	Originating from the patient receiving treatment. (Aastrom uses only autologous cells)
BLA — Biologics License Application . . . . .	An application containing product safety, efficacy and manufacturing information required by the FDA to market biologics products in the U.S (equivalent to NDA)
BRC — Bone Repair Cell . . . . .	Aastrom’s proprietary Tissue Repair Cells for bone indications. (Also see TRC — Tissue Repair Cell)
CBER — Center for Biologics Evaluation and Research . . . . .	Branch of the FDA that regulates biological products for disease prevention and treatment that are inherently more complex than chemically synthesized pharmaceuticals.
CLI — Critical Limb Ischemia . . . . .	A vascular disease characterized by insufficient blood flow in the lower extremities that causes severe pain, tissue loss or both.
Controlled Clinical Trial . . . . .	A clinical study that compares patients receiving a specific treatment to patients receiving an alternate treatment for the condition of interest. The alternate treatment may be another active treatment, standard of care for the condition and/or a placebo (inactive) treatment.
CRC — Cardiac Repair Cell . . . . .	Aastrom’s proprietary Tissue Repair Cells for cardiac indications. (Also see TRC — Tissue Repair Cell)
DCM — Dilated Cardiomyopathy . . . . .	A chronic cardiac disease where expansion of the patient’s heart reduces the pumping function to a point that the normal circulation of blood cannot be maintained.
Double-Blind Clinical Trial . . . . .	Clinical trials in which neither the patient nor the physician know if the patient received the experimental treatment or a control/placebo.

<u>Term</u>	<u>Definition</u>
EMEA — European Medicines Agency . . . . .	European Union body responsible for coordinating the existing scientific resources put at its disposal by Member States for the evaluation, supervision and pharmacovigilance of medicinal products. The Agency provides the Member States and the institutions of the EU the best-possible scientific advice on any question relating to the evaluation of the quality, safety and efficacy of medicinal products for human or veterinary use referred to it in accordance with the provisions of EU legislation relating to medicinal products. EMEA is similar in function to the US FDA (see FDA below).
EU — European Union . . . . .	The economic and political union of 27 member states, located primarily in Europe, for which the EMEA holds the medical regulatory power.
<i>Ex vivo</i> . . . . .	Outside the body
FDA — Food & Drug Administration. . . . .	The U.S. FDA ensures that medicines, medical devices, and radiation-emitting consumer products are safe and effective. Authorized by Congress to enforce the Federal Food, Drug, and Cosmetic Act and several other public health laws, the agency monitors the manufacture, import, transport, storage, and sale of \$1 trillion worth of goods annually.
GMP — Good Manufacturing Practice . . . . .	GMP regulations require that manufacturers, processors, and packagers of drugs, medical devices, some food, and blood take proactive steps to ensure that their products are safe, pure, and effective. GMP regulations require a quality approach to manufacturing, enabling companies to minimize or eliminate instances of contamination, mix-ups, and errors.
GTP — Good Tissue Practice. . . . .	GTP regulations help ensure that donors of human cellular and tissue-based products are free of communicable diseases and that the cells and tissues are not contaminated during manufacturing and maintain their integrity and function. Key elements of the proposed rule are: Establishment of a quality program, which would evaluate all aspects of the firm’s operations, to ensure compliance with GTP; Maintenance of an adequate organizational structure and sufficient personnel; Establishment of standard operating procedures for all significant steps in manufacturing; Maintenance of facilities, equipment and the environment; Control and validation of manufacturing processes; Provisions for adequate and appropriate storage; Record keeping and management; Maintenance of a complaint file; Procedures for tracking the product from donor to recipient, and from recipient to donor.
Hematopoietic Stem Cells . . . . .	Stem cells that give rise to all the blood cell types including myeloid (monocytes and macrophages, neutrophils, basophils, eosinophils, erythrocytes, megakaryocytes/platelets, dendritic cells), and lymphoid lineages (T-cells, B-cells, NK-cells).



<u>Term</u>	<u>Definition</u>
IMPACT-DCM . . . . .	Aastrom’s U.S. Phase II dilated cardiomyopathy clinical trial.
IMPD — Investigational Medicinal Product Dossier . . . . .	An IMPD is now required to accompany an application to perform clinical trials in any European Member State. It provides a summary of information on the quality of the product being evaluated in a clinical trial planned to occur in a European Member State, including reference products and placebos. It also provides data from non-clinical studies and available previous clinical experience with the use of the investigational medicinal product.
<i>In vitro</i> . . . . .	In a laboratory dish or test tube; in an artificial environment
IND — Investigational New Drug . . . . .	An application submitted to the FDA for a new drug or biologic that, if allowed, will be used in a clinical trial.
IRB — Institutional Review Board . . . . .	A committee designated to formally approve, monitor, and review biomedical research at an institution involving humans. Institutional Review Boards aim to protect the rights and welfare of the research subjects. For Aastrom-sponsored clinical trials, IRB approval must be obtained at each individual clinical site in order for patient recruitment and treatment to commence at that site.
LVEF — Left Ventricular Ejection Fraction . . . . .	The fraction of blood pumped out of the left ventricle with each heart beat.
Non-union Fractures . . . . .	Broken bones that have failed to unite and heal
NRC — Neural Repair Cell . . . . .	Aastrom’s proprietary Tissue Repair Cells for Neural indications (Also see TRC — Tissue Repair Cell)
ON — Osteonecrosis . . . . .	A progressive bone disease characterized by death of bony tissue due to insufficient blood flow within the bone.
ON-CORE . . . . .	Aastrom’s U.S. Phase III osteonecrosis of the femoral head clinical trial
Open-label Clinical Trial . . . . .	A trial in which both the treating physician and the patient know whether they are receiving the experimental treatment or control/placebo treatment.
Orphan Drug Designation . . . . .	“Orphan drug” refers to a drug or biologic that is intended for use in the treatment of a rare disease or condition. Orphan drug designation from the U.S. Food and Drug Association (FDA) qualifies the sponsor to receive certain benefits from the Government in exchange for developing the drug for a rare disease or condition. The drug must then go through the FDA marketing approval process like any other drug or biologic which evaluates for safety and efficacy. Usually a sponsor receives a quicker review time and lower application fees for an orphan product.
Osteoblast . . . . .	A bone forming cell
Phase I Clinical Trial . . . . .	A Phase I trial represents an initial study in a small group of patients to test for safety and other relevant factors
Phase II Clinical Trial . . . . .	A Phase II trial represents a study in a moderate number of patients to assess the safety and efficacy of a product

<u>Term</u>	<u>Definition</u>
Phase IIb Clinical Trial . . . . .	A Phase IIb trial is a moderately-sized Phase II study that is more specifically designed assess the efficacy of a product than a Phase IIa trial
Phase III Clinical Trial . . . . .	Phase III studies are initiated to establish safety and efficacy in an expanded patient population at multiple clinical study sites and are generally larger than trials in earlier phases of development.
Progenitor Cells . . . . .	A “parent” cell that gives rise to a distinct cell lineage by a series of cell divisions.
Prospective Clinical Trial. . . . .	A clinical trial in which participants are identified and then followed for a period of time during and after the conclusion of a clinical trial.
Randomized Clinical Trial . . . . .	A clinical trial in which the participants are assigned randomly to different treatment groups.
Somatic Cell . . . . .	Any of the cells responsible for forming the body of an organism such as internal organs, bones, skin, connective tissues and blood.
SPP — Single-Pass Perfusion . . . . .	SPP is Aastrom’s proprietary technology that controls gas and cell culture media exchange to enable the replication of early-stage stem and progenitor cells while preventing their differentiation into mature cells.
Standard of care treatment . . . . .	The treatment normally prescribed in medical practice for a particular illness, injury or procedure.
Stem Cell . . . . .	<p>Unspecialized (undifferentiated) cells that retain the ability to divide throughout a lifetime and give rise to more specialized (differentiated) cells which take the place of cells that die or are lost.</p> <p>In culture, these undifferentiated cells possess the ability to divide for indefinite periods in culture and may give rise to highly specialized cells.</p>
TRC — Tissue Repair Cell . . . . .	Aastrom’s cell manufacturing process begins with the collection of a small aspirate of bone marrow from the patient’s hip in an outpatient procedure. The sample of bone marrow is shipped to a manufacturing facility, and transferred into Aastrom’s cell manufacturing system. In this fully automated, sterile process, the stem and progenitor cell populations present in the bone marrow are greatly expanded to yield cellular products based on Aastrom’s Tissue Repair Cell (TRC) technology. The finished TRC-based product is shipped back to the physician who administers it to the original patient as an autologous cell therapy.
VRC — Vascular Repair Cell . . . . .	Aastrom’s proprietary Tissue Repair Cells for Vascular indications. (Also see TRC — Tissue Repair Cell)

## SHAREHOLDER INFORMATION

### Annual Shareholders' Meeting

Monday, December 14, 2009  
4:00 pm (EST)  
Aastrom Biosciences, Inc.  
Domino's Farms, Lobby K  
24 Frank Lloyd Wright Drive  
Ann Arbor, MI 48105  
Phone: (734) 930-5555

### Market for Registrant's Common Stock

Aastrom Biosciences, Inc. Common Stock is traded on the Nasdaq Stock Market under the symbol ASTM.

### Auditors

PricewaterhouseCoopers LLP  
1900 St. Antoine Street  
Detroit, MI 48226-2263  
Phone: (313) 394-6000

### Registrar and Transfer Agent

Continental Stock Transfer & Trust Company  
17 Battery Place, 8th Floor  
New York, NY 10004  
Website: [www.continentalstock.com](http://www.continentalstock.com)  
Phone: (212) 509-4000

### Company Information

For information regarding Aastrom Biosciences, Inc., please visit our website at [www.aastrom.com](http://www.aastrom.com).

Additional information is available at [www.nasdaq.com](http://www.nasdaq.com).

### Investor Relations

General shareholder inquiries, including requests for the Company's Annual Report on Form 10-K should be directed to:

Investor Relations Department  
Aastrom Biosciences, Inc.  
P.O. Box 376  
Ann Arbor, MI 48106  
Phone: (734) 930-5777  
Fax: (734) 665-0485  
Email: [mail@aastrom.com](mailto:mail@aastrom.com)

### General Counsel

Seyfarth Shaw LLP  
131 South Dearborn, Suite 2400  
Chicago, IL 60603-5577  
Phone: (312) 460-5000

### Cover Photos:

- #2 – Analysis of Tissue Repair Cells (TRCs) by flow cytometry
- #3 – Loading cassette into incubator for TRC manufacturing
- #4 – Microscopic evaluation of TRCs
- #5 – Preparation of cells for TRC manufacturing
- #6 – Initiation of application key with patient-specific information

- Annual Report cover design and artwork by Cheri Gearhart of Gearhart Design
- Cover Photos courtesy of Phil Groatorex of Phil Groatorex Photography



# Aastrom

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