# 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, 2008

or

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

For the transition period from

to

Commission File Number 0-22025

# **Aastrom Biosciences, Inc.**

(Exact name of registrant as specified in its charter,

Michigan

(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 Registe

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 o 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 o 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  $\square$  No o

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.  $\square$ 

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 - 

Smaller reporting company - 

Output

Description:

(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 o 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, 2007 was approximately \$69 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 July 31, 2008, 132,860,282 shares of Common Stock, no par value, were outstanding.

# DOCUMENTS INCORPORATED BY REFERENCE

Proxy Statement for the Annual Meeting of Shareholders scheduled for October 17, 2008

Document

Items 10, 11, 12, 13 and 14 of

Form 10-K Reference

Part III

# AASTROM BIOSCIENCES, INC.

# ANNUAL REPORT ON FORM 10-K

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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 focused 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, bone and neural. TRC-based products have been used in over 290 patients, and are currently in the following stages of development:

- Cardiac regeneration Cardiac Repair Cells (CRCs):
  - Dilated cardiomyopathy (DCM) (severe chronic disease of the heart):
    - U.S.: IMPACT-DCM Phase II clinical trial initiating clinical sites; patient treatments expected to begin in September 2008;
       Orphan Drug Designation from the FDA for use in the treatment of DCM
    - · Germany: Encouraging data reported in April 2008 from compassionate use treatment in patients; clinical activity is ongoing
- Vascular regeneration Vascular Repair Cells (VRCs):
  - Critical limb ischemia (CLI):
    - U.S.: RESTORE-CLI Phase IIb clinical trial enrolling patients
    - Germany: Phase I/II clinical trial has completed enrollment and patient follow-up is ongoing; positive interim data reported in October 2007
- Bone regeneration Bone Repair Cells (BRCs):
  - · Osteonecrosis of the femoral head:
    - · U.S.: ON-CORE Phase III clinical trial active, but not enrolling additional patients; Orphan Drug Designation from
    - the FDA for use in the treatment of osteonecrosis of the femoral head
    - · Spain: Pivotal clinical trial enrolling patients
    - Germany: Positive data reported in October 2007 from compassionate use treatment cases
  - · Non-union fractures:
    - U.S.: Positive 12 month results from Phase I/II clinical trial reported by investigator in October 2007
    - Spain: 24 month follow-up continuing on fully-enrolled 10-patient Phase II clinical trial

- Neural regeneration Neural Repair Cells (NRCs):
  - · Spinal cord injury:
    - Plans for clinical program under development

Our platform TRC technology is based on:

- 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
- The means to produce these products in an automated process.

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 cell component 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 in Ann Arbor, MI and three contract facilities in the EU located in Stuttgart, Germany (Fraunhofer Institute for Interfacial Engineering and Biotechnology), Bad Oeynhausen, Germany (Institute of Laboratory and Transfusion Medicine at the Heart Center) and Barcelona, Spain (Tissue and Cell Therapy Center at the Blood and Tissue Bank).

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. 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.

Our current focus is 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 primarily focus 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 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 the 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 obtaining required capital in a similar manner. As a development stage company, we have never been profitable and do not anticipate having net income unless and until significant product sales commence. 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, 2008, we have accumulated a net loss of approximately \$179 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.

#### **Clinical Development**

Currently, our clinical development programs are primarily focused on the utilization of our TRC technology for cardiac regeneration, as well as vascular regeneration. 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 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) 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.

It should be noted that 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

In June 2008, we announced plans to initiate a 40 patient U.S. Phase II clinical trial (called IMPACT-DCM) to study 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, after the U.S. Food & Drug Administration (FDA) approved our Investigational New Drug (IND) application. This randomized, controlled, prospective, open-label, Phase II study will seek to enroll 20 patients with ischemic DCM and 20 patients with non-ischemic DCM at up to 5 clinical sites in the U.S. Participants must have a left ventricular ejection fraction 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 left ventricular ejection fraction and other cardiac function parameters as well as heart failure stage will be monitored. Patients will be followed for 12 months post treatment.

The clinical sites have been identified and currently have completed various steps necessary to begin patient enrollment, including clinical trial agreements, Investigational Review Board (IRB) review and approval, and clinical site training. As clinical sites open for patient enrollment our website will be updated. It is anticipated that patient treatments in the IMPACT-DCM trial will begin in September 2008.

CRCs, manufactured using Aastrom's TRC technology, received an Orphan Drug Designation from the FDA for the treatment of DCM in February 2007.

In April 2008, we reported data from the first two compassionate use patients treated with our autologous stem cell therapy for DCM. An investigator 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 two patients late in 2007. The data from these two critically ill patients was encouraging, therefore additional compassionate use patients are being evaluated for this treatment. Compassionate use patient treatments will provide additional clinical experience that will assist in the development of future clinical protocols and the improvement of the patient treatment process.

DCM is a chronic cardiac disease that leads to enlargement of the heart and is associated with the reduced pump function to a 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 often represents the end stage of chronic ischemic heart disease in patients who have experienced multiple heart attacks. Patient prognosis depends on the stage of the disease but is characterized by a high mortality rate. Other than heart transplantation, there are 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 the results of 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).

In April 2007, we opened patient 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 critical limb ischemia, the end stage of peripheral arterial disease. This study is allowed to enroll up to 150 patients at up to 30 sites, randomized into two patient groups, to evaluate the safety and efficacy of VRCs in the treatment of critical limb ischemia. Currently, 20 clinical sites have been initiated, and our website will be updated as sites are open for patient enrollment. Patients will be followed for a period of twelve months post-treatment. Twelve months after the 30th patient treatment, we will unblind and analyze the clinical data. In addition to assessing the safety of the VRCs, secondary objectives include assessing major amputation rates, wound healing and blood flow in the affected limbs, patient quality of life, pain scores and analgesic use. Patient enrollment began in June 2007 when the first patient was randomized and treated.

In October 2007, positive interim results from the first 13 patients treated 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. All 30 patients have been enrolled and patient follow-up is ongoing.

#### **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. 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.

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. Six clinical sites have been initiated; however, while 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. This trial may enroll up to 120 patients, randomized into two patient groups, at up to 20 clinical sites. The primary efficacy endpoint of this trial is to delay disease progression to a more severe stage in patients treated with BRCs as assessed during the 24 months post-treatment follow-up period. Disease progression will be measured by third party review of X-ray and MRI results conducted by an individual naïve to whether the patient was in the control or treatment group. We intend this to be a pivotal trial with the goal of demonstrating clinical safety and efficacy for the submission of a Biologics License Application (BLA); however, we do not anticipate reactivating clinical bone activity without additional financial resources. We may have to provide or generate further patient data to support a U.S. BLA submission. 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 four 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. 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. 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.

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 ongoing with 7 of 10 planned patients currently treated. All patients will be followed for 24 months post-treatment.

# Other Bone

In October 2007, positive 12 month results from our U.S. Phase I/II clinical trial for the treatment of severe long bone non-union fractures were reported at the Orthopedic Trauma Association Annual Meeting in Boston, MA by the lead clinical investigator. In the study, patients with non-union tibia, humerus or femur fractures that had failed to heal after one or more medical procedures (average 1.75) showed an overall healing rate of 91% after one year. Overall, 34 patients completed the six month post-treatment follow-up and 33 completed the 12 month follow-up. The 33 patients followed for 12 months showed an overall healing rate of 91%, as determined by bone bridging observed with radiographic imaging or computed tomography. Results showed healing in 91% (21 of 23) of tibia fractures, 100% (3 of 3) of humerus fractures, and 86% (6 of 7) of femur fractures. In addition to the 91% healing rate observed after 12 months, results at six months showed that early bone bridging successfully occurred in 85% (29 of 34) of patients and that signs of early healing (callus formation) were present in 97% (33 of 34) of patients. Three patients failed to complete the required follow-up visits. Though final data could not be collected from these three patients, two showed healing by 18 weeks. No cell-related adverse events were reported. The following centers participated in the multicenter, prospective, open-label clinical trial: Lutheran General Hospital,

Park Ridge, IL; the University of Michigan Health System, Ann Arbor, MI; William Beaumont Hospital, Royal Oak, MI; and Lutheran Medical Center, Brooklyn, NY.

An initial five patient bone regeneration study was conducted at three centers in Spain under Ethical Committee approval; positive results were disclosed in May 2005. Following this trial, a ten patient Phase II non-union fracture trial was initiated. The Phase II study has completed enrollment and BRC treatment of all ten patients, and we are continuing the specified 24 months follow-up of these patients.

A Phase I/II spine fusion clinical trial is currently open at William Beaumont Hospital, Royal Oak, MI. Patients are no longer being enrolled but we are continuing regular patient follow-up for treated patients.

# 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 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.

We are in the process of developing a proprietary Neural Repair Cell (NRC) product for the treatment of spinal cord injuries and intend to initiate compassionate use patient treatments in the EU when sufficient financial resources are available. We expect that early compassionate use patient treatments will provide clinical experience that will assist us in the development of future clinical protocols.

#### 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 patient and physician see a potential benefit from using TRC-based products. We do not anticipate generating significant sales outside of the U.S. until we have sufficient evidence of clinical 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 compassionate use and other patient 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 cell products, 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 290 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. Our programs are also exploring the capability of TRC-based products to generate different types of human tissues. 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.

Additionally, 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, 2006, 2007 and 2008 were \$9,484,000, \$11,443,000 and \$15,249,000, respectively.

#### Strategic Relationships

In June 2003, we announced a strategic alliance with the Musculoskeletal Transplant Foundation (MTF) to jointly develop and commercialize innovative treatments for the regeneration of tissues such as bone and cartilage. Under the terms of the alliance, Aastrom and MTF may develop products that are based on combinations of MTF's allograft matrices and our TRC-based products. Matrix material from MTF is utilized in our Phase III ON-CORE trial.

In March 2006, we announced a collaboration to develop products for the orthopedics market using Orthovita's synthetic ceramic matrices and ceramic-collagen matrices (VITOSS) and our TRC-based products. We use matrix material supplied by Orthovita in some of our clinical studies in the EU, including our Spanish Phase II long bone fracture and osteonecrosis trials.

#### 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 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.

#### 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 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 Astro pursuant to this agreement.

In February 2004, we entered into a five-year continuing agreement 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, 2006, 2007 and 2008 were \$74,000, \$44,000 and \$78,000, respectively. Foreign product sales and rentals for the fiscal years ended June 30, 2006, 2007 and 2008 were \$85,000, \$50,000 and \$130,000, 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 a licensed biologic 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 file an IND submission 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 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) will be required for any cell-based medicinal product distributed in the EU. Sponsors must submit proof of safety and efficacy to the

European Medicines Agency (EMEA). 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 EMEA is expensive and may take several years to complete. There can be no assurance that the EMEA 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 EMEA approvals. In turn, this could delay or preclude us from marketing any products we may develop. The EMEA 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.

In August 2005, the Bad Oeynhausen site in Germany received Ethics Committee approval to conduct its vascular regeneration trial. In October 2005 and September 2006, the site in Barcelona, Spain, received CTA approval from the AEMPS for the non-union fracture and the osteonecrosis studies, respectively.

#### Product Approval in the European Union

Under the current EU drug directive, our TRC-based cell products will be regulated as a medicinal product. For products that are regulated as a medicinal product, 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. Although an MS is currently allowed to independently approve medicinal products, in the future, 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 will be 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 new revised law becomes effective, provided that we have introduced a product into the German market, we may fall under the "grandfathered" regulations for some period of time before we would need to apply for a centralized marketing authorization.

# **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 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, Arteriocyte, Bioheart, Athersys, Cytori Therapeutics, Gamida Cell, Geron, Isologen, 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 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**

The global economy and capital markets have been challenging for the small cap biotech sector for the past year. In May 2008 we reduced costs and expenses through a combination of 1) development and clinical program reprioritizations which adjusted our primary focus to our cardiac regeneration program and 2) reductions in our staff. As of August 15, 2008, we employed approximately 45 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**

Our executive officer, and his respective age as of August 15, 2008, is as follows:

 Name
 Age
 Position

 George W. Dunbar
 61
 President, Chief Executive Officer, Chief Financial Officer and Director

George W. Dunbar joined Aastrom as President, Chief Executive Officer and a member of the Company's Board of Directors in July 2006. Mr. Dunbar also currently serves as the Company's Chief Financial Officer. Over the last 15 years, 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 on the board of Accuri Cytometers, as well as the MBA Advisory Board of the College of Business at Auburn University. Previous boards of director appointments include: DepoTech, LJL 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.

# **Available Information**

Additional information about Aastrom is contained at our website, <a href="www.aastrom.com">www.aastrom.com</a>. 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.

#### 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, 2008, we have incurred a cumulative net loss totaling approximately \$179 million, and we have continued to incur losses since that date. These losses have resulted principally from costs incurred in the research and development 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. In addition, we may not be able to achieve or sustain profitability.

The global economy and capital markets have been challenging for the small cap biotech sector for the past year or so. This situation makes the timing and potential for future equity financings uncertain. As a result, we have taken actions intended to reduce our estimated average cash utilization to approximately \$1.2 million per month for fiscal year ending June 30, 2009, through a combination of development and clinical program reprioritizations and adjustments focusing on our cardiac regeneration program, along with reductions in overhead and staff which occurred in May 2008.

#### 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 December 20, 2007, we received a deficiency letter from the Nasdaq Stock Market indicating that for 30 consecutive trading days our common stock had a closing bid price below the \$1.00 per share minimum closing bid as required for continued listing set forth in Nasdaq Marketplace Rule 4310(c)(4). In accordance with Nasdaq Marketplace Rule 4310(c)(8)(D), we were provided a compliance period of 180 calendar days, or until June 17, 2008, to regain compliance with this requirement. On June 17, 2008, we had not yet regained compliance with the requirement and were granted an additional 180-day compliance period, or until December 15, 2008 to regain compliance. 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 additional 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 delisting determination to a Nasdaq Listing Qualifications Panel.

We cannot provide any assurance that our stock price will again 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 would 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.

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
- · 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.

# We have experienced significant management turnover, and 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.

# 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 regulations of the EMEA. If we cannot demonstrate the safety and efficacy of our cell product candidates, or of the cells 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, 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 mixtures (such as our TRC-based products) is, under current regulations, regulated as a biologic product, which requires a Biological 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. Recent changes to the EU Medicinal Products Prime Directive (including added annexes and new regulations) shifted patient-derived cells to the medicinal products category, which will require Marketing Authorizations in order to market and sell these products. These new requirements will require clinical trials with data submission and review by one or more European regulatory bodies. There is uncertainty about which clinical trial activities and data are required, and because of the recent nature of these new directives, laws and regulations, there is no established precedent to understand the timeline or other requirements for 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 component parts or provide limited source supplies, or the imposition of additional regulation, would impair our new product development and our sales activities.

We rely solely on third parties such as Astro, Ethox, Moll and Lonza 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, the Institute of Laboratory and Transfusion Medicine at the Heart Center in Bad Oeynhausen, Germany, and the Tissue and Cell Therapy Center at the Blood and Tissue Bank in Barcelona, Spain, 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 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 \$0.35 and \$1.37 during the twelve month period ended June 30, 2008. 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 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. Certain of these foreign patents are due expire beginning in 2008. 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. 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, contain 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. We also lease office space in Berlin, Germany, for our German subsidiary, Aastrom Biosciences GmbH, and in Barcelona, Spain, for our Spanish subsidiary, Aastrom Biosciences, SL.

# 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 Stock 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**

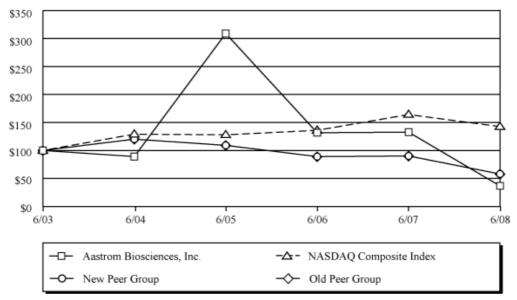
	High	Low
Year ended June 30, 2007:		
1st Quarter	\$1.50	\$1.13
2nd Quarter	1.60	1.13
3rd Quarter	1.58	1.24
4th Quarter	1.58	1.33
Year ended June 30, 2008:		
1st Quarter	1.34	1.10
2nd Quarter	1.37	0.52
3rd Quarter	0.76	0.38
4th Quarter	0.47	0.35

As of July 31, 2008, there were approximately 588 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), an old peer group consisting of the following regenerative medicine companies: Advanced Cell Technology, Inc., Athersys, Inc., Cytori Therapeutics, Geron Corp., Isolagen, Inc., Osiris Therapeutics, Inc., and StemCells, Inc. and a new 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, 2003 and ending on June 30, 20081. The new peer group includes the old peer group and Bioheart, which was added as the result of the May 2008 reprioritization of our clinical development programs which primarily focuses on cardiac regeneration.

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



\* \$100 invested on 6/30/03 in stock & index-including reinvestment of dividends. Fiscal year ending June 30.

Aastrom/Index	6/30/03	6/30/04	6/30/05	6/30/06	6/30/07	6/30/08
Aastrom Biosciences, Inc.	\$100.00	\$ 89.11	\$308.91	\$131.68	\$132.67	\$ 36.63
Nasdaq Composite Index	100.00	129.09	127.97	136.00	164.15	142.67
New Peer Group	100.00	120.21	109.09	89.01	90.18	57.93
Old Peer Group	100.00	120.21	109.09	89.01	90.18	57.93

<sup>&</sup>lt;sup>1</sup> Assumes that \$100.00 was invested on June 30, 2003 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, 2008**

The following table sets forth information as of June 30, 2008 with respect to compensation plans (including individual compensation arrangements) under which equity securities are authorized for issuances:

	Number of Securities to be Issued upon Exercise of Outstanding Options, Warrants and Rights	Weighted Average Exercise Price of Outstanding Options, Warrants and Rights		Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans	
Equity compensation plans approved by security					
holders (employees and directors)(1)	9,911,872	\$	1.34	5,970,047	
Equity compensation plans not approved by security					
holders (financings or services related)(1)	495,868	\$	1.74	_	
Balance, June 30, 2008	10,407,740	\$	1.36	5,970,047(2)	

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

<sup>(2)</sup> 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, 2006, 2007 and 2008 and for the period from March 24, 1989 (Inception) to June 30, 2008 and the balance sheet data at June 30, 2007 and 2008, 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, 2004 and 2005, and the balance sheet data at June 30, 2004, 2005 and 2006, 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 (Inception) to		
	2004	2005	2006	2007	2008	June 30, 2008
		(In	thousands, exc	ept per share	amounts):	
Statement of Operations Data						
Revenues:						
Product sales and rentals	\$ 49	\$ 387	\$ 159	\$ 94	\$ 208	\$ 1,579
Research and development agreements	75		704	501	21.4	2,105
Grants	1,178	522	704	591	314	9,657
Total revenues	1,302	909	863	685	522	13,341
Costs and expenses:	• • • •					• 000
Cost of product sales and rentals(1)	280	148	11	29	56	2,889
Research and development	6,289	7,206	9,484	11,443	15,249	136,819
Selling, general and administrative	5,390	5,972	9,101	8,682	6,436	63,708
Total costs and expenses	11,959	13,326	18,596	20,154	21,741	203,416
Loss from operations	(10,657)	(12,417)	(17,733)	(19,469)	(21,219)	(190,075)
Other income (expense):		10				1.240
Other income	1.00	12	1.250	1.075	1 170	1,249
Interest income	169	594	1,258	1,875	1,170	10,268
Interest expense	Φ (10, 100)	Φ (11 011)	Φ (1.6.455)	A (15 504)	(84)	(351)
Net loss(2)	<u>\$ (10,488)</u>	\$ (11,811)	\$ (16,475)	\$ (17,594)	\$ (20,133)	\$ (178,909)
Net loss applicable to common shares	<u>\$ (10,488)</u>	\$ (11,811)	<u>\$ (16,475)</u>	<u>\$ (17,594</u> )	\$ (20,133)	
Net loss per common share (basic and diluted)	<u>\$ (.14)</u>	\$ (.13)	\$ (.15)	\$ (.15)	\$ (.16)	
Weighted average number of common shares outstanding (basic and diluted)	73,703	93,541	106,314	119,523	129,120	
				June 30,		
	2004	2005	(In thou		2007	2008
Balance Sheet Data:						
Cash, cash equivalents and short-term investments	\$ 16,926	\$ 32,4		2,997 \$		\$ 22,462
Working capital	17,274	32,2		1,126	26,677	21,963
Total assets	18,166	33,8	97 44	4,881	32,848	26,217
Long-term debt				_	1,536	1,229
Deficit accumulated during the development stage	(113,864)				(159,744)	(179,877)
Total shareholders' equity	17,608	33,0	28 42	2,342	28,251	23,334

<sup>(1)</sup> Cost of product sales and rentals for the years ended June 30, 2004 and 2005 and for the period from Inception to June 30, 2008 include a charge of \$253, \$9 and \$2,239 for excess inventories, respectively.

<sup>(2)</sup> Net loss for fiscal years ended June 30, 2006, 2007 and 2008 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 and \$1.6 million, respectively, related to employee and director stock-based awards. For the years ended June 30, 2004 and 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 focused 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, bone and neural. TRC-based products have been used in over 290 patients, and are currently in the following stages of development:

- Cardiac regeneration Cardiac Repair Cells (CRCs):
  - Dilated cardiomyopathy (DCM) (severe chronic disease of the heart):
    - U.S.: IMPACT-DCM Phase II clinical trial initiating clinical sites; patient treatments expected to begin in September 2008;
       Orphan Drug Designation from the FDA for use in the treatment of DCM
    - · Germany: Encouraging data reported in April 2008 from compassionate use treatment in patients; clinical activity is ongoing
- Vascular regeneration Vascular Repair Cells (VRCs):
  - Critical limb ischemia (CLI):
    - U.S.: RESTORE-CLI Phase IIb clinical trial enrolling patients
    - Germany: Phase I/II clinical trial has completed enrollment and patient follow-up is ongoing; positive interim data reported in October 2007
- Bone regeneration Bone Repair Cells (BRCs):
  - · Osteonecrosis of the femoral head:
    - · U.S.: ON-CORE Phase III clinical trial active, but not enrolling additional patients; Orphan Drug Designation from
    - the FDA for use in the treatment of osteonecrosis of the femoral head
    - · Spain: Pivotal clinical trial enrolling patients
    - Germany: Positive data reported in October 2007 from compassionate use treatment cases
  - · Non-union fractures:
    - U.S.: Positive 12 month results from Phase I/II clinical trial reported by investigator in October 2007
    - Spain: 24 month follow-up continuing on fully-enrolled 10-patient Phase II clinical trial
- Neural regeneration Neural Repair Cells (NRCs):
  - Spinal cord injury:
    - · Plans for clinical program under development

Our platform TRC technology is based on:

- 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
- The means to produce these products in an automated process.

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 cell component 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 in Ann Arbor, MI and three contract facilities in the EU located in Stuttgart, Germany (Fraunhofer Institute for Interfacial Engineering and Biotechnology), Bad Oeynhausen, Germany (Institute of Laboratory and Transfusion Medicine at the Heart Center) and Barcelona, Spain (Tissue and Cell Therapy Center at the Blood and Tissue Bank).

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. 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.

Our current focus is 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 primarily focus 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 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 the 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 obtaining required capital in a similar manner. As a development stage company, we have never been profitable and do not anticipate having net income unless and until significant product sales commence. 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, 2008, we have accumulated a net loss of approximately \$179 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.

# **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 optionpricing 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 has implemented SAB 110 and is continuing to use the "simplified" method for estimating the expected term of its "plain-vanilla" stock options as the Company has 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 — Over the last two years, the Board of Directors granted performance-based stock options (performance options) to certain key employees. As of June 30, 2008, there were 1,287,868 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, 2008 is approximately \$1,277,000. 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, 2008, 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. For 789,931 of the performance options, the vesting criteria were not met and, therefore, expired unvested during the fiscal year ended June 30, 2008.

Due, in part, to the complexity of measuring the performance conditions, the Compensation Committee of the Board of Directors is considering offering employees with performance-based stock options the opportunity to convert them to a reduced number of service-based stock options.

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 \$522,000 in 2008, \$685,000 in 2007, and \$863,000 in 2006. Product sales and rental revenues increased to \$208,000 in 2008 from \$94,000 in 2007 and \$159,000 in 2006. The increase in product revenues for 2008 resulted from 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.

Grant revenues decreased to \$314,000 in 2008 from \$591,000 in 2007 and \$704,000 in 2006. 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, 86% for 2007 and 82% for 2006 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 \$21,741,000 in 2008, \$20,154,000 in 2007 and \$18,596,000 in 2006. The increases in costs and expenses during the periods reflect 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 \$56,000 in 2008, \$29,000 in 2007 and \$11,000 in 2006. The increase in cost of product sales and rentals is due to the changes in the volume of product sales.

Costs and expenses included an increase in research and development expenses to \$15,249,000 in 2008 from \$11,443,000 in 2007 and \$9,484,000 in 2006. These increases reflect 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. In May 2008, we reprioritized our clinical development programs to focus 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 relative clinical and market potential. Research and development expenses also include a non-cash charge of \$515,000 in 2008, \$702,000 in 2007 and \$300,000 in 2006 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 2008 to \$6,436,000 from \$8,682,000 in 2007 and \$9,101,000 in 2006. The decrease is due to lower salaries and benefits as a result of management and employee changes; decreases in relocation and recruitment expenses; reduced supplemental compensation relating to the 2007 management performance bonuses; and the elimination of the management performance bonus plan and the associated costs for 2008. Selling, general and administrative expenses also include a non-cash charge of \$1,088,000 in 2008, \$2,104,000 in 2007 and \$734,000 in 2006 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 \$1,170,000 in 2008, \$1,875,000 in 2007 and \$1,258,000 in 2006. 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 \$20,133,000, or \$.16 per common share in 2008, \$17,594,000, or \$.15 per common share in 2007, and \$16,475,000, or \$.15 per common share in 2006. These increases in net loss are primarily the result of increased costs and expenses, as discussed above, offset on a per share basis by an increase in the weighted average number of common shares outstanding. 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 have been initiated 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 immunotherapy programs, 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, 2008 (in thousands):

	Year Ended June 30,					
R&D Project	2006	2007	2008			
TRC-based products	\$ 8,347	\$ 10,497	\$14,159			
Other	1,137	946	1,090			
Total	\$ 9,484	\$ 11,443	\$15,249			

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 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, 2008, we have generated cumulative Federal tax net operating loss and tax credit carryforwards of, \$98,270,000 and \$1,600,000, respectively, which will expire in various periods between 2008 and 2028, 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, 2008, have totaled approximately \$203 million and, to a lesser degree, through grant funding, payments received under research agreements and collaborations, interest earned on cash, cash equivalents, and short-term investments, and funding under equipment leasing agreements. These financing sources have generally allowed us to maintain adequate levels of cash and other liquid investments.

Our combined cash, cash equivalents and short-term investments totaled \$22,462,000 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 combined cash, cash equivalents and short-term investments totaled \$28,325,000 at June 30, 2007, a decrease of \$14,672,000 from June 30, 2006. During the year ended June 30, 2007, the primary source of cash, cash equivalents and short-term investments equity transactions from the employee stock option plans and the Direct Stock Purchase Plan, with net proceeds of \$697,000 and from a secured loan with Key Equipment Finance Inc. in the amount of \$751,000, payable over 36 months at a 7.24% fixed interest rate. The primary uses of cash, cash equivalents and short-term investments during the year ended June 30, 2007 included \$14,826,000 to finance our operations and working capital requirements, and \$1,064,000 in capital equipment additions for cell manufacturing and laboratory equipment and furniture.

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.

The global economy and capital markets have been challenging for the small cap biotech sector for the past year. This situation makes the timing and potential for future equity financings uncertain. As a result, we have reduced costs and expenses in an attempt to achieve an estimated average cash utilization of approximately \$1.2 million per month for the fiscal year ending June 30, 2009, through a combination of development and clinical program reprioritizations and adjustments focusing on our cardiac regeneration program, along with reductions in overhead and staff.

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 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 beyond the end of fiscal year 2009 (ending June 30, 2009), 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.

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):

	Payments Due				Period	
Contractual Obligations	Total	2009	2010	2011	2012	re then Years
Purchase order commitments	\$ 343	\$ 343	\$ —	\$ —	\$ —	\$ _
Operating leases	5,347	1,073	1,092	1,111	1,131	940
Long-term debt	1,229	446	479	225	79	_
Total	\$ 6,919	\$1,862	\$1,571	\$1,336	\$1,210	\$ 940

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 December 2007, the FASB issued Statement No. 141 (revised), *Business Combinations* (SFAS No. 141(R)). The standard changes the accounting for business combinations including the measurement of acquirer shares issued in consideration for a business combination, the recognition of contingent consideration, the accounting for pre-acquisition gain and loss contingencies, the recognition of capitalized in-process research and development, the accounting for acquisition-related restructuring cost accruals, the treatment of acquisition related transaction costs and the recognition of changes in the acquirer's income tax valuation allowance. SFAS No. 141(R) is effective for fiscal years beginning after December 15, 2008, with early adoption prohibited. The Company is currently assessing the impact of the pending adoption of SFAS 141(R) on the accounting and financial statements for any potential future business combinations entered into by the Company. The Company will adopt and apply the provision if future acquisitions were to occur.

In June 2007, the FASB ratified Emerging Issues Task Force (EITF) 07-3, Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities (EITF 07-3). EITF 07-3 requires that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities be deferred and capitalized and recognized as an expense as the goods are delivered or the related services are performed. EITF 07-3 is effective, on a prospective basis, for fiscal years beginning after December 15, 2007. The Company is currently assessing the impact of the pending adoption of EITF 07-3 on its results of operations and financial condition.

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

As of June 30, 2008, 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. Due to the short duration and credit quality of our investment portfolio, an immediate 10% change in interest rates would not have a material effect on the fair market value of our portfolio, therefore, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a sudden change in market interest rates 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

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#### 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, 2008 and 2007, and the results of their operations and their cash flows for each of the three years in the period ended June 30, 2008, and for the period from March 24, 1989 (Inception) to June 30, 2008, 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, 2008, 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 (which were integrated audits for the fiscal years ended June 30, 2008, 2007 and 2006). 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/ PRICEWATERHOUSE COOPERS LLP Pricewaterhouse Coopers LLP Detroit, Michigan August 29, 2008

### CONSOLIDATED BALANCE SHEETS

	June	,	
	2007 (In the	usands.	
	except sh	are data)	
ASSETS			
CURRENT ASSETS:			
Cash and cash equivalents	\$ 13,439	\$ 16,492	
Short-term investments	14,886	5,970	
Receivables, net	78	18	
Inventories	8	_	
Other current assets	1,766	1,583	
Total current assets	30,177	24,063	
PROPERTY AND EQUIPMENT, NET	2,671	2,154	
Total assets	\$ 32,848	\$ 26,217	
LIABILITIES AND SHAREHOLDERS' EQUITY			
CURRENT LIABILITIES:			
Accounts payable and accrued expenses	\$ 1,823	\$ 907	
Accrued employee benefits	1,238	747	
Current portion of long-term debt	439	446	
Total current liabilities	3,500	2,100	
LONG-TERM DEBT	1,097	783	
COMMITMENTS AND CONTINGENCIES (Notes 5 and 6)			
SHAREHOLDERS' EQUITY:			
Common Stock, no par value; shares authorized — 250,000,000; shares issued and			
outstanding — 120,012,869 and 132,858,736, respectively	187,995	203,211	
Deficit accumulated during the development stage	(159,744)	(179,877)	
Total shareholders' equity	28,251	23,334	
Total liabilities and shareholders' equity	\$ 32,848	\$ 26,217	

### CONSOLIDATED STATEMENTS OF OPERATIONS

	V	March 24, 1989 (Inception) to		
	2006	ear Ended June 30 2007	2008	June 30, 2008
	(	In thousands, exce	pt per share amo	unts)
REVENUES:				
Product sales and rentals	\$ 159	\$ 94	\$ 208	\$ 1,579
Research and development agreements	_	_	_	2,105
Grants	704	591	314	9,657
Total revenues	863	685	522	13,341
COSTS AND EXPENSES:				
Cost of product sales and rentals	11	29	56	650
Cost of product sales and rentals — provision for excess inventories				2,239
Research and development	9,484	11,443	15,249	136,819
Selling, general and administrative	9,101	8,682	6,436	63,708
Total costs and expenses	18,596	20,154	21,741	203,416
LOSS FROM OPERATIONS	(17,733)	(19,469)	(21,219)	(190,075)
OTHER INCOME (EXPENSE):				
Other income	_		<del></del>	1,249
Interest income	1,258	1,875	1,170	10,268
Interest expense			(84)	(351)
Total other income	1,258	1,875	1,086	11,166
NET LOSS	\$ (16,475)	\$ (17,594)	\$ (20,133)	\$ (178,909)
NET LOSS PER SHARE (Basic and Diluted)	\$ (.15)	\$ (.15)	\$ (.16)	
Weighted average number of common shares outstanding (Basic and Diluted)	106,314	119,523	129,120	

### AASTROM BIOSCIENCES, INC.

(a development stage company)

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

	Preferred	Stock	Common	Stock	Deficit Accumulated During the Development	Total Shareholders'
	Shares	Amount	Shares	Amount	Stage	Equity
			In thousands, exc	ept per share		
BALANCE, MARCH 24, 1989 (Inception)	_	s —	_	s —	s —	s —
Net loss and comprehensive loss Net loss		-			(124,707)	(124,707)
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			6,947,704	4,857		4,857
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				1,574		1,574
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 \$7,523			68,946,548	73,935		73,935
Issuance of stock under Direct Stock Purchase Plan		166	28,905	43	(0.60)	43
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, 2005	_	_	102,328,785	158,703	(125,675)	33,028
Net loss and comprehensive loss			205.002	2.52	(16,475)	(16,475)
Exercise of stock purchase warrants			205,883	253		253
Exercise of stock options			528,083	473		473
Issuance of restricted stock			342,817	143		143
Issuance of stock under Direct Stock Purchase Plan  Compensation expense related to stock options and restricted stock awards and units granted granted			90,294	1,034		1,034
Issuance of common stock, net of issuance costs of \$1,624			15,943,750	23,886		23,886
					(1.42.150)	
BALANCE, JUNE 30, 2006	_	_	119,439,612	184,492	(142,150)	42,342
Net loss and comprehensive loss			176.484	133	(17,594)	(17,594) 133
Exercise of stock options Issuance of restricted stock			39,675	133		133
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			720,323	2,806		2,806
BALANCE, JUNE 30, 2007			120,012,869	187,995	(159,744)	28,251
Net loss and comprehensive loss			120,012,009	167,993	(20,133)	(20,133)
Exercise of stock options and stock purchase warrants			846,392	995	(20,133)	995
Issuance of restricted stock			64,300	773		
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		<u>s</u> —	132,858,736	\$ 203,211	\$ (179,877)	\$ 23,334
20 x 20 x 10 20 y 20 00 00 00 00 00 00 00 00 00 00 00 00		<u> </u>	152,050,750	<u> 203,211</u>	<del>(177,077)</del>	25,554

### CONSOLIDATED STATEMENTS OF CASH FLOWS

		Year Ended June 30, 2006 2007 2008			
	2000		housands)	Ju	ne 30, 2008
OPERATING ACTIVITIES:					
Net loss	\$ (16,475)	\$ (17,594)	\$ (20,133)	\$	(178,909)
Adjustments to reconcile net loss to net cash used for operating activities:	, ( , , , , )	, ( ,,,, ,	, ( , , , , ,		(, ,
Depreciation and amortization	326	500	732		5,296
Loss on property held for resale	_	_	_		110
Amortization of discounts and premiums on Investments	(135)	(547)	(381)		(1,674)
Stock compensation expense	1,034	2,806	1,603		7,027
Inventories write downs and reserves	_	_	_		2,239
Stock issued pursuant to license agreement	_	_	_		3,300
Provision for losses on accounts receivable	39	_	_		204
Changes in assets and liabilities:					
Receivables	15	61	60		(267)
Inventories	115	(7)	8		(2,335)
Other current assets	(107)	(461)	(58)		(1,026)
Accounts payable and accrued expenses	551	633	(867)		850
Accrued employee benefits	1,119	(217)	(491)		747
Net cash used for operating activities	(13,518)	(14,826)	(19,527)		(164,438)
INVESTING ACTIVITIES:					
Organizational costs	_	_	_		(73)
Purchase of short-term investments	(43,900)	(49,376)	(30,703)		(212,041)
Maturities of short-term investments	28,078	69,000	40,000		207,745
Property and equipment purchases	(789)	(1,064)	(215)		(5,726)
Proceeds from sale of property held for resale					400
Net cash provided by (used for) investing activities	(16,611)	18,560	9,082		(9,695)
FINANCING ACTIVITIES:					
Net proceeds from issuance of preferred stock	_	_	_		51,647
Net proceeds from issuance of common stock	24,755	697	13,613		136,811
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		(536)
Proceeds from long-term debt	_	751	_		751
Principal payments under long-term debt			(356)		(1,530)
Net cash provided by financing activities	24,755	671	13,498		190,625
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(5,374)	4,405	3,053		16,492
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	14,408	9,034	13,439		_
CASH AND CASH EQUIVALENTS AT END OF PERIOD	\$ 9,034	\$ 13,439	\$ 16,492	\$	16,492
SUPPLEMENTAL CASH FLOW INFORMATION:				=	
Interest paid	\$ —	s —	\$ 84	\$	351
Equipment acquired under capital lease obligations	\$ — \$ —	\$ — \$ —	\$ —	\$	1,174
Equipment acquired under capital lease obligations	ψ	Ψ —	Ψ —	Ψ	1,1/7

#### 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 2009 (ending June 30, 2009), 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, 2008, 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.

Short-Term Investments — Short-term investments consist of highly rated corporate debt securities with original maturities of over three months and less than one year. Short-term investments are classified as available-for-sale, and are presented at market value, with unrealized gains and losses on investments, if any, reflected as a component of accumulated other comprehensive income within shareholders' equity. Interest earned on available-for-sale securities is included in interest income. Discounts or premiums arising at acquisition of these investments are amortized over the remaining term of the investment and reported in interest income. The Company has not experienced significant unrealized gains or losses on its investments.

Diversity of Credit Risk — The Company invests its excess cash in U.S. government securities and highly rated corporate debt securities and has established guidelines relative to diversification and maturities 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.

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

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 \$326,000, \$500,000, \$732,000 and \$5,296,000 for the years ended June 30, 2006, 2007, 2008 and for the period from Inception to June 30, 2008, 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 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, 2006, 2007 and 2008 is approximately 8,939,000, 16,106,000 and 20,072,000, 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

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

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 December 2007, the FASB issued Statement No. 141 (revised), Business Combinations (SFAS No. 141(R)). The standard changes the accounting for business combinations including the measurement of acquirer shares issued in consideration for a business combination, the recognition of contingent consideration, the accounting for pre-acquisition gain and loss contingencies, the recognition of capitalized in-process research and development, the accounting for acquisition-related restructuring cost accruals, the treatment of acquisition related transaction costs and the recognition of changes in the acquirer's income tax valuation allowance. SFAS No. 141(R) is effective for fiscal years beginning after December 15, 2008, with early adoption prohibited. The Company is currently assessing the impact of the pending adoption of FAS 141(R) on the accounting and financial statements for any potential future business combinations entered into by the Company.

In June 2007, the FASB ratified Emerging Issues Task Force (EITF) 07-3, Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities (EITF 07-3). EITF 07-3 requires that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities be deferred and capitalized and recognized as an expense as the goods are delivered or the related services are performed. EITF 07-3 is effective, on a prospective basis, for fiscal years beginning after December 15, 2007. The Company is currently assessing the impact of the pending adoption of EITF 07-3 on its results of operations and financial condition.

#### 2. Selected Balance Sheet Information

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

	June	30,
	2007	2008
Machinery and equipment	\$ 2,561	\$ 2,715
Office equipment	1,159	1,192
Leasehold improvements	891	891
	4,611	4,798
Less accumulated depreciation and amortization	(1,940)	(2,644)
	\$ 2,671	\$ 2,154

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

	Jun	ie 30,
	2007	2008
Accounts payable	\$ 532	\$344
Accrued expenses:		
Clinical studies	227	154
Manufacturing and engineering	76	99
Professional services	311	146
Lessor payment	386	_
Other	291	164
	\$1,823	\$907

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

At June 30, 2007, the Company recorded accrued expenses related to the purchase of leasehold improvements of approximately \$106,000.

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

	June	30,
	2007	2008
Accrued vacation pay	\$ 310	\$373
Performance bonuses	775	_
Payment to stay to former CEO	142	_
Severance payments	_	366
Other	11	8
	\$1,238	\$747

#### 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, 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 market 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, 2008, there were 5,970,047 of awards available for future grant under the Option Plans.

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

#### Service-Based Stock Options

During the year ended June 30, 2008, the Company granted 2,690,900 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 non-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, 2006, 2007 and 2008 was \$2.55, \$0.88 and \$0.67, respectively.

In May 2008, in an effort reduce costs and expenses, the Company implemented a reduction in staff. As a result of this reduction certain unvested stock options previously granted to these employees were forfeited. The impact of these forfeitures resulted in a reduction of stock compensation in the amount of \$370,000 for the year ended June 30, 2008.

The net compensation costs recorded for the service-based stock options related to employees and directors were approximately \$724,000, \$2,598,000 and \$1,597,000 for the years ended June 30, 2006, 2007 and 2008, 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 assumptions noted in the following table.

	Year	Year Ended June 30,		
	2006	2007	2008	
Stock Option Plans:				
Expected dividend rate	0%	0%	0%	
Expected stock price volatility	72%	67%	61%	
Risk free interest rate	4.3%	4.9%	4.2%	
Estimated forfeiture rate	10%	10%	10%	
Expected life (years)	6.6	6.6	6.6	

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

Weighted Average

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

	Options	nted Average rcise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at July 1, 2005	4,085,953	\$ 1.55		
Granted	289,900	\$ 2.55		
Exercised	(528,083)	\$ 0.90		\$ 840,000
Forfeited or expired	(323,217)	\$ 2.17		
Outstanding at June 30, 2006	3,524,553	\$ 1.67	6.5	\$ 860,000
Granted	5,326,200	\$ 1.29		
Exercised	(176,484)	\$ 0.75		\$ 83,000
Forfeited or expired	(316,733)	\$ 1.27		
Outstanding at June 30, 2007	8,357,536	\$ 1.46	7.8	\$ 1,093,000
Granted	2,690,900	\$ 1.05		
Exercised	(18,518)	\$ 0.38		\$ 3,000
Forfeited or expired	(2,494,737)	\$ 1.53		
Outstanding at June 30, 2008	8,535,181	\$ 1.31	7.8	\$ 1,000
Exercisable at June 30, 2008	3,806,865	\$ 1.45	6.6	\$ 1,000

As of June 30, 2008 there was approximately \$1,297,000 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 2.7 years.

#### 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.

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

For the years ended June 30, 2007 and 2008, 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.

		June 30, 2007	June 30, 2008
Stock	ek Option Plans:		
Ex	xpected dividend rate	0%	0%
Ex	xpected stock price volatility	66%	66%
Ri	isk free interest rate	4.7%	4.7%
Es	stimated forfeiture rate	0%	0%
Ex	xpected life (years)	6.8	6.9

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

Options	Shares	ited Average rcise Price	Remaining Contractual Term	Intr	egate insic lue
Outstanding at June 30, 2006	_	_			
Granted	2,800,400	\$ 1.50			
Exercised	_	_			
Forfeited or expired	(320,000)	\$ 1 .53			
Outstanding at June 30, 2007	2,480,400	\$ 1.50	9.3	\$	0
Granted	69,400	\$ 1.53			
Exercised	_	_			
Forfeited or expired	(1,261,932)	\$ 1 .51			
Outstanding at June 30, 2008	1,287,868	\$ 1.49	8.5	\$	0

The aggregate estimated fair value of awards that are outstanding as of June 30, 2008 is approximately \$1,300,000.

#### Restricted Stock Awards

Restricted stock awards generally vest over a four year period and entitle the recipient to receive common stock upon vesting. The net compensation costs charged as operating expenses for restricted stock for the years ended June 30, 2006, 2007 and 2008 were \$310,000, \$208,000 and \$6,000, respectively.

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

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

Non-Vested Restricted Shares	Shares	ghted Average Grant Date Fair Value
Non-vested at July 1, 2005	_	_
Granted	374,217	\$ 2.35
Vested	_	_
Forfeited	(7,100)	\$ 2.36
Non-vested at June 30, 2006	367,117	\$ 2.35
Granted	39,400	\$ 1.17
Vested	(116,204)	\$ 2.31
Forfeited	(70,250)	\$ 2.26
Non-vested at June 30, 2007	220,063	\$ 2.19
Granted	64,300	\$ 0 .70
Vested	(107,480)	\$ 1.75
Forfeited	(88,058)	\$ 2.15
Non-vested at June 30, 2008	88,825	\$ 1.68

The total market value (at the vesting date) of restricted stock award shares that vested during the year ended June 30, 2007 and 2008 was \$93,000 and \$63,000, respectively. There were no such shares that vested during the years ended June 30, 2006.

As of June 30, 2008 there was approximately \$53,000 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 2.2 years.

#### Stock Purchase Warrants

In April 2004, the Company issued 8,000,000 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 for 5 years, or until April 5, 2009, subject to mandatory exercise at the Company's option, in certain circumstances of stock price escalation after April 5, 2006, to purchase up to 3,000,000 shares of common stock at an exercise price of \$1.65 per share. At June 30, 2008, warrants to purchase up to 2,400,000 shares of common stock pursuant to these warrant agreements remained outstanding.

In October 2004, the Company issued 8,264,463 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, exercisable from April 28, 2005 through October 27, 2008, to purchase up to 2,561,984 shares of common stock at an exercise price of \$1.74 per share. At June 30, 2008, warrants to purchase up to 1,838,843 shares of common stock pursuant to these warrant agreements remained outstanding.

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, 2008, warrants to purchase up to 5,921,053 shares of common stock pursuant to these warrant agreements remained outstanding.

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

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

#### 4. 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):

	Year Ended June 30,			
	2006	2007	2008	
Loss before income taxes	\$16,475	\$13,450	\$20,130	
Federal statutory rate	34%	34%	34%	
Taxes computed at federal statutory rate	(5,600)	(4,570)	(6,845)	
State taxes, net of federal taxes		_		
Increase (decrease) in taxes from:				
Stock compensation	(110)	950	175	
Other, net	(10)	(270)	(250)	
Loss attributable to foreign operations		_	630	
Valuation allowance	5,480	3,890	6,290	
Reported income taxes	<u>\$                                    </u>	<u>\$</u>	<u>\$</u>	

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

	Jun	ie 30,
	2007	2008
Net operating loss carryforwards	\$ 29,900	\$ 36,400
Research and development credit carryforwards	1,200	1,600
Inventories	435	_
Property and equipment	120	104
Employee benefits	460	276
Other, net	220	280
Total deferred tax assets	32,335	38,660
Valuation allowance	(32,335)	(38,660)
Net deferred tax assets	<u></u>	\$ —

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, 2008 the Company estimates the maximum Federal tax net operating loss and tax credit carryforwards, which could be utilized, were \$98,270,000 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 2010, \$9,000,000 between 2011 and 2015, and \$54,600,000 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.

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

#### 5. 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 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.

#### 6. 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 fair 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 \$537,000 at June 30, 2008, which is recorded as a component of other current assets.

As of June 30, 2008, future minimum payments related to our operating leases and long-term debt is as follows (in thousands):

Year Ending June 30,	Uperating Leases	Debt
2009	\$ 1,073	\$ 446
2010	1,092	479
2011	1,111	225
2012	1,131	79
2013	940	
Total	\$ 5,347	\$1,229

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

Rent expense for the years ended June 30, 2006, 2007 and 2008, was \$626,000, \$679,000 and \$1,107,000, respectively, and \$8,117,000 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.

#### 7. 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 \$160,000, \$172,000 and \$217,000 for the years ended June 30, 2006, 2007 and 2008, respectively and \$1,062,000 for the period from Inception to June 30, 2008.

#### 8. Quarterly Financial Data (Unaudited) (in thousands, except per share data):

Year Ended June 30, 2008	First Quarter		Second Quarter		Third Quarter		Fourth Quarter		Fiscal Year	
Revenues	\$	87	\$	84	\$	202	\$	149	\$	522
Loss from operations	(	(5,400)		(5,537)		(5,289)		(4,993)	(2	1,219)
Net loss	(	(5,050)		(5,172)		(5,048)		(4,863)	(2	0,133)
Net loss per common share		(.04)		(.04)		(.04)		(.04)	(.10	
Year Ended June 30, 2007	First Q	uarter_	Second	Quarter	Third	l Quarter	Fourth	Quarter	Fisca	al Year

Year Ended June 30, 2007	First Quarter		Second Quarter		Third Quarter		Fourth Quarter		Fiscal Year	
Revenues	\$	104	\$	158	\$	258	\$	165	\$	685
Loss from operations		(4,584)		(4,740)		(4,922)		(5,223)	(1	9,469)
Net loss		(4,057)		(4,225)		(4,483)		(4,829)	(1	7,594)
Net loss per common share		(.03)		(.04)		(.04)		(.04)		(.15)

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 ("CEO")/Chief Financial Officer ("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, 2008, 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, 2008 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, 2008, and has expressed unqualified opinions thereon in their report which appears under Item 8.

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

During our fourth quarter of fiscal 2008, 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.

On February 11, 2008, Gerald D. Brennan, Jr., submitted his resignation from all officer responsibilities at the Company, including those in his capacity as Chief Financial Officer. Mr. Brennan's resignation did not have a material effect on the Company's internal controls over financial reporting for the quarter ended June 30, 2008 as Mr. Brennan continued his employment with the Company through July 15, 2008 and, as a part of that arrangement, continued to perform some of the same internal control activities as he did as an officer of Aastrom. We have evaluated the longer-term impact to our internal controls over financial reporting due to Mr. Brennan's resignation and have modified our internal controls accordingly.

#### Item 9B. Other Information

Not applicable.

#### 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 2008 Annual Meeting of Shareholders scheduled for October 17, 2008.

#### 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

Title

Date: August 29, 2008

Signature

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below on August 29, 2008 by the following persons in the capacities indicated.

/s/ George W. Dunbar, Jr.	President and Chief Executive Officer
George W. Dunbar, Jr.	(Principal Executive Officer)
	Chief Financial Officer
	(Principal Financial and Accounting Officer)
/s/ Nelson M. Sims	Chairman
Nelson M. Sims	
/s/ Timothy M. Mayleben	Director
Timothy M. Mayleben	
/s/ Alan L. Rubino	Director
Alan L. Rubino	Director
Alan L. Rubino	
/s/ Stephen G. Sudovar	Director
Stephen G. Sudovar	
/s/ Susan L. Wyant, Pharm D	Director
Susan L. Wyant, Pharm D	
/s/ Robert L. Zerbe, M.D.	Director
Robert L. Zerbe, M.D.	Director
Robert E. Zerbe, W.D.	

#### EXHIBIT INDEX

Exhibi	t No. <u>Description</u>
3.1	Restated Articles of Incorporation of Aastrom, as amended, attached as Exhibit 3.1 to Aastrom's Quarterly Report on Form 10-Q for the quarter ended September 30, 2006, incorporated herein by reference.
3.2	Bylaws, as amended, attached as Exhibit 3.1 to Aastrom's Current Report on Form 8-K filed on September 12, 2007, 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 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#	Employment Agreement with Gerald D. Brennan, Jr. dated June 10, 2005, attached as Exhibit 10.86 to Aastrom's Annual Report on Form 10-K for the year ended June 30, 2005, incorporated herein by reference.
10.13	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.
10.14#	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.
10.15#	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.
10.16#	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.
10.17#	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.

Exhibi	t No. Description
10.18	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.
10.19	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.
10.20	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.
10.21	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.
10.22	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.
10.23#	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.
10.24#	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.
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.

<sup>#</sup> Management contract or compensatory plan or arrangement covering executive officers or directors of Aastrom.

#### **GLOSSARY**

Term **Definition** Adult Stem Cell A cell present in adults that can generate a limited range of cell types as well as renew itself. Adverse Events 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 Regulatory Agency 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. Dendritic Cells A special type of cells that are key regulators of the immune system, acting as a professional antigen-presenting cells (APC) capable of activating naïve T cells and stimulating the growth and differentiation of B cells. 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.

Term

LVEF — Left Ventricle Ejection Fraction The fraction of blood pumped out of the left ventricle with each heart beat. 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). Ex vivo 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, at a cost to taxpayers of about \$3 a 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).

Definition

Term

IMPACT-DCM

IMPD — Investigational Medicinal Product Dossier

In vitro

IND — Investigational New Drug

IRB — Institutional Review Board

Non-union Fractures

NRC — Neural Repair Cell

ON — Osteonecrosis

**ON-CORE** 

Open-label Clinical Trial

Orphan Drug Designation

Osteoblast

Phase I Clinical Trial

Phase II Clinical Trial

#### Definition

Aastrom's U.S. Phase II dilated cardiomyopathy clinical trial. 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.

In a laboratory dish or test tube; in an artificial environment An application submitted to the FDA for a new drug or biological drug that, if approved, will be used in a clinical trial.

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.

Broken bones that have failed to unite and heal

Aastrom's proprietary Tissue Repair Cells for Neural indications (Also see TRC — Tissue Repair Cell)

A progressive bone disease characterized by death of bony tissue due to insufficient blood flow within the bone.

Aastrom's U.S. Phase III osteonecrosis of the femoral head 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" 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.

A bone forming cell

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 moderate number of patients to assess the safety and efficacy of a product

Term

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 that are 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	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.  In culture, these undifferentiated cells possesse the ability to divide for indefinite periods in culture and may give rise to highly specialized cells.
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)

Definition

### SUBSIDIARIES OF REGISTRANT

Aastrom Biosciences, Ltd., Ireland Aastrom Biosciences GmbH, Germany Aastrom Biosciences SL, Spain

#### CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (Nos. 333-123570, 333-108963, 333-108989, 333-108964 and 333-107579) and Form S-8 (Nos. 333-121006, 333-115505, 333-81340, 333-51556, 333-38886, 333-140624 and 333-25021) of Aastrom Biosciences, Inc. (a development stage company) of our report dated August 29, 2008 relating to the consolidated financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP

PricewaterhouseCoopers LLP Detroit, Michigan August 29, 2008

#### CERTIFICATION

### I, George W. Dunbar, certify that:

- 1. I have reviewed this Annual Report on Form 10-K of Aastrom Biosciences, Inc. for the fiscal year ended June 30, 2008;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report:
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared; and
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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; and
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.
- 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 29, 2008

/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)

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

In connection with the Annual Report of Aastrom Biosciences, Inc. (the "Company") on Form 10-K for the year ended June 30, 2008, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, George W. Dunbar, Chief Executive Officer and President of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 ("Section 906"), that to my knowledge:

- (1) The Report fully complies with the requirements of section 13(a) and 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 29, 2008

/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)

A signed original of this written statement required by Section 906 has been provided to Aastrom Biosciences, Inc. and will be retained by Aastrom Biosciences, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.