		CHANGE COMMISSION n, D.C. 20549
	Form	n 10-K
	ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(	d) OF THE SECURITIES EXCHANGE ACT OF 1934
	The fiscal year ended June 30, 2007	
		or
0	TRANSITION REPORT PURSUANT TO SECTION 13 OI	R 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
	For the transition period from to	
	Commission fil	le number 0-22025
		DSCIENCES, INC. nt as specified in its charter)
	Michigan (State or other jurisdiction of incorporation or organization)	94-3096597 (I.R.S. Employer Identification No.)
	24 Frank Llo P. O. Ann Arb	yd Wright Drive Box 376 or, MI 48106 utive offices, including zip code)
	Registrant's telephone number,	including area code: (734) 930-5555
	Securities registered pursu	ant to Section 12(b) of the Act:
	Title of Class	Name of Each Exchange on Which Registered
	Common Stock (\$0 par value)	The Nasdaq Stock Market, Inc.
	• • •	ant 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	5 of the Securities Act. Yes o No $\square$
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 🛛
	check mark whether the registrant (1) has filed all reports required to be filed by Se tt the registrant was required to file such reports), and (2) has been subject to such fi	ection 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such ling requirements for the past 90 days. Yes $\Box$ No o
	check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S- tion statements incorporated by reference in Part III of this Form 10-K or any amen	K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive dment to this Form 10-K. $\square$
Indicate by	check mark whether the registrant is a large accelerated filer, an accelerated filer, or	r a non-accelerated filer (as defined in Rule 12b-2 of the Exchange Act).
	Large accelerated filer - o Acce	elerated filer - 🗹 🛛 Non-accelerated filer - o
Indicate by	check mark whether the registrant is a shell company (as defined in Rule 12b-2 of t	the Exchange Act). Yes o No ☑
Stock as reported	on the Nasdaq Capital Market) on December 31, 2006 was approximately \$147 mil more of the outstanding shares of Common Stock, since such persons may be deem	mmon Stock"), held by non-affiliates of the registrant (based on the closing sales price of the Common llion. This computation excludes shares of Common Stock held by directors, officers and each person led to be affiliates of the registrant. This determination of affiliate status is not necessarily a conclusive
As of Augu	ist 31, 2007, 120,874,063 shares of Common Stock, no par value, were outstanding.	
	DOCUMENTS INCORP	ORATED BY REFERENCE

Document

Proxy Statement for the Annual Meeting of Shareholders scheduled for November 7, 2007 Form 10-K Reference Items 10, 11, 12, 13 and 14 of Part III

## AASTROM BIOSCIENCES, INC.

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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) 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 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 bone, vascular, cardiac and neural. TRC-based products have been used in over 250 patients, and are currently in the following stages of development:

- Bone regeneration Bone Repair Cells (BRCs):
  - Osteonecrosis of the femoral head:
    - U.S.: ON-CORE Phase III clinical trial; Orphan Drug Designation from the FDA for use in the treatment of osteonecrosis of the femoral head
    - Spain: Pivotal clinical trial
  - Non-union fractures:
    - U.S.: Patient enrollment completed in Phase I/II clinical trial; final patient results expected to be reported in October 2007
- Vascular regeneration Vascular Repair Cells (VRCs):
  - Critical limb ischemia:
    - U.S.: RESTORE-CLI Phase IIb clinical trial
    - Germany: Phase I/II clinical trial; interim data expected to be reported in October 2007
- Cardiac regeneration Cardiac Repair Cells (CRCs):
  - · Chronic heart disease:
    - Preclinical research underway; clinical program under development; Orphan Drug Designation from the FDA for use in the treatment of dilated cardiomyopathy, a severe chronic disease of the heart
- Neural regeneration Neural Repair Cells (NRCs):
  - Spinal cord injury:
    - Preclinical research underway; 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 patented and proprietary 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 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 bone, vascular, cardiac, neural, and the hematopoietic and immune system.

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 that time we have phased out our marketing efforts promoting the cell manufacturing system as a commercial product in the U.S. Currently, we have product sales consisting of limited sales of manufacturing supplies to academic collaborators for research and limited revenue related to cell-based products.

Our current focus is on utilizing our TRC Technology to produce autologous cell-based products for use in regenerative medicine. 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 more 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 dendritic cell and T-cell manufacturing supplies to our academic collaborators, grant revenue, research funding and potential licensing fees or other financial support from potential future corporate collaborators.

We are beginning to explore the possibility of entering into complementary regenerative medicine business activities, whether through acquisition or otherwise.

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, 2007, we have accumulated a net loss of approximately \$159 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 regulatory approvals, or complete additional corporate partnering or acquisition transactions.

## **Clinical Development**

Currently, our active clinical development programs are focused on the utilization of our TRC Technology in the areas of vascular tissue and bone regeneration, and we anticipate beginning clinical trials in the cardiac and neural regeneration therapeutic areas.

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 osteoblast (bone cell) and endothelial (blood vessel) cell lineages. Based on these preclinical observations, clinical trials have been initiated in the U.S. and European Union (EU) for bone regeneration in patients with severe long bone fractures, and for vascular tissue regeneration in patients with critical limb ischemia.

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, Marketing Authorization (MA), for our TRC-based products in a timely fashion, or at all. See "Risk Factors."



## **Clinical Trials Summary**

#### Bone Regeneration

### Osteonecrosis of the Femoral Head:

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. We are currently initiating clinical sites for this trial. This trial will seek to enroll 120 patients, randomized into two patient groups, at up to 20 clinical sites. The primary efficacy variable of this trial is to delay disease progression to a more severe stage in patients treated with BRCs by at least 24 months post-treatment. Disease progression will be measured by a blinded third-party reviewer by x-ray and MRI. 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). We may have to provide or generate further patient data, such as data from the ongoing pivotal trial in Spain, 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 January 2007, we initiated patient enrollment and treatment in a pivotal 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 for up to 10 patients.

#### Fractures, Spine and Jaw:

In June 2007, all 36 patients enrolled in our U.S. Phase I/II clinical trial for the treatment of severe long bone non-union fractures completed their twelve-month follow-up at the following centers: 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. Data collection was completed in July 2007, and after analysis, we expect that final results from this trial will be reported in October 2007 at the Orthopedic Trauma Association Annual Meeting in Boston, MA. In February 2007, we reported interim results from all 36 patients enrolled in this trial. Of these 36 patients, 18 of 20 patients (90%) who had completed the twelve-month follow-up period, and 26 of 31 patients (84%) who have completed at least 6 months of follow-up showed multiple bone bridges at the fracture site, indicating radiographic evidence of healing by third-party image analysis. No cell-related adverse events were reported.

An initial bone regeneration study was conducted at three centers in Spain under Ethical Committee approvals. Results from this feasibility study conducted at Hospital General de l'Hospitalet, Teknon and Hospital de Barcelona-SCIAS in Spain were disclosed in May 2005. All five patients, with a total of 6 treated fractures, have been reported as healed by a third party independent reviewer using radiographic images, or by clinical observation. No cell-related adverse events were observed to date. Following the feasibility trial, an IMPD was approved by the AEMPS to commence a 10-patient Phase II non-union fracture trial. The Phase II study has completed enrollment and BRC treatment of all 10 patients, and we are continuing the specified 24-months follow-up of these patients.

We are conducting a Phase I/II spine fusion clinical trial at William Beaumont Hospital, Royal Oak, MI that may enroll up to 25 patients. No cell-related adverse events have been reported.

We have completed a jaw bone (maxilla) regeneration clinical feasibility trial in Barcelona, Spain, for edentulous patients with severe bone loss who needed a sinus lift procedure so that dental implants could be placed. This feasibility trial has enrolled the targeted 5 patients. No cell-related adverse events have been reported.



## Vascular Tissue Regeneration

#### Critical Limb Ischemia:

Based on our laboratory observations that TRC-based products have the ability to form small blood vessels, and 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 critical limb ischemia.

In April 2007, we initiated 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 expected to enroll 120 patients at up to 20 sites, randomized into two patient groups, to evaluate the safety and efficacy of VRCs in the treatment of critical limb ischemia. Currently, six clinical sites have been initiated for patient enrollment, and our website will be updated as additional sites are initiated. Patients will be followed for a period of twelve months post-treatment. In addition to assessing the safety of the VRCs, secondary objectives include assessing the number of patients requiring major amputation, wound closure 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 accrued and treated.

We entered into a clinical trial agreement with the Heart & Diabetes Center located in Bad Oeynhausen, Germany, to conduct a pilot trial to evaluate the safety and potential of VRCs to improve peripheral circulation in diabetic patients with open foot wounds and critical limb ischemia. Patient accrual is ongoing. No cell-related adverse events have been reported for patients treated with VRCs. We expect to report interim data from this study in October 2007.

#### Cardiac Regeneration

In February 2007, our proprietary Cardiac Repair Cells (CRCs) based on our TRC Technology received an Orphan Drug Designation from the FDA for use in the treatment of dilated cardiomyopathy (DCM). 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 transplant, there are no effective long-term 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.

We are in the process of preparing clinical activities in the EU that will include treating patients suffering from DCM. We expect that these patient treatments will provide early clinical experience that will assist us in the development of the clinical protocols we are preparing for a U.S. IND submission targeting this indication.

#### 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 productuse experience and refine our clinical development strategies through compassionate use and standard of care patient treatment in countries where it is allowed. We do not anticipate generating significant sales outside of the U.S. until we have sufficient evidence of clinical efficacy 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 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 bone regeneration applications (severe fractures and osteonecrosis), vascular tissue regeneration (critical limb ischemia), cardiac tissue regeneration and neural tissue regeneration. Our TRC-based products have been used in over 250 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 and Stanford University to produce dendritic cells for non-Aastrom 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, 2005, 2006 and 2007 were \$7,206,000, \$9,484,000 and \$11,443,000, 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. The collaboration aligns us with the leading provider of allograft, or donor-derived tissue materials (matrices) with a focus on forming a coordinated business and clinical approach for new products and treatments needed in orthopedic medicine. Under the terms of the alliance, Aastrom and MTF may develop products that are based on combinations of MTF's allograft matrices and our TRC-based products. We continue to utilize matrix material from MTF in some of our clinical trials.

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.

#### Manufacturing

#### Cell Manufacturing

Our TRC-based cell products will be regulated in the U.S., EU and other markets as 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 for clinical trials 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, 2005, 2006 and 2007 were \$194,000, \$74,000 and \$44,000, respectively. Foreign product sales and rentals for the fiscal years ended June 30, 2005, 2006 and 2007 were \$193,000, \$85,000 and \$50,000, 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 25 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, peripheral blood, until a bioreactor suitable for culturing human stem cells or human hematopoietic cells; (ii) 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. Certain of these forigin patents are due to expire beginning in 2008. In addition, we have field applications for patents in the U.S. and equivalent applications in certain other countries claiming other aspects of our products and processes, including a number of 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 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 tests. 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 which 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 as 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 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). We conduct various phases of clinical trials utilizing all available data, and do not necessarily initiate trials as a Phase I or II study.

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 is 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 new EU Directives (laws) have become effective, and have influenced the requirements for manufacturing cell products and the conduct of clinical trials. These changes have delayed or in some cases temporarily halted clinical trials in the EU. The recent changes to the EU Medicinal Products Prime Directive shifted patient-derived cells to the medicinal products category. The EU has approved a regulation specific to cell and tissue products and when published, we expect our products will be regulated under this Advanced Therapy Medicinal Product (ATMP) regulation.

## Clinical Trials in the European Union

As provided for in the new 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 tests. 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 which 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).

The regulatory requirements to market somatic cellular and ATMP products have changed significantly with the approval of the EU ATMP regulation. We do not know when the regulation will come into effect, but once it is officially published there will be a one year transition, and up to a four year "grandfather" marketing allowance for products that were on the market on or before the end of the transition period.

Germany does not require marketing authorization to distribute autologous tissue products. 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, orthopedics, vascular, cardiac 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, Biomet, Boston Scientific, Genzyme, Johnson & Johnson, Miltenyi Biotec, Medtronic, Smith & Nephew, Stryker, Synthes and Zimmer.

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, Boston Scientific, Genzyme, J&J/Cordis, 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, formerly, Bthc VI, Cytori Therapeutics, Gamida Cell, Geron, Isologen, Mesoblast, Osiris Therapeutics, StemCells, and ViaCell.

#### 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

As of August 31, 2007, we employed approximately 67 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 officers, and their respective ages as of August 31, 2007, are as follows:

Name	Age	Position
George W. Dunbar	61	Chief Executive Officer, President and Director
Gerald D. Brennan, Jr., J.D.	56	Vice President, Administrative & Financial Operations and Chief Financial Officer

*George W. Dunbar* joined Aastrom as Chief Executive Officer, President, and a member of the Company's Board of Directors in July 2006. 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 Sonus Pharmaceuticals and 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 and The Valley Medical Center Foundation. Mr. Dunbar received a B.S. in Electrical Engineering and an MBA from Auburn University.

Gerald D. Brennan, Jr., J.D. joined Aastrom in July 2005 as its Vice President Administrative & Financial Operations and Chief Financial Officer. He comes to the Company from Great Lakes Chemical Corporation, where he served as Director New Ventures, and previously served as Chief Financial Officer of Great Lakes Fine Chemical Division and Monsanto Pharma Tech. Prior to that time, Mr. Brennan was Chief Financial Officer and Chief Operating Officer of Capcom Coin-Op, Inc., and he served in various management positions at Tupperware including Vice President of Distributor Operations and Administration for Tupperware North America, President of Tupperware Canada and General Counsel of Tupperware Worldwide. He has also served as Tax Counsel at Premark and as a Tax Manager at Coopers & Lybrand. Mr. Brennan holds a BSBA in Accounting and Business Economics, from Marquette University, and a JD from the University of Illinois. Mr. Brennan is a member of the Illinois Bar, and is a Certified Public Accountant in the State of Illinois.

#### **Available Information**

Additional information about Aastrom is contained at our website, <u>www.aastrom.com</u>. Information on our website is not incorporated by reference into this report. We make available on our website our Annual Report 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

In 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, 2007, we have incurred a cumulative net loss totaling approximately \$159 million, and we have continued 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 incur significant operating losses 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.

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

We will require substantial capital resources in order to conduct our operations and develop our products and cell manufacturing facilities. We expect that our available cash, cash equivalents, short-term investments and interest income will be sufficient to finance currently planned activities beyond the end of fiscal year 2008 (ending June 30, 2008). However, 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 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 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.

#### 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 certain countries in the EU. 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 technologies and product candidates, or if one or more patients die or suffer severe complications, the FDA or other regulatory authorities could delay or withhold regulatory approval of our product candidates.

Finally, even if we obtain regulatory approval of a product, that approval may be subject to limitations on the indicated uses for which it may be marketed. Even after granting regulatory approval, the FDA and regulatory agencies in other countries continue to review and inspect marketed products, manufacturers and manufacturing facilities, which may create additional regulatory burdens. Later discovery of previously unknown problems with a product, manufacturer or facility, may result in restrictions on the product or manufacturer, including a withdrawal of the product from the market. Further, regulatory agencies may establish additional regulations that could prevent or delay regulatory approval of our products.

## Any changes in the governmental regulatory classifications of our products could prevent, limit or delay our ability to market or develop our products.

The FDA establishes regulatory requirements based on the classification of a product. 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 have delayed some of our current planned clinical trials with TRC-based products in the EU, and 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.

Commercialization in the U.S. and the EU of our cell product candidates will require completion of substantial clinical trials, and obtaining 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 power to be safe and efficacious in clinical trials, and we may not obtain the requisite regulatory approvals for our technologies or product candidates. 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 are sufficient for a marketable or regulatory approvable product.

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

We rely solely on third parties such as Astro, 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 a third party manufacturer, Fraunhofer Institute for Interfacial Engineering and Biotechnology in Stuttgart, Germany, to supply our TRC-based cell products for certain EU clinical trials. 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. Both sites could be subject to ongoing, periodic, unannounced inspection by regulatory agencies to ensure strict compliance with cGMP 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 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 market place 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 payors 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. 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 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 \$1.13 and \$1.60 during the twelve month period ended June 30, 2007. 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

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

### Our stock 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) to maintain the listing of our common stock on the Nasdaq Capital Market. In May 2003 and in July 2004, we received notification from Nasdaq of potential delisting as a result of our stock trading below \$1.00 for more than thirty consecutive business days. While in each case our stock price recovered within the permitted grace periods and Nasdaq notified us that we were again in full compliance, we cannot provide any assurance that our stock price would again recover within the specified times if future closing bid prices below \$1.00 triggered another potential delisting. The qualitative tests we must meet address various corporate governance matters, including Audit Committee and Board composition. In the past, we experienced director resignations and are devoting increased resources to Board member recruitment and retention. If we do not maintain compliance with the Nasdaq requirements within specified periods and subject to permitted extensions, our common stock may be recommended for delisting (subject to any appeal we would file). 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.

### 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.

#### 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 two 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.

## 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 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 that 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 prospectus, 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 not currently 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

Beginning on 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

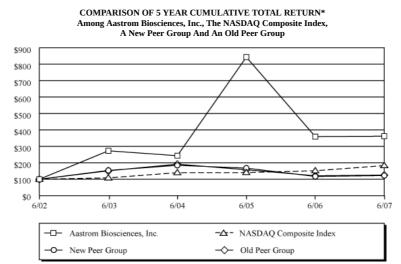
	High	Low
Year ended June 30, 2006:		
1st Quarter	\$ 3.49	\$ 2.19
2nd Quarter	2.37	1.94
3rd Quarter	2.24	1.65
4th Quarter	1.92	1.11
Year ended June 30, 2007:		
1st Quarter	1.50	1.13
2nd Quarter	1.60	1.13
3rd Quarter	1.58	1.24
4th Quarter	1.58	1.33

As of August 31, 2007, there were approximately 576 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: Cytori Therapeutics, GenVec, Inc., Geron Corp., Isolagen, Inc., Orthovita, StemCells, Inc. and ViaCell, Inc., and a new peer group consisting of the following regenerative medicine companies: Advanced Cell Technology, Inc., Athersys, Inc., formerly Bthc VI, Inc., Cytori Therapeutics, Geron Corp., Isolagen, Inc., Osiris Therapeutics, Inc., StemCells, Inc. and ViaCell, Inc., for the period commencing on June 30, 2002 and ending on June 30, 2007. <sup>1</sup>



\* \$100 invested on 6/30/02 in stock or index-including reinvestment of dividends. Fiscal year ending June 30.

Aastrom/Index	6/30/02	6/30/03	6/30/04	6/30/05	6/30/06	6/30/07
Aastrom Biosciences, Inc.	\$100.00	\$272.97	\$243.24	\$843.24	\$359.46	\$362.16
Nasdaq Composite Index	100.00	108.29	139.82	140.70	151.54	183.10
New Peer Group	100.00	153.59	184.63	167.55	116.96	122.43
Old Peer Group	100.00	151.33	191.71	157.70	120.96	125.55

<sup>1</sup> Assumes that \$100.00 was invested on June 30, 2002 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, 2007

The following table sets forth information as of June 30, 2007 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)	11,057,999	\$	1.48	2,783,751
Equity compensation plans not approved by security holders (financings or				
services related)(2)	495,868	\$	1.74	_
Balance, June 30, 2007	11,553,867	\$	1.50	2783,751(1)

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

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

#### Selected Financial Data Item 6.

The statement of operations data for the years ended June 30, 2005, 2006 and 2007 and for the period from March 24, 1989 (Inception) to June 30, 2007 and the balance sheet data at June 30, 2006 and 2007, 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, 2003 and 2004, and the balance sheet data at June 30, 2003, 2004 and 2005, 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."

Statement of Operations Data	2003	2004	<u>ear Ended Jun</u> 2005 (In thousands,	20		2007 amounts):	(	Iarch 24, 1989 Inception) to June 30, 2007
Revenues:								
Product sales and rentals	\$ 314	\$ 49	\$ 387	\$	159	\$ 94	\$	1,371
Research and development agreements	10	75						2,105
Grants	520	1,178	522		704	591		9,343
Total revenues	844	1,302	909		863	685		12,819
Costs and expenses:								
Cost of product sales and rentals(1)	893	280	148		11	29		2,833
Research and development	5,647	6,289	7,206		9,484	11,443		121,570
Selling, general and administrative	4,017	5,390	5,972		9,101	8,682		57,272
Total costs and expenses	10,557	11,959	13,326		8,596	20,154		181,675
Loss from operations	(9,713)	(10,657)	(12,417)	(1	7,733)	(19, 469)		(168,856)
Other income (expense):								
Other income	_	_	12		_	_		1,249
Interest income	134	169	594		1,258	1,875		9,098
Interest expense								(267)
Net loss	<u>\$ (9,579</u> )	\$ (10,488)	<u>\$ (11,811)</u>	<b>\$</b> (1	6,475)	\$ (17,594)	\$	(158,776)
Net loss applicable to common shares	\$ (9,579)	\$ (10,488)	\$ (11,811)	\$ (1	6,475)	\$ (17,594)		
Net loss per common share (basic and diluted)	\$ (.19)	\$ (.14)	\$ (.13)	\$	(.15)	<u>\$ (.15</u> )		
Weighted average number of common shares outstanding (basic and diluted)	50,984	73,703	93,541	10	6,314	119,523		
				June 30,				
	 2003	2004	20 (In tho			2006		2007
Balance Sheet Data:								
Cash, cash equivalents and short-term investments	\$ 10,512	\$ 16,93		32,414	\$	42,997	\$	28,325
Working capital	11,273	17,2		32,275		41,126		26,677
Total assets	12,155	18,1		33,897		44,881		32,848
Deficit accumulated during the development stage	(103,376)	(113,8		25,675)		(142,150)		(159,744)
Total shareholders' equity	11,575	17,6	08	33,028		42,342		28,251

Cost of product sales and rentals for the years ended June 30, 2003, 2004 and 2005 and for the period from Inception to June 30, 2007 include a charge of \$748, \$253, \$9 and \$2,239 for excess inventories, respectively.
 Net loss for fiscal years ended June 30, 2006 and 2007 included stock-based compensation expense under Financial Accounting Standards Board Statement No. 123R, "Share-Based Payment," ("SFAS 123R") of \$1.0 and \$2.8 million, respectively, related to employee and directors in accordance with Accounting Principles Board Option No. 25, "Accounting for Stock-based awards be comployees" ("APB 25") and its related interpretations, accordingly, we recognized no compensation expense for stock-based awards because the awards bad 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.

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

### Overview

We are a regenerative medicine company focused on the clinical development of autologous cell products for the repair or regeneration of multiple human tissues, based on 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 bone, vascular, cardiac and neural. TRC-based products have been used in over 250 patients, and are currently in the following stages of development:

- Bone regeneration Bone Repair Cells (BRCs):
  - Osteonecrosis of the femoral head:
    - U.S.: ON-CORE Phase III clinical trial; Orphan Drug Designation from the FDA for use in the treatment of osteonecrosis of the femoral head
    - Spain: Pivotal clinical trial
  - Non-union fractures:
    - U.S.: Patient enrollment completed in Phase I/II clinical trial; final patient results expected to be reported in October 2007
- Vascular regeneration Vascular Repair Cells (VRCs):
- · Critical limb ischemia:
  - U.S.: RESTORE-CLI Phase IIb clinical trial
- · Germany: Phase I/II clinical trial; interim data expected to be reported in October 2007
- Cardiac regeneration Cardiac Repair Cells (CRCs):
  - Chronic heart disease:
    - Preclinical research underway; clinical program under development; Orphan Drug Designation from the FDA for use in the treatment of dilated cardiomyopathy, a severe
      chronic disease of the heart
- Neural regeneration Neural Repair Cells (NRCs):
  - Spinal cord injury:
  - · Preclinical research underway; 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 patented and proprietary 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 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 bone, vascular, cardiac, neural, and the hematopoietic and immune systems.

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 that time we have phased out our marketing efforts promoting the cell manufacturing system as a commercial product in the U.S. Currently, we have product



sales consisting of limited sales of manufacturing supplies to academic collaborators for research and limited revenue related to cell-based products.

Our current focus is on utilizing our TRC Technology to produce autologous cell-based products for use in regenerative medicine. 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 more significant TRC-based cell product sales commence. Until that time, we expect that our revenue sources will consist of only minor sales of our cell products, and dendritic cell and T-cell manufacturing supplies to our academic collaborators, grant revenue, research funding and potential licensing fees or other financial support from potential future corporate collaborators.

We are beginning to explore the possibility of entering into complementary regenerative medicine business activities, whether through acquisition or otherwise.

To date, we have financed our operations primarily through public and private sales of our equity securities, and we expect to continue obtaining required capital in a similar manner. As a development stage company, we have never been profitable and do not anticipate having net income unless and until significant product sales commence. This is not likely to occur until we obtain significant additional funding, complete the required clinical trials for regulatory approvals, and receive the necessary approvals to market our products. Through June 30, 2007, we have accumulated a net loss of approximately \$159 million, and we have continued to incur losses since that date. 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. Note 1 to our consolidated financial statements "Overview and Summary of Significant Accounting Policies" summarizes each of our significant accounting policies. We believe the following critical accounting policy affects our more significant judgments and estimates used in the preparation of our consolidated financial statements.

Stock-Based Compensation — Effective July 1, 2005, we adopted SFAS 123R using the modified prospective method and therefore have not restated prior periods' results. Under the fair value recognition provisions of SFAS 123R, 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 123R, we accounted for stock-based payments under APB 25 and its interpretations.

Calculating stock-based compensation expense requires the input of highly subjective assumptions. We apply the Black-Scholes option-pricing model to determine the fair value of our stock options. Inherent in this model are assumptions related to expected stock-price volatility, option life, risk-free interest rate and dividend yield. We estimate the volatility of our common stock at the date of grant based on historical volatility. We estimate the expected life of options that vest solely on service, using the simplified method provided for in the Securities and Exchange Commission Staff Accounting Bulletin No. 107 for "plain vanilla options." The risk-free interest rate is based on the U.S. Treasury zero-coupon yield curve on the grant date for a maturity similar to the expected life of the options. The dividend rate is based on our historical rate, which we anticipate to remain at zero. The assumptions used in calculating the fair value of stock options represent our best estimates, but these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and different assumptions are used, the stock-based compensation expense could be materially different in the future. In addition, we are required to estimate the expected forfeiture rate and only recognize expense for those stock options and restricted

stock awards and units expected to vest. We estimate the forfeiture rate based on historical experience of our stock-based awards. If the actual forfeiture rate is different from the estimate, we would report the effect of any change in estimated forfeiture rate in the period of change.

*Performance-Based Stock Options* — During the year ended June 30, 2007, the Board of Directors granted performance-based stock options (performance options) to certain key employees. These performance 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 these awards that are outstanding as of June 30, 2007 is approximately \$2,400,000. 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, 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. To date, no compensation expense has been recorded related to these options.

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

The first tranche (826,800 options) would vest if performance conditions are met by March 2008; the second tranche (826,800 options) would vest if performance conditions are met by June 2011; and, the third tranche (826,800 options) would vest if performance conditions are met by June 2012. None of these tranches can vest in less than one year from the date of the performance based option grant. 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.

On a quarterly basis, management reviews the progress toward the performance conditions necessary for these options to vest and has 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. However, it is possible that for the first tranche of options, progress toward the necessary performance conditions in the next three to six months may cause management to determine that this tranche of options is probable of vesting. If management had concluded that, as of June 30, 2007, this first tranche of options was probable of vesting, the Company would have recognized expense related to such options of approximately \$560,000.

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 \$685,000 in 2007, \$863,000 in 2006, and \$909,000 in 2005. Product sales and rentals revenues decreased to \$94,000 in 2007 from \$159,000 in 2006 and from \$387,000 in 2005. Total revenues decreased in 2007 primarily from the reduced volume of cell manufacturing supply sales for clinical trials and research by others, and revenue in 2005 included \$120,000 from the sale of a cell manufacturing system as a stand-alone product. Based upon our current business strategy, we are not marketing our cell manufacturing system as a stand-alone product. Our current focus is on utilizing our TRC Technology in cell manufacturing facilities to support our regenerative medicine development programs. At such time as we satisfy applicable regulatory approval requirements, we expect the sales of our TRC and related cell-based products will constitute nearly all of our product sales revenues.

Grant revenues decreased to \$591,000 in 2007 from \$704,000 in 2006 and increased from \$522,000 in 2005. Grant revenues in 2007 decreased from 2006 as a result of decreased activity on grants from the National Institutes of Health. Grant revenues in 2006 increased from 2005 due to increased grant activity. Grant revenues accounted for 86% of total revenues for 2007, 82% for 2006 and 57% for 2005 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 \$20,154,000 in 2007, \$18,596,000 in 2006 and \$13,326,000 in 2005. The increase in costs and expenses during the periods reflect the continued expansion of our research and development

activities to support regulatory submissions, on-going and planned tissue regeneration clinical trials in the U.S. and EU and the development of facilities for product manufacturing.

Cost of product sales and rentals were \$29,000 in 2007, \$11,000 in 2006 and \$139,000 in 2005. The fluctuation in cost of product sales and rentals is due to the changes in the volume of product sales and, for 2005, a provision to write- down inventory. Based upon our current business strategy, we do not expect to generate revenues from the sale of cell manufacturing system inventories in future periods.

Costs and expenses included an increase in research and development expenses to \$11,443,000 in 2007 from \$9,484,000 in 2006 and \$7,206,000 in 2005. These increases reflect continued expansion of our research and development activities to support regulatory submissions, on-going and planned tissue regeneration clinical trials in the U.S. and EU and the development of facilities for product manufacturing. Research and development expenses also include a non-cash charge of \$702,000 in 2007 and \$300,000 in 2006 relating to stock compensation recognized following our adoption of SFAS 123R 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. Research and development expenses for 2005, includes a non-cash charge of \$101,000 relating to a stock option awarded to a consultant.

Selling, general and administrative expenses decreased in 2007 to \$8,682,000 from \$9,101,000 in 2006 and increased from \$5,972,000 in 2005. The decrease from 2006 to 2007 is due to lower salaries and benefits as a result of management and employee changes and decreases in relocation and recruitment expenses. The increase from 2005 to 2006 is due to additional employee costs that included: salaries and benefits for additional staffing requirements, bonuses for certain employees, expenses associated with our management performance bonus plan, and expenses related to the separation of the former CEO. The amount of compensation expense in 2006 resulting from the separation of our former CEO was \$589,000, and the expenses associated with our management performance bonus plan was \$600,000. Selling, general and administrative expenses also include a non-cash charge of \$2,104,000 in 2007 and \$734,000 in 2006 relating to stock-based compensation recognized in accordance with SFAS 123R. 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. Additionally, in 2005 there was a non-cash charge of \$59,000 related to a variable stock option that was exercised.

Interest income was \$1,875,000 in 2007, \$1,258,000 in 2006 and \$594,000 in 2005. 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 and improved yields from our investments.

Our net loss was \$17,594,000, or \$.15 per common share in 2007, \$16,475,000, or \$.15 per common share in 2006, and \$11,811,000, or \$.13 per common share in 2005. These increases in net loss are primarily the result of increased research and development 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 development of TRC-based products, bone marrow-derived adult stem and early progenitor cells, for use in bone regeneration and vascular regeneration, as well as cardiac and neural regeneration. Clinical trials using TRC-based products have been initiated to evaluate: (i) the treatment of osteonecrosis of the femoral head (in the U.S. and EU) (ii) bone formation in patients with long bone fractures (in the U.S. and EU); and (iii) bone formation in spine fusion (in the U.S.). Clinical trials are open for patient enrollment in the U.S. and EU for the treatment of limb ischemia resulting from peripheral vascular disease. 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 shell life, and to decrease the cost of manufacturing our TRC-based products. Research and 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, 2007 (in thousands):

		Year Ended June 30	,
R&D Project	2005	2006	2007
TRC-based products	\$ 5,916	\$ 8,347	\$ 10,497
Other	1,290	1,137	946
Total	\$ 7,206	\$ 9,484	\$ 11,443

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," 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 1 a 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, 2007, we have generated cumulative Federal tax net operating loss and tax credit carryforwards of, \$80,700,000 and \$1,200,000, respectively, which will expire in various periods between 2007 and 2027, 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, 2007, have totaled approximately \$188 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 \$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. This loan is collateralized by manufacturing equipment, laboratory equipment and furniture acquired for our new leased facility and by a compensating cash balance equal to the stipulated loss value of the equipment and furniture. This balance declines ratably over the term of the loan. 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 combined cash, cash equivalents and short-term investments totaled \$42,997,000 at June 30, 2006, an increase of \$10,583,000 from June 30, 2005. During the year ended June 30, 2006, we raised net proceeds of \$24,755,000 through the sale of our equity securities. The primary uses of cash, cash equivalents and short-term investments during the year ended June 30, 2006 included \$13,518,000 to finance our operations and working capital requirements, and \$789,000 in capital equipment additions.

We expect that our total capital expenditures, other than possible business acquisitions for the fiscal year ending June 30, 2008 to be approximately \$436,000. The primary purpose of these expenditures will be for the acquisition of cell manufacturing and laboratory equipment. We expect our monthly cash utilization to average approximately \$1.7 million per month during fiscal year 2008.

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 2008 (ending June 30, 2008), 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 likely 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.

Contractual Obligations	Total	2008	2009 (In th	2010 ousands)	2011	More then 5 Years
Purchase order commitments	\$ 303	\$ 303	\$ —	\$ —	\$ —	\$ —
Operating leases	6,624	1,047	1,079	1,111	1,145	2,242
Long-term debt	1,536	439	441	474	182	_
Total	\$ 8,463	\$ 1,789	\$ 1,520	\$ 1,585	\$ 1,327	\$ 2,242

nts Due by Period

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 \$2.9 million.

#### New Accounting Standards

In September 2006, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards No. 157 (SFAS No. 157), "Fair Value Measurements" which clarifies the principle that fair value should be based on the assumptions market participants would use when pricing an asset or liability and establishes a fair value hierarchy that prioritizes the information used to develop those assumptions. Under the standard, fair value measurements would be separately disclosed by level within the fair value hierarchy. SFAS No. 157 is effective for us beginning the first quarter of fiscal year 2008. We do not believe SFAS No. 157 will have a material impact on their financial statements.

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

As of June 30, 2007, our cash and cash equivalents included money market securities and short-term investments consisting of short-term corporate debt securities with original maturities of less than twelve months. Due to the short duration of our investment portfolio, an immediate 10% change in interest rates would not have a material effect on the fair market value of our portfolio, therefore, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a sudden change in market interest rates.

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 consolidated financial statements listed in the accompanying index present fairly, in all material respects, the financial position of Aastrom Biosciences, Inc. and its subsidiaries (a development stage company) at June 30, 2007 and 2006, and the results of their operations and their cash flows for each of the three years in the period ended June 30, 2007, and for the period from March 24, 1989 (Inception) to June 30, 2007, 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, 2007, 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 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 audits (which were integrated audits for the fiscal years ended June 30, 2007, 2006 and 2005). 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, evidence supporting the amounts and disclosures in the 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 reporting included obtaining an understanding of internal control over financial reporting included obtaining an understanding of internal control over fina

As discussed in Notes 1 and 3 to the consolidated financial statements, the Company adopted Statement of Financial Accounting Standards No. 123R, "Share-Based Payment," on July 1, 2005.

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

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

/s/ PRICEWATERHOUSECOOPERS LLP Detroit, Michigan September 13, 2007

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

	 June 30, 2006 2007 (In thousands)			
ASSETS				
CURRENT ASSETS:				
Cash and cash equivalents	\$ 9,034	\$	13,439	
Short-term investments	33,963		14,886	
Receivables, net	139		78	
Inventories	1		8	
Other current assets	 528		1,766	
Total current assets	43,665		30,177	
PROPERTY AND EQUIPMENT, NET	 1,216		2,671	
Total assets	\$ 44,881	\$	32,848	
LIABILITIES AND SHAREHOLDERS' EQUITY				
CURRENT LIABILITIES:				
Accounts payable and accrued expenses	\$ 1,084	\$	1,823	
Accrued employee benefits	1,455		1,238	
Current portion of long-term debt	 		439	
Total current liabilities	2,539		3,500	
LONG-TERM DEBT	_		1,097	
COMMITMENTS AND CONTINGENCIES (Notes 5 and 6)				
SHAREHOLDERS' EQUITY:				
Common Stock, no par value; shares authorized — 250,000,000; shares issued and outstanding — 119,439,612 and 120,012,869,				
respectively	184,492		187,995	
Deficit accumulated during the development stage	 (142,150)		(159,744)	
Total shareholders' equity	 42,342		28,251	
Total liabilities and shareholders' equity	\$ 44,881	\$	32,848	

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

# AASTROM BIOSCIENCES, INC. (a development stage company) CONSOLIDATED STATEMENTS OF OPERATIONS

	2005	Year Ended June 30, 2006 (In thousands, exc	2007 cept per share amounts)	March 24, 1989 (Inception) to June 30, 2007
REVENUES:				
Product sales and rentals	\$ 387	\$ 159	\$ 94	\$ 1,371
Research and development agreements	_	—	—	2,105
Grants	522	704	591	9,343
Total revenues	909	863	685	12,819
COSTS AND EXPENSES:				
Cost of product sales and rentals	139	11	29	594
Cost of product sales and rentals — provision for excess inventories	9	_	_	2,239
Research and development	7,206	9,484	11,443	121,570
Selling, general and administrative	5,972	9,101	8,682	57,272
Total costs and expenses	13,326	18,596	20,154	181,675
LOSS FROM OPERATIONS	(12,417)	(17,733)	(19,469)	(168,856)
OTHER INCOME (EXPENSE):				i
Other income	12	_	_	1,249
Interest income	594	1,258	1,875	9,098
Interest expense	—	—	—	(267)
Total other income	606	1,258	1,875	10,080
NET LOSS	\$ (11,811)	\$ (16,475)	\$ (17,594)	\$ (158,776)
NET LOSS PER SHARE (Basic and Diluted)	\$ (.13)	\$ (.15)	\$ (.15)	
Weighted average number of common shares outstanding (Basic and Diluted)	93,541	106,314	119,523	

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

# CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY AND COMPREHENSIVE LOSS

			<b>6 0</b>		Deficit Accumulated During the	Total
	Preferred		Common St		Development	Shareholders'
	Shares	Amount	Shares	Amount	Stage	Equity
			(In thousands, exc	ept per share data	a)	
BALANCE, MARCH 24, 1989 (Inception)		\$ —	_	\$ -	\$ —	\$ —
Net loss and comprehensive loss Net loss					(112,896)	(112,896)
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 warrants, and issuance of stock under Employee Stock Purchase Plan			3,310,436	1,087		1,087
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				1,414		1,414
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 \$1,894			51,651,674	50,672		50,672
Issuance of stock under Direct Stock Purchase Plan			5,453	5		5
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, 2004	_		81,373,191	131,472	(113,864)	17.608
Net loss and comprehensive loss				. ,	(11,811)	(11,811)
Exercise of stock purchase warrants			2.043.826	2.873	( )- )	2.873
Exercise of stock options and issuance of stock under Employee Stock Purchase Plan			1,593,442	897		897
Issuance of stock under Direct Stock Purchase Plan			23,452	38		38
Compensation expense related to stock options granted granted				160		160
Issuance of common stock, net of issuance costs of \$5,629			17.294.874	23.263		23.263
BALANCE, JUNE 30, 2005			102.328.785	158,703	(125,675)	33.028
Net loss and comprehensive loss			102,020,700	100,700	(16,475)	(16,475)
Exercise of stock purchase warrants			205.883	253	(10,475)	253
Exercise of stock options			528,083	473		473
Issuance of restricted stock			342.817			475
Issuance of stock under Direct Stock Purchase Plan			90,294	143		143
Compensation expense related to stock options and restricted stock awards and units granted granted			50,254	1.034		1.034
Issuance of common stock, net of issuance costs of \$1.624			15.943.750	23,886		23,886
BALANCE, JUNE 30, 2006			119,439,612	184,492	(142,150)	42,342
DALANCE, JUNE 30, 2000 Net loss and comprehensive loss		_	115,435,012	104,452	(17,594)	(17,594)
Exercise of stock options			176.484	133	(17,354)	(17,354) 133
Issuance of restricted stock			39.675	135		155
Summe of restricted stock			(69,425)			
Issuance of stock under Direct Stock Purchase Plan			426.523	564		564
Source of sock under Direct Stock Functionse France Compensation expense related to stock options and restricted stock awards and units granted			420,323	2.806		2.806
Compensation expense related to Stock options and restricted stock awards and units granted BALANCE, JUNE 30, 2007		e	120.012.869	\$ 187,995	\$ (159,744)	\$ 28.251
DALAINCE, JUINE 30, 2007		» —	120,012,869	\$ 167,995	\$ (159,744)	» 28,251

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

# CONSOLIDATED STATEMENTS OF CASH FLOWS

	=	Year Ended June 30, 2005 2006 2007 (In thousands)				March 24, 1989 (Inception) to June 30, 2007		
OPERATING ACTIVITIES:				(III)	tious	musj		
Net loss	s	(11,811)	\$	(16,475)	\$	(17,594)	\$	(158,776)
Adjustments to reconcile net loss to net cash used for operating activities:		( )- )		(-, -,		( ) )		(
Depreciation and amortization		167		326		500		4,564
Loss on property held for resale		_		_		_		110
Amortization of discounts and premiums on Investments		(68)		(135)		(547)		(1,293)
Stock compensation expense		160		1,034		2,806		5,424
Inventories write downs and reserves		9		_		_		2,239
Stock issued pursuant to license agreement		_		_		_		3,300
Provision for losses on accounts receivable		9		39		—		204
Changes in assets and liabilities:								
Receivables		42		15		61		(327)
Inventories		264		115		(7)		(2,343)
Other current assets		(148)		(107)		(461)		(968)
Accounts payable and accrued expenses		151		551		633		1,717
Accrued employee benefits		160		1,119		(217)		1,238
Net cash used for operating activities		(11,065)		(13,518)		(14,826)		(144,911)
INVESTING ACTIVITIES:			_		_			
Organizational costs		_		_		_		(73)
Purchase of short-term investments		(25,938)		(43,900)		(49,376)		(181,338)
Maturities of short-term investments		8,000		28,078		69,000		167,745
Property and equipment purchases		(586)		(789)		(1,064)		(5,511)
Proceeds from sale of property held for resale				_		_		400
Net cash provided by (used for) investing activities		(18,524)		(16,611)		18,560		(18,777)
FINANCING ACTIVITIES:								
Net proceeds from issuance of preferred stock		_		_		_		51,647
Net proceeds from issuance of common stock		27,071		24,755		697		123,198
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)		(777)
Proceeds from long-term debt		_		—		751		751
Principal payments under capital lease obligations		_		_		_		(1,174)
Net cash provided by financing activities		27,071		24,755		671		177,127
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS		(2,518)		(5,374)		4,405		13,439
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD		16,926		14,408		9,034		_
CASH AND CASH EQUIVALENTS AT END OF PERIOD	\$	14,408	\$	9,034	\$	13,439	\$	13,439
SUPPLEMENTAL CASH FLOW INFORMATION:	<u>.</u>		_		-		-	
Interest paid	\$	_	\$	_	\$	_	\$	267
Equipment acquired under capital lease obligations	\$	_	s	_	\$	_	\$	1,174
Equipment acquirea ander capital lease obligations	<sup>b</sup>		φ		φ		Ψ	1,1/4

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

#### 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 it's operations at least until the end of fiscal year 2008 (ending June 30, 2008), 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, 2007, 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 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 significant losses on its cash equivalents or short-term investments.

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Inventories — The Company values its inventories, which consist primarily of our cell manufacturing system and our disposable cell production cassettes and base medium, at the lower of cost (specific identification using the first in, first out method) or market. The Company regularly reviews inventory quantities on hand and, when necessary, records a provision to write down excess inventories to their estimated net realizable value.

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 \$167,000, \$326,000, \$500,000 and \$4,564,000 for the years ended June 30, 2005, 2006, 2007 and for the period from Inception to June 30, 2007, 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 and rentals. 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. If there are remaining obligations, including training and installation (which the Company believes to be significant), revenue is not recognized until the completion of these obligations. Revenue from licensing fees under licensing agreements and rental revenue 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 123R using the modified prospective method and therefore did not restate prior periods' results. Under the fair value recognition provisions of SFAS 123R, 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. Prior to the adoption of SFAS 123R, the Company accounted for stock-based payments under APB 25 and its interpretations.

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 per share calculation where the effect of their inclusion would be anti-dilutive. The aggregate number of common equivalent shares that have been excluded from the computations of net loss per common share for the periods ended June 30, 2005, 2006 and 2007 is approximately 9,340,000, 8,939,000 and 16,106,000, 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.

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

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

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

New Accounting Standards — In September 2006, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards No. 157 (SFAS No. 157), "Fair Value Measurements" which clarifies the principle that fair value should be based on the assumptions market participants would use when pricing an asset or liability and establishes a fair value hierarchy that prioritizes the information used to develop those assumptions. Under the standard, fair value measurements would be separately disclosed by level within the fair value hierarchy. SFAS No. 157 is effective for the Company beginning the first quarter of fiscal year 2008. The Company does not believe SFAS No. 157 will have a material impact on their financial statements.

# 2. Selected Balance Sheet Information

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

		June 30,
	2006	2007
Machinery and equipment	\$ 1,957	\$ 2,561
Office equipment	1,029	1,159
Leasehold improvements	622	891
Equipment in process	111	
	3,719	4,611
Less accumulated depreciation and amortization	(2,503)	) (1,940)
	\$ 1,216	\$ 2,671

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

		June 30,	
	20	006	2007
Accounts payable	\$	356 5	\$ 532
Accrued expenses:			
Clinical studies		169	227
Manufacturing and engineering		273	76
Professional services		98	311
Lessor payment		—	386
Other		188	291
	\$	1,084	\$ 1,823
	\$	1,084	

# 

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):

		Jun	ie 30,	
	2	2006		2007
Accrued vacation pay	\$	251	\$	310
Performance bonuses		600		775
Payment to stay to former CEO		589		142
Other		15		11
	\$	1,455	\$	1,238

# 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 shares on the date of grant. The 2004 Plan replaced the 2001 Stock Option Plan and no new awards will be granted under the 2004 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 amendments to the 2004 Plan include the addition of 8,000,000 awards available for issuance under the 2004 Plan and the addition of certain performance criteria to permit the deductibility of performance-based compensation.

In September 2006, a new compensation program for outside directors was approved. Each non-employee director who continues to serve beyond an Annual Shareholder Meeting will receive a stock option, granted on the date of each Annual Meeting, to purchase 55,000 shares of common stock. These options will have an exercise price equal to the fair market value of common stock on the date of the grant, and will vest in equal quarterly increments over a period of one year. Newly elected directors joining the board during the period between Annual Meetings will receive a stock option grant for a pro rata amount of the 55,000 shares (reflecting the period of time until next Annual Meeting).

As of June 30, 2007, there were 5,912,095 of awards available for future grant under the Option Plans.

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# Service-Based Stock Options

During the year ended June 30, 2007, the Company granted 5,326,200 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 and 2007 was \$2.55 and \$0.88, respectively.

The Company's Option Plans allow a stock option holder continued vesting of stock options as well as exercisability of vested options through the original option term, as long as that stock option holder provides continued service to the Company. The Company's former Chief Executive Officer (CEO) ceased his employment with the Company in July 2006; however, he continued to provide service to the Company through November 2, 2006, through his participation on the Company's Board of Directors. On November 2, 2006 the former CEO ceased providing service as a member of the Board of Directors however the Company allowed him to continue to vest in his non-vested stock options through November 2, 2007, and also allowed him the ability to exercise his vested stock options for approximately 15 months subsequent to his termination of services. During the year ended June 30, 2007, the Company recorded approximately \$257,000 of stock-based compensation expense related to the additional vesting of non-vested options and longer exercisability of vested options after the former CEO terminated his services to the Company.

The net compensation costs recorded for the service-based stock options related to employees and directors (including the impact of the forfeitures and modifications described above) were approximately \$724,000 and \$2,598,000 for the years ended June 30, 2006 and 2007, 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 E June	
	2006	2007
Stock Option Plans:		
Expected dividend rate	0%	0%
Expected stock price volatility	72%	67%
Risk free interest rate	4.3%	4.9%
Estimated forfeiture rate	10%	10%
Expected life (years)	6.6	6.6

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

	Options	Weighted Average Exercise 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)	\$	.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)	\$	.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
Exercisable at June 30, 2007	2,777,951	\$	1.72	5.3	\$ 586,000

As of June 30, 2007 there was approximately \$1,865,000 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 3.0 years.

To date in fiscal year 2008, the Company granted to certain employees additional service-based options for the purchase of 1,631,800 of the Company's common stock.

# Performance-Based Stock Options

During the year ended June 30, 2007, the Board of Directors granted 2,800,400 performance-based stock options to certain key employees in three equal tranches of 933,467 options. The weighted average grant-date fair value of performance-based options granted under the Company's Option Plans during the year ended June 30, 2007 was \$0.95. 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. The aggregate estimated fair value of these awards that are outstanding as of June 30, 2007 is approximately \$2,400,000.

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.

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The first tranche would vest if performance conditions are met by March 2008; 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. None of these tranches can vest in less than one year from the date of the performance-based option grant. Each tranche of options is forfeited if its performance conditions are not met by the required timeframe, and vesting for any tranche of options is not dependent on the vesting of the other tranches of options.

For the year ended June 30, 2007, 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
Stock Option Plans:	
Expected dividend rate	0%
Expected stock price volatility	66%
Risk free interest rate	4.7%
Estimated forfeiture rate	0%
Expected life (years)	6.8

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

Options	Shares	hted Average ercise Price	Weighted Average Remaining Contractual Term	Aggre Intri Val	
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

### **Restricted Stock Awards**

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

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A summary of the Company's restricted stock activity for the years ended June 30, 2006 and 2007 is presented below:

Non-Vested Restricted Shares	Shares	 Weighted 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

The total market value (at the vesting date) of restricted stock award shares that vested during the year ended June 30, 2007 was \$93,000. There were no such shares that vested during the years ended June 30, 2005 and 2006.

As of June 30, 2007 there was approximately \$140,000 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 2.4 years.

# 2005 Employee Stock-Based Compensation

During fiscal year 2005 the Company recorded and reported its employee stock-based grants under the recognition and measurement principles of APB Opinion No. 25, "Accounting for Stock Issued to Employees" and related Interpretations. The following table illustrates the effect on net loss and net loss per share if the Company had applied the fair value recognition provisions of Statement of Financial Accounting Standards (SFAS) No. 123, "Accounting for Stock-Based Compensation" for the year ended June 30, 2005 (in thousands, except per share data):

	 June 30, 2005
Reported net loss	\$ (11,811)
Add: Stock-based employee compensation expense included in reported net loss	160
Deduct: Stock-based employee compensation expense determined under fair value based method for all awards	(721)
Pro forma net loss	\$ (12,372)
Earnings per share:	
As reported	\$ (.13)
Pro forma	\$ (.13)

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The fair value of options was estimated at the date of grant using the Black-Scholes option pricing model with the following assumptions:

	June 30, 2005
Dividend rate	None
Expected stock price volatility	72%
Risk-free interest rate	3.5% — 3.9%
Expected life of options	5 years

The weighted average fair value of options granted during the year ended June 30, 2005 was \$1.33 per share.

# Stock Purchase Warrants

In July 2003, the Company issued 5,058,824 shares of common stock to multiple private placement investors. As part of this transaction, the Company issued warrants to the private placement investors and placement agent, exercisable for 4 years, or until July 9, 2007, to purchase up to 1,568,235 shares of common stock at \$1.23, as well as warrants to purchase up to 1,011,765 shares of common stock at \$1.50 per share prior to October 31, 2003. These later warrants expired unexercised. At June 30, 2007, warrants to purchase up to 808,824 shares of common stock pursuant to these warrant agreements remained outstanding, however, as of July 9, 2007 all of these warrants were exercised for proceeds of \$995,000.

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 3.0 million shares of common stock at an exercise price of \$1.65 per share At June 30, 2007, warrants to purchase up to 2.4 million shares of common stock purchase.

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 and placement agent, 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, 2007, warrants to purchase up to 1,838,843 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,					
	2005		2006		-	2007
Loss before income taxes	\$	11,811	\$	16,475	\$	13,450
Federal statutory rate		34%		34%		34%
Taxes computed at federal statutory rate		(4,015)		(5,600)		(4,570)
State taxes, net of federal taxes		(354)		—		—
Increase (decrease) in taxes from:						
Stock compensation		80		(110)		950
Other, net		85		(10)		(270)
Valuation allowance		4,534		5,480		3,890
Reported income taxes	\$		\$		\$	

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

	June 30,				
	2006			2007	
Net operating loss carryforwards	\$	25,500	\$	29,900	
Research and development credit carryforwards		935		1,200	
Inventories		435		435	
Property and equipment		120		120	
Employee benefits		550		460	
Other, net		190		220	
Total deferred tax assets		27,730		32,335	
Valuation allowance		(27,730)		(32,335)	
Net deferred tax assets	\$	_	\$	_	

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

The Company has issued shares of common stock in prior years, which resulted in multiple ownership changes under Section 382 of the Internal Revenue Code. Consequently, the utilization of net operating loss and tax credit carryforwards is significantly limited. Such limitations may result in these carryforwards expiring before the Company utilizes them. At June 30, 2007 the Company estimates the maximum Federal tax net operating loss and tax credit carryforwards, which could be utilized, were \$80,700,000 and \$1,200,000, respectively. If this Federal tax net operating loss and tax credit carryforwards may become subject to further annual limitation in the event of future change in ownership events.

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#### 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 totaled approximately \$6,000 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

On January 31, 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 \$785,000 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.

On June 25, 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 \$777,000 at June 30, 2007, which is recorded as a component of other current assets.

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As of June 30, 2007, future minimum payments related to our operating leases and long-term debt are as follows (in thousands):

Year Ending June 30,	Operating Leases	Debt		
2008	\$ 1,047	\$ 439		
2009	1,079	441		
2010	1,111	474		
2011	1,145	182		
2012	1,179	—		
Thereafter	1,063	_		
Total	\$ 6,624	\$ 1,536		

Rent expense for the years ended June 30, 2005, 2006 and 2007, was \$626,000, \$626,000 and \$679,000, respectively, and \$7,010,000 for the period from Inception to June 30, 2007.

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 \$2.9 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 \$137,000, \$160,000 and \$172,000 for the years ended June 30, 2005, 2006 and 2007, respectively and \$845,000 for the period from Inception to June 30, 2007.

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

Year Ended June 30, 2007	Firs	First Quarter Se		econd Quarter		Third Quarter		Fourth Quarter		Fiscal Year	
Revenues	\$	104	\$ 158 \$		258	\$ 165		\$	685		
Loss from operations		(4,584)		(4,740)		(4,922)		(5,223)		(19,469)	
Net loss		(4,057)		(4,225)		(4,483)		(4,829)		(17,594)	
Net loss per common share		(.03)		(.04)		(.04)		(.04)		(.15)	
		First Quarter Second Quarter									
Year Ended June 30, 2006	Firs	t Quarter	Seco	nd Quarter	Third	Quarter	Fourt	h Quarter	Fi	scal Year	
Year Ended June 30, 2006 Revenues	Firs	t Quarter 180	Secon \$	nd Quarter 117	Third \$	Quarter 238	Fourt \$	h Quarter 328	Fi \$	scal Year 863	
-	Firs \$	-	-		¢						
Revenues	Firs \$	180	-	117	¢	238		328		863	

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**

As required by Rule 13a-15(b) under the Securities Exchange Act of 1934, as amended, we conducted an evaluation under the supervision and with the participation of our management, including the Company's Chief Executive Officer and Chief Financial Officer, we evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that our current disclosure controls and procedures were effective in ensuring that all information required to be disclosed in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission rules and forms.

#### 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 Chief Executive Officer and Chief Financial Officer 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 under the supervision and with the participation of the Company's Chief Executive Officer and Chief Financial Officer, assessed the effectiveness of our internal control over financial reporting as of June 30, 2007 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, 2007, and has expressed an unqualified opinions thereon in their report which appears under Item 8.

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

During our fourth quarter of fiscal 2007 there were no changes made in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

#### 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 2007 Annual Meeting of Shareholders scheduled for November 7, 2007.

#### 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

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, 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".

# Item 15. Exhibits

(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.

By:

/s/ GEORGE W. DUNBAR George W. Dunbar Chief Executive Officer and President (Principal Executive Officer)

Date: September 13, 2007

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below on September 13, 2007 by the following persons in the capacities indicated.

 Signature
 Title

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

# EXHIBIT INDEX

Number	Notes	
3.1	K	Restated Articles of Incorporation of Aastrom, as amended.
3.2	Н	Bylaws, as amended.
10.1#	Α	Form of Indemnification Agreement.
10.2#	Α	Amended and Restated 1992 Incentive and Non-Qualified Stock Option Plan and forms of agreements thereunder.
10.3#	Α	1996 Outside Directors Stock Option Plan and forms of agreements thereunder.
10.20#	Α	Form of Employment Agreement.
10.21	Α	License Agreement, dated July 17, 1992, between J.G. Cremonese and Aastrom and related addenda thereto dated July 14, 1992 and July 7, 1993.
10.26	А	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.
10.27#	Α	Employee Proprietary Information and Invention Agreement, effective June 1, 1991, between Aastrom and R. Douglas Armstrong.
10.72#	В	Aastrom Biosciences 2001 Stock Option Plan.
10.76	С	Master Supply Agreement with Astro Instrumentation, LLC
10.77	E	Supply Agreement between Aastrom and Moll Industries, Inc., dated December 16, 2003.
10.78#	F	Employment Agreement with James Cour dated June 11, 2004.
10.80#	F	Employment Agreement with R. Douglas Armstrong dated August 27, 2004.
10.81#	F	Amended and Restated Employment Agreement with Brian Hampson dated August 27, 2004.
10.82#	F	2004 Equity Incentive Plan.
10.83#	G	Employment Agreement with Robert Bard dated March 1, 2005.
10.84#	Н	Form of Option and Restricted Stock Award Agreements for Grants under 2004 Equity Incentive Plan
10.85	Н	Employee Compensation Guidelines.
10.86#	Н	Employment Agreement with Gerald D. Brennan, Jr. dated June 10, 2005.
10.87	Н	Amendment dated December 5, 2002 to License Agreement with the University of Michigan.
10.88#	I	Revised Employment Agreement with R. Douglas Armstrong dated December 27, 2005.
10.89#	I	Revised Employment Agreement with James A. Cour dated January 12, 2006.
10.90#	J	Employment Agreement with George W. Dunbar dated July 17, 2006.
10.91#	J	Consulting Agreement with R. Douglas Armstrong dated July 17, 2006.
10.92#	J	Separation Agreement with James A. Cour dated July 14, 2006.
10.93#	Μ	Summary of Changes to Employee Compensation Guidelines.
10.94#	L	2004 Equity Incentive Plan, as amended.
10.95#	L	Forms of Grant Notice and Stock Option Agreement for Grants under 2004 Equity Incentive Plan, as amended.
21		Subsidiaries of Registrant.
23.1		Consent of Independent Registered Public Accounting Firm.
31.1		Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2		Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1		Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2		Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
T		a ta Anstrony's Disciptorian Catherina an France C 1 (No. 202 15415). Judand effectivo en Fabricano 2, 1007

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

B Incorporated by reference to Aastrom's Annual Report on Form 10-K for the year ended June 30, 2002.

C Incorporated by reference to Aastrom's Annual Report on Form 10-K for the year ended June 30, 2003.

D Incorporated by reference to Aastrom's Quarterly Report on Form 10-Q for the quarter ended September 30, 2005.

E Incorporated by reference to Aastrom's Annual Report on Form 10-K for the year ended June 30, 2004.

- F Incorporated by reference to Aastrom's Quarterly Report on Form 10-Q for the quarter ended September 30, 2004.
- G Incorporated by reference to Aastrom's Quarterly Report on Form 10-Q for the quarter ended March 31, 2005.
- H Incorporated by reference to Aastrom's Current Report on Form 8-K filed on September 12, 2007.
- I Incorporated by reference to Aastrom's Quarterly Report on Form 10-Q for the quarter ended December 31, 2005.
- J Incorporated by reference to Aastrom's Current Report on Form 8-K filed on July 18, 2006.
- K Incorporated by reference to Aastrom's Quarterly Report on Form 10-Q for the quarter ended September 30, 2006.
- L Incorporated by reference to Aastrom's Current Report on Form 8-K filed on November 8, 2006.
- M Incorporated by reference to Aastrom's Quarterly Report on Form 10-Q for the quarter ended December 31, 2006.
- # Management contract or compensatory plan or arrangement covering executive officers or directors of Aastrom.

# 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-8 (Nos. 333-121006, 333-115505, 333-81340, 333-51556, 333-38886, 333-140624 and 333-25021) and Form S-3 (Nos. 333-123570, 333-108963, 333-108964), 333-108964 and 333-107579) of Aastrom Biosciences, Inc. (a development stage company) of our report dated September 13, 2007 relating to the financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

PricewaterhouseCoopers LLP Detroit, Michigan September 13, 2007

# CERTIFICATION

I, George W. Dunbar, certify that:

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1. I have reviewed this Form 10-K of Aastrom Biosciences, Inc.;

- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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.

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: September 13, 2007

/s/ George W. Dunbar

George W. Dunbar Chief Executive Officer and President

# CERTIFICATION

I, Gerald D. Brennan, Jr., certify that:

1. I have reviewed this Form 10-K of Aastrom Biosciences, Inc.;

- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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.

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: September 13, 2007

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/s/ GERALD D. BRENNAN, JR. Gerald D. Brennan, Jr. Vice President, Administrative & Financial Operations and Chief Financial 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, 2007, 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: September 13, 2007

/s/ George W. Dunbar

George W. Dunbar Chief Executive Officer and President

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.

## 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, 2007, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Gerald D. Brennan, Jr., Vice President Administrative and Financial Operations and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 ("Section 906"), that 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: September 13, 2007

/s/ Gerald D. Brennan, Jr.

Gerald D. Brennan, Jr. Vice President, Administrative & Financial Operations and Chief Financial 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.