

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
Form 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
The fiscal year ended **June 30, 2006**

or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____

Commission file number 0-22025

Aastrom Biosciences, Inc.

(Exact name of registrant as specified in its charter)

Michigan
(State or other jurisdiction of
incorporation or organization)

94-3096597
(I.R.S. Employer
Identification No.)

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

(Address of principal executive offices, including zip code)

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

Securities registered pursuant to Section 12(b) of the Act:
Common Stock, no par value

Securities registered pursuant to Section 12(g) of the Act:
None

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer (as defined in Rule 12b-2 of the Exchange Act).

Large accelerated filer Accelerated filer Non-accelerated filer

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

The approximate aggregate market value of the registrant's Common Stock, no par value ("Common Stock"), held by non-affiliates of the registrant (based on the closing sales price of the Common Stock as reported on the Nasdaq Capital Market) on December 31, 2005 was approximately \$216 million. This computation excludes shares of Common Stock held by directors, officers and each person who holds 5% or more of the outstanding shares of Common Stock, since such persons may be deemed to be affiliates of the registrant. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of August 31, 2006, 119,487,843 shares of Common Stock, no par value, were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Document	Form 10-K Reference
Proxy Statement for the Annual Meeting of Shareholders scheduled for November 2, 2006	Items 10, 11, 12, 13 and 14 of Part III

AASTROM BIOSCIENCES, INC.
ANNUAL REPORT ON FORM 10-K
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Except for the historical information presented, the matters discussed in this Report, including our product development and commercialization goals and expectations, our plans and anticipated 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" in "Management's Discussion and Analysis of Financial Condition and Results of Operations." 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 development stage company focused on the development of autologous cell products for use in regenerative medicine. Our pre-clinical and clinical product development programs utilize patient-derived bone marrow stem and progenitor cell populations, and are being investigated for their ability to aid in the regeneration of tissues such as vascular, bone, cardiac and neural.

Our platform Tissue Repair Cell (TRC) technology is based on 1) our cell products which are a unique cell mixture containing large numbers of stromal, stem and progenitor cells, produced outside of the body from a small amount of bone marrow taken from the patient, and 2) the means to produce these products in an automated process. TRC-based products have been used in over 225 patients, and are currently in active clinical trials for bone regeneration (long bone fractures and spine fusion) and vascular regeneration (diabetic patients with critical limb ischemia) applications. We have reported positive interim clinical trial results for TRCs suggesting both the clinical safety and the ability of TRCs to induce tissue regeneration in long bone fractures and jaw bone reconstruction. Recently, our proprietary TRC cell product received an Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) for use in the treatment of osteonecrosis of the femoral head. In addition, we are developing plans for a TRC-based therapy for cardiac regeneration.

Our primary business is to develop our TRC-based products for use in multiple therapeutic areas. Currently, we intend to pursue TRC-based cell products for the following therapeutic areas:

- Vascular tissue regeneration
- Bone tissue regeneration
- Cardiac tissue regeneration
- Neural tissue regeneration

We have developed a patented manufacturing system to produce human cells for clinical use. This automated cell manufacturing system enables our "single-pass perfusion" cell culture process. Single-pass perfusion is our patented technology for growing large quantities of human cells. These cells include adult stromal, stem and progenitor cell populations, which are considered to be required in the formation of tissues such as vascular, bone, cardiac and neural, as well as the hematopoietic system and its supporting stroma.

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 cell product sales commence. Until that time, we expect that our revenue sources will consist of only minor sales of our cell products such as TRCs, and our dendritic cell and T-cell kits to academic research centers, grant revenue and research funding, and potential licensing fees or other financial support from potential future corporate collaborators.

To date, we have financed our operations primarily through public and private sales of our equity securities, and we expect to continue obtaining required capital in a similar manner. As a development-stage company, we have never been profitable and do not anticipate having net income unless and until significant product sales commence. This is not likely to occur until we obtain significant additional funding, complete the required clinical trials for

regulatory approvals, and receive the necessary approvals to market our products. Through, June 30, 2006, we have accumulated a net loss of approximately \$141 million. We cannot provide any assurance that we will be able to achieve profitability on a sustained basis, if at all, obtain the required funding, obtain the required regulatory approvals, or complete additional corporate partnering or acquisition transactions.

Clinical Development

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

The pre-clinical data for our TRCs have shown a substantial increase in the stem and progenitor cells that can develop into tissues such as hematopoietic (i.e., blood forming) or mesenchymal, (i.e., developing into tissues characteristic of certain internal organs) as well as certain key populations of stromal progenitor cells that produce various growth factors. We have demonstrated in the laboratory that TRCs can progress into bone cell and blood vessel cell lineages. Based on these pre-clinical observations, we initiated clinical trials in the U.S. and European Union (EU) for bone regeneration in patients with severe long bone fractures, and in the EU for vascular tissue regeneration in patients with critical limb ischemia as a result of peripheral arterial disease.

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 TRCs in a timely fashion, or at all. See "Risk Factors."

Clinical Trials Summary

Vascular Tissue Regeneration

Critical Limb Ischemia:

Based on our laboratory observations that TRCs 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 a trial to evaluate the safety and efficacy of TRCs in the treatment of diabetics with critical limb ischemia.

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 efficacy of TRCs to improve peripheral circulation in diabetic patients with critical limb ischemia. An approved Investigational Medicinal Product Dossier (IMPD) — the required filing in the EU for a clinical trial — and the cell manufacturing license required in Germany were obtained, and patient accrual is ongoing.

We are in the process of preparing to submit a clinical trial protocol in the U.S. to treat patients suffering from critical limb ischemia with the goal of reducing of the incidence of major amputations.

Bone Regeneration

Long Bone Fractures:

A U.S. Phase I/II clinical trial for the treatment of severe long bone non-union fractures is ongoing under an FDA-approved Investigational New Drug (IND) application 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; Lutheran Medical Center, Brooklyn, NY; and, the University of Nebraska Medical Center, Omaha, NE, with enrollment of up to 36 patients. As of June 30, 2006, we have accrued and treated all 36 patients in this trial, and are continuing the required follow-up of those patients. Data collection will be completed in July 2007, and we will initiate data analysis thereafter.

In March 2006, results based on clinical experience with the first seven patients treated in the U.S. Phase I/II long bone fracture trial were presented by the Principal Investigator at the combined Orthopaedic Research Society

and American Academy of Orthopaedic Surgeons meetings in Chicago, IL. The report stated that all seven patients exhibited bone healing by the 6 month endpoint, and four of the seven patients exhibited early healing by 3 months. These patients had previously failed to heal after an average of two prior surgeries utilizing standard of care treatments. No TRC-related adverse events were reported.

Bone regeneration studies in the EU were conducted at centers in Spain and Germany, under Ethical Committee approvals. Results from the Phase I clinical trial conducted at Hospital General de l'Hospitalet, Centro Médico 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 observations. No TRC-related adverse events were observed. Following the Phase I trial, an IMPD was filed and we obtained permission from the Spanish Drug Agency (AEMPS) to commence a Phase II non-union fracture trial in Spain. This study can accrue up to 10 patients, and is actively enrolling.

Spine Fusion:

We are conducting a Phase I/II spine fusion clinical trial in the U.S., to accrue up to 25 patients. In addition, we are preparing for a clinical study in Spain to evaluate the use of TRCs in spine fusions.

Osteonecrosis:

In March 2006, our proprietary TRCs received an Orphan Drug Designation from the FDA for use in the treatment of osteonecrosis of the hip. We are in the process of preparing a clinical trial protocol in the U.S.; we are also preparing for similar clinical studies in the EU.

Jaw Bone Reconstruction:

We have completed a jaw (maxilla) bone regeneration clinical feasibility control 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 trial has enrolled the targeted 5 patients for the evaluation of bone regeneration resulting from TRCs compared with a standard bone grafting procedure. Four months after cell therapy, the treatments that included TRCs had reduced swelling, and significant height increase of the bone in the grafted area as determined in radiographic images. Histologic observations made on tissue sections adjacent to the grafted area showed changes consistent with the stimulation of bone turnover and with the induction of new connective tissue.

Additional Activity

In certain non-U.S. regions, autologous cell products such as TRCs may be marketed without further registration or marketing authorization. We are exploring these types of markets through commercial supply agreements to gain additional clinical information to support our clinical trial strategy. We have completed one limited commercial evaluation agreement under this type of arrangement.

Product Development

Our current product development efforts are focused on the development of our autologous cell products, TRCs, for use in vascular tissue regeneration (critical limb ischemia), bone regeneration applications (fractures, spine fusion and osteonecrosis), cardiac tissue regeneration and neural tissue regeneration. Our TRCs have been used in over 225 human patients in several clinical trials. (See "Clinical Development.") We believe that TRCs 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 functionality for certain clinical indications, improving product shelf life, and decreasing the cost of manufacturing our TRC products. Our programs are also exploring the capability of TRCs to generate different types of human tissues. These production process changes may alter the functionality of our TRCs, 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.

Research and development expenses for the fiscal years ended June 30, 2004, 2005 and 2006 were \$6,289,000, \$7,206,000 and \$9,484,000, 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 TRCs.

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 TRCs.

Manufacturing

Cell Manufacturing

Aastrom's TRC cell products will be regulated in the U.S., EU and other markets as biologics/pharmaceuticals. With this classification, commercial manufacturing of TRCs 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 TRCs 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 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 three-year 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 includes an annual provision for automatic 12 month extensions. 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 agreement continuing with Moll Industries as our supplier of the cell culture cassettes used in the production of TRCs. Under this agreement, Moll will perform 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 the options to seek a development and/or commercialization partnerships, or to make the investment to complete development and commercialize a product alone will be evaluated. 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, 2004, 2005 and 2006 were \$10,000, \$194,000 and \$74,000, respectively. Foreign product sales and rentals for the fiscal years ended June 30, 2004, 2005 and 2006 were \$39,000, \$193,000 and \$85,000, 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, and non-exclusive rights to one other issued U.S. patent. These patents present various claims related to the following, as well as other, areas: (i) certain methods for enabling *ex vivo* stem cell division (for cells derived from bone marrow, peripheral blood, umbilical cord blood, or the spleen) or improving the *ex vivo* production of progenitor cells, and the therapeutic use of these cells where normal bone marrow has a therapeutic effect; (ii) certain apparatus for cell culturing, including a bioreactor suitable for culturing human stem cells or human hematopoietic cells; (iii) certain methods of infecting or transfecting target cells with vectors; and (iv) a cell composition containing human stem cells or progenitor cells, or genetically modified stem cells, when such cells are produced in an *ex vivo* medium exchange culture and have been originally derived from bone marrow, peripheral blood, umbilical cord blood, or the spleen. Certain patent equivalents to the U.S. patents have also been issued in other jurisdictions including Australia and Canada and under the European Patent Convention. Certain of these foreign patents are due to expire beginning in 2008. In addition, we have filed applications for patents in the U.S. and equivalent applications in certain other countries claiming other aspects of our products and processes, including 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 shortly before a patent's issuance, 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 and others 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 have not conducted freedom of use patent searches and no assurance can be given that patents do not exist or could not be filed which would have an adverse affect on our ability to market our products or maintain our competitive position with respect to our products. If our technology components, designs, products, processes or other subject matter are claimed under other existing U.S. or foreign patents, or are otherwise protected by third party proprietary rights, we may be subject to infringement actions. In such event, we may challenge the validity of such patents or other proprietary rights or we may be required to obtain licenses from such companies in order to develop, manufacture or market our products. There can be no assurances that we would be able to obtain such licenses or that such licenses, if available, could be obtained on commercially reasonable terms. Furthermore, the failure to either develop a commercially viable alternative or obtain such licenses could result in delays in marketing our proposed products or the inability to proceed with the development, manufacture or sale of products requiring such licenses, which could have a material adverse affect on our business, financial condition and results of operations. If we are required to defend ourselves against charges of patent infringement or to protect our proprietary rights against third parties, substantial costs will be incurred regardless of whether we are successful. Such proceedings are typically protracted with no certainty of success. An adverse outcome could subject us to significant liabilities to third parties and force us to curtail or cease our development and sale of our products and processes.

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

Research and License Agreements

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

In December 2002, we entered into an agreement with Corning Incorporated that granted them an exclusive sublicense relating to our cell transfection technology for increased efficiency in loading genetic material into cells. We own the intellectual property rights to methods, compositions and devices that increase the frequency and efficiency of depositing particles into cells to modify their genetic code. Under terms of the agreement, Corning's Life Sciences business will utilize our unique technology to enhance the development of their molecular and cell culture applications in areas that are not competitive to our core business interest. We retain exclusive rights to the

applications of the technologies involving cells for therapeutic applications, and received an upfront payment in addition to future royalties we may receive from Corning. Corning is currently in the development stage for products subject to this license.

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 cell products, through a BLA.

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 pre-clinical and clinical testing. This process takes a number of years and the expenditure of significant resources. There can be no assurance that Aastrom's 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 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 pre-clinical 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 pre-clinical 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 cell products, and we have conducted clinical studies under these INDs.

Our TRC 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) pre-clinical 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.

Astrom conducts pre-clinical testing for internal use, and as support for submissions to the FDA. Pre-clinical testing 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 prior to use in human studies. Clinical trials are identified as phases (i.e., Phase I, Phase II and Phase III). Depending on the type of pre-clinical 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). Astrom conducts various phases of clinical trials utilizing all available data, and does not necessary initiate trials as a Phase I or II.

The results of the pre-clinical 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 affects 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 pre-clinical 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 European Union Medicinal Products Prime Directive shifted patient-derived cells to the medicinal products category. The EU is in the process of drafting a regulation specific to cell and tissue products and when approved, our products will be regulated under this Advanced Therapy Medicinal Product regulation.

Clinical Trials in the European Union

In order to obtain approval of a new medicinal product in the EU, sponsors must submit proof of safety and efficacy to the European Medicines Agency (EMA). In most cases, such proof entails extensive pre-clinical and clinical tests. The required testing and preparation for necessary applications and processing of those applications by the EMA is expensive and may take several years to complete. There can be no assurance that the EMA will act favorably or in a timely manner in reviewing submitted applications, and we may encounter significant difficulties or costs in our efforts to obtain EMA approvals. In turn, this could delay or preclude us from marketing any products we may develop. The EMA may also require post-marketing testing and surveillance of approved products, or place other conditions on the approvals. These requirements could cause it to be more difficult or expensive to sell the products, and could therefore restrict the commercial applications of such products. Product approvals may be withdrawn if compliance with applicable regulations are 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 an IMPD submission 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 pre-clinical and laboratory testing. Following submission of the 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 approval for its IMPD to conduct the vascular regeneration trial. In October 2005, the Barcelona, Spain, site received IMPD approval from the AEMPS for the non-union fracture study.

Product Approval in the European Union

Under the current EU drug directive, our TRC cell products will be regulated as a medicinal product. For products which are regulated as a medicinal product, the EU Directive requires: (i) pre-clinical laboratory and animal testing; (ii) submission of an IMPD to the Competent Authorities of the MS where the clinical trial will be conducted, which must be approved prior to the initiation of human clinical studies; (iii) adequate and well-controlled clinical trials to establish the safety and efficacy of the product for its intended use; (iv) submission to EMA for an MA; and, (v) review and approval of the MA. Although an MS is currently allowed to independently approve medicinal products, the trend for cellular products is for the EMA to provide a “centralized” review of the submission.

The EMA is currently reviewing changes to the regulatory requirements for somatic cellular products and Advanced Therapy Medicinal Products which could have significant effects on the requirements for our MA submissions. We do not know if or when these changes will occur, if at all, or what effect they may have on cellular products that may have previously been approved, or submissions that are under review, when the regulation is approved and becomes effective.

Some MSs currently do not require an MA for commercialization of Tissue Engineered Products that use autologous somatic cellular products (e.g., TRCs). Germany is one such MS which does not require an MA to distribute autologous tissue products. The status in Germany is likely to change when the Government issues a revision to its Drug Laws. When the new revised law becomes effective, provided that we have introduced a product into the German market, we may be “grandfathered” for some period of time before we would need to apply for a centralized MA.

Competitive Environment

The biotechnology and medical device industries are characterized by rapidly evolving technology and intense competition. Our competitors include major multinational 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, Wright Medical and Zimmer. A number of other competitors are active with a variety of tissue-derived and tissue substitution products. These competitors include both large companies with significantly greater resources and smaller companies. Examples include Exactech, Kensey Nash, Musculoskeletal Transplant Foundation, Orthovita, Osteotech and Regeneration Technologies.

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 Arteriocyte, Athersys, Bioheart, Cytori Therapeutics, Gamida Cell, Geron, 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 therapy kits 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 is subject to a number of risks and uncertainties. Please see the section entitled "Risk Factors".

Employees

As of August 31, 2006, we employed approximately 59 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 of Aastrom

Our executive officers, and their respective ages as of August 31, 2006, are as follows:

<u>Name</u>	<u>Age</u>	<u>Position</u>
George W. Dunbar	60	Chief Executive Officer, President and Director
Robert J. Bard, J.D., R.A.C.	55	Vice President Regulatory/Clinical Affairs and Quality Systems
Gerald D. Brennan, Jr., J.D.	55	Vice President Administrative and Financial Operations and Chief Financial Officer
Brian S. Hampson	49	Vice President Product Development
Janet M. Hock, B.D.S., Ph.D.	62	Vice President Global Research and Chief Scientific 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 boards of Competitive Technologies, Sonus Pharmaceuticals, and the MBA Advisory Board of the College of Business at Auburn University. Previous boards of director appointments include: DepoTech, LJI Biosystems, Metrika, Molecular Probes, Quidel and The Valley Medical Center Foundation. Mr. Dunbar received a B.S. in Electrical Engineering and an MBA from Auburn University.

Robert J. Bard, J.D., R.A.C. joined Aastrom in October 2002 as its Vice President Regulatory/Clinical Affairs & Quality Systems, with over 30 years of domestic and international regulatory experience in the biotechnology sector. Prior to joining Aastrom, Mr. Bard served in senior management capacities for a number of companies in the medical industry, including: Gliatech, Inc., McKinley Medical, LLLP, I-Flow Corp., IVAC Corp. and Ultra Medical Devices, Inc., where he was responsible for regulatory compliance, quality assurance and manufacturing operations for biotech pharmaceuticals and medical devices. Mr. Bard earned a law degree from the American College of Law, and has a B.S. in Microbiology, with a minor in Biological Chemistry, from the University of California-Los Angeles. In addition, he has studied Pharmaceutical Sciences at Idaho State University and Mechanical Engineering at California State University-Long Beach. Mr. Bard is a member of the California Bar. He completed his ISO 9001 Lead Assessor Training in 1995, is a certified member of the Regulatory Affairs Professional Society, and is an ASQ-certified Quality Engineer. Mr. Bard is also the author of numerous professional and scientific papers and articles.

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.

Brian S. Hampson joined the Company in July 1993 as Director, Product Engineering and became Vice President Product Development in June 2000. He has been a principal leader in the development and engineering of the AastromReplicell Cell Production System. Previously, Mr. Hampson served as Manager, In Vitro Systems at Charles River Laboratories and held other positions after joining that company in January 1986. While at Charles

River, he managed a number of programs to develop and commercialize novel bioreactor systems to support large-scale cell culture and biomolecule production. Prior to that, Mr. Hampson held several engineering positions at Corning Incorporated from September 1979 to January 1986, including assignments with KC Biological, a wholly owned subsidiary of Corning at the time. Mr. Hampson received his Bachelor of Science and Master of Engineering degrees in Electrical Engineering from Cornell University.

Janet M. Hock, B.D.S., Ph.D., joined Aastrom in September 2004 as its Vice President Global Research, and also became Chief Scientific Officer in May 2005. She was previously on the faculty of Indiana University Schools of Medicine and Dentistry (IU), where she was Professor, Department of Anatomy and Cell Biology, School of Medicine, and Professor, Department of Periodontics, School of Dentistry. Dr. Hock was also program director and founder of the Indiana University Cancer Center Bone Cancers Research program, and founder of Thetis Consulting LLC, a scientific advisory firm focused on the treatment of skeletal diseases and bone cancer. Prior to her tenure at IU, she was employed by Eli Lilly and Company (Lilly) to lead the discovery and development of anabolic drugs for the treatment of osteoporosis. She served in various senior technology development positions including: Senior Research Advisor for Product Development, Head of the Bone Formation Group, Director of the Skeletal Diseases Research Group, and Product Team Research Advisor/Chief Scientific Officer. Dr. Hock's responsibilities included product development, preclinical pharmacology, drug discovery and development, regulatory, patent strategy, and formation of research alliances. During her leadership at Lilly, Dr. Hock contributed to the successful clinical development of two important new drug treatments for osteoporosis: Evista® and Forteo®. Dr. Hock holds a B.D.S. Degree in Dental Surgery (D.D.S. equivalent) from the University of London, Guy's Hospital Dental School, UK, an L.D.S., R.C.S. Licentiate in Dental Surgery, Royal College of Surgeons, UK, and a Ph.D. from the University of London, UK, for thesis work done at the University of Iowa and California Institute of Technology. In addition, Dr. Hock holds an M.S. for Oral Diagnosis and a Clinical Certificate in Periodontology from the University of Iowa. In addition to her academic and industry roles, since 1977, Dr. Hock has served the National Institutes of Health, the U.S. Department of Veterans' Affairs, the U.S. Department of Defense and the U.S.D.A. in a variety of capacities, including peer grant reviewer and committee chair. She serves on the Scientific Advisory Board for the Indiana University/Purdue University at Indianapolis (IUPUI) Center for Regenerative Medicine and Biology, and the University of Michigan Center for Oral Health Research. Dr. Hock also serves on the editorial boards for several research journals.

Available Information

Additional information about Aastrom is contained at our website, www.aastrom.com. 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 and our Quarterly Reports on Form 10-Q as soon as reasonably practicable after those reports are filed with the Securities and Exchange Commission.

Item 1A. Risk Factors

Our business is subject to a number of uncertainties, including those discussed below.

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, 2006, we have incurred a cumulative net loss totaling approximately \$141 million. These losses have resulted principally from costs incurred in the research and development of our cell culture technologies and the AastromReplisell 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 pre-clinical studies and clinical trials, and the establishment of marketing and distribution capabilities necessary to support commercialization efforts for our products. We cannot predict with any certainty the amount of future losses. Our ability to achieve profitability will depend, among other things, on successfully completing the development of our product candidates, obtaining regulatory approvals, establishing manufacturing, sales and marketing arrangements with third parties, maintaining supplies of key manufacturing components, and raising sufficient cash to fund our operating activities. In addition, we may not be able to achieve or sustain profitability.

Failure to obtain and maintain required regulatory approvals would severely limit our ability to sell our products.

We must obtain the approval of the FDA before commercial sales of our cell product candidates may commence in the 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, such as the EU. If we cannot demonstrate the safety, reliability and efficacy of our cell product candidates, or of the cells produced in our device products, 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. The AastromReplisell System is used to produce different cell mixtures, and each of these cell mixtures (such as our TRCs) is, under current regulations, regulated as a biologic product, which requires a BLA.

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 of cellular products in the EU. Recent changes and annexes to the European Union Medicinal Products Prime Directive shifted patient-derived cells to the medicinal products category, which will require MA(s) in order to market and sell these products. These new laws have delayed some of our current planned clinical trials with TRCs 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 MA.

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 prove to be safe and efficacious in clinical trials, and we may not obtain the requisite regulatory approvals for our technologies or product candidates and the cells produced in such products. If any of these events occur, we may not have adequate resources to continue operations for the period required to resolve the issue delaying commercialization and we may not be able to raise capital to finance our continued operation during the period required for resolution of that issue.

We must successfully complete our clinical trials to be able to market certain of our products.

To be able to market therapeutic cell products in the U.S. and in 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 functionality for certain clinical indications, improving product shelf life, and decreasing the cost of manufacturing our TRC products. These production process changes may alter the functionality of our TRCs, and require various 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.

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 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 TRCs will face competition from existing, and/or potential other new treatments in the future which could limit revenue potential. It may be necessary to increase the yield and/or cell type purity for certain of our AastromReplicell System cell processes to gain commercial acceptance. Our technologies or product candidates may not be employed in all potential applications being investigated, and any reduction in applications would limit the market acceptance of our technologies and product candidates, and our potential revenues.

The market for our products will be heavily dependent on third party reimbursement policies.

Our ability to successfully commercialize our product candidates will depend on the extent to which government healthcare programs, such as Medicare and Medicaid, as well as private health insurers, health maintenance organizations and other third party payors will pay for our products and related treatments. Reimbursement by third party payors depends on a number of factors, including the payor's determination that use of the product is safe and effective, not experimental or investigational, medically necessary, appropriate for the specific patient and cost-effective. Reimbursement in the U.S. or foreign countries may not be available or maintained for any of our product candidates. If we do not obtain approvals for adequate third party reimbursements, we may not be able to establish or maintain price levels sufficient to realize an appropriate return on our investment in product development. Any limits on reimbursement from third party payors may reduce the demand for, or negatively affect the price of, our products. For example, in the past, published studies have suggested that stem cell transplantation for breast cancer, that 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, our TRC manufacturing processes involve the use of animal-derived products, including fetal bovine serum. Suppliers or regulatory authorities may limit or restrict the availability of such compounds for clinical and commercial use. For example, the occurrence of so-called "mad cow disease" in New Zealand or in Australia may lead to a restricted supply of the serum currently required for the TRC manufacturing process. Any restrictions on these compounds would impose a potential competitive disadvantage for our products or prevent our ability to manufacture TRC 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. 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 expect 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 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 our TRCs 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.

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

We will require substantial capital resources in order to conduct our operations and develop our products and cell manufacturing facilities. We expect that our available cash and interest income will be sufficient to finance currently planned activities at least through the end of fiscal year 2007 (ending June 30, 2007). However, in order to grow and expand our business, and to introduce our new product candidates into the marketplace, we will need to

raise additional funds. We will also need additional funds or a collaborative partner, or both, to finance the research and development activities of our product candidates for the expansion of additional cell types. Accordingly, we are continuing to pursue additional sources of financing.

Our future capital requirements will depend upon many factors, including:

- continued scientific progress in our research, 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

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.

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

As noted above, we will need additional equity funding to provide us with the capital to reach our objectives. At such time, we may enter into financing transactions at prices, which are at a substantial discount to market. Such an equity issuance would cause a substantially larger number of shares to be outstanding and would dilute the ownership interest of existing stockholders.

Our stock price has been volatile and future sales of substantial numbers of our shares could have an adverse affect on the market price of our shares.

The market price of shares of our common stock has been volatile, ranging in closing price between \$1.11 and \$3.49 during the twelve month period ended June 30, 2006. 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 tissue engineering 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. Over the last year, we have 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.

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

We rely solely on third parties such as Astro, Moll and Cambrex 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 fail 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 of 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 are 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, our clinical trial programs and other business prospects would be adversely affected.

If we do not keep pace with our competitors and with technological and market changes, our products may become obsolete and our business may suffer.

The markets for our products are very competitive, subject to rapid technological changes, and vary for different candidates and processes that directly compete with our products. Our competitors may have developed, or could in the future develop, new technologies that compete with our products or even render our products obsolete. As an example, in the past, published studies have suggested that hematopoietic stem cell therapy use for bone marrow transplantation, following marrow ablation due to chemotherapy, may have limited clinical benefit in the treatment of breast cancer, which was a significant portion of the overall hematopoietic stem cell transplant market. This resulted in the practical elimination of this market for our cell-based product for this application.

Our cell manufacturing system, the AastromReplicell 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.

On December 28, 2005, we announced that we would begin a search for a new Chief Executive Officer to succeed Dr. Armstrong, who announced his intention to transition out of day-to-day management of the Company. On July 17, 2006 we announced that George W. Dunbar had joined the Company as CEO, President and a Director, and that Dr. Armstrong will continue in his role as Chairman of the Board for the remainder of his term. We also announced that James A. Cour, former President and COO, had left the Company to pursue other opportunities.

If our patents and proprietary rights do not provide substantial protection, then our business and competitive position will suffer.

Our success depends in large part on our ability to develop or license and protect proprietary products and technologies. However, patents may not be granted on any of our pending or future patent applications. Also, the scope of any of our issued patents may not be sufficiently broad to offer meaningful protection. In addition, our issued patents or patents licensed to us could be successfully challenged, invalidated or circumvented so that our patent rights would not create an effective competitive barrier. Furthermore, we rely on exclusive, world-wide licenses relating to the production of human cells granted to us by the University of Michigan for certain of our patent rights. If we materially breach such agreements or otherwise fail to materially comply with such agreements, or if such agreements expire or are otherwise terminated by us, we may lose our rights under the patents held by the University of Michigan. At the latest, these licenses will terminate when the patent underlying the license expires. The first of these underlying patents will expire on March 21, 2012. We also rely on trade secrets and unpatentable know-how that we seek to protect, in part, by confidentiality agreements with our employees, consultants, suppliers and licensees. These agreements may be breached, and we might not have adequate remedies for any breach. If this were to occur, our business and competitive position would suffer.

Intellectual property litigation could harm our business.

Our success will also depend in part on our ability to develop commercially viable products without infringing the proprietary rights of others. Although we have not been subject to any filed infringement claims, other patents could exist or could be filed which would prohibit or limit our ability to market our products or maintain our competitive position. In the event of an intellectual property dispute, we may be forced to litigate. Intellectual property litigation would divert management's attention from developing our products and would force us to incur

substantial costs regardless of whether we are successful. An adverse outcome could subject us to significant liabilities to third parties, and force us to curtail or cease the development and sale of our products and processes.

The government maintains certain rights in technology that we 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 use of the AastromReplicell System and/or TRCs 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 affect of making it more difficult for a third party to acquire, or of discouraging a third party from attempting to acquire control of our company. This affect could occur even if our shareholders consider the change in control to be in their best interest.

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 management's assessment of such internal controls and independent registered public accounting firm's assessment of 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 attest that our management's report is fairly stated or they are 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 contains certain forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act. These forward-looking statements include statements regarding:

- potential strategic collaborations with others

- future capital needs
- adequacy of existing capital to support operations for a specified time
- product development and marketing plan
- clinical trial plans and anticipated results
- anticipation of future losses
- replacement of manufacturing sources
- commercialization plans
- revenue expectations and operating results

These statements are subject to risks and uncertainties, including those set forth in this Risk Factors section, and actual results could differ materially from those expressed or implied in these statements. All forward-looking statements included in this registration statement are made as of the date hereof. We assume no obligation to update any such forward-looking statement or to update any reason why actual results might differ.

Item 1B. *Unresolved Staff Comments*

None

Item 2. *Properties*

We lease approximately 23,700 square feet of office and research and development space in Ann Arbor, Michigan under a lease agreement. This lease was renegotiated in July 2006 and increased the leased space to 30,230 square feet. This new lease covers a period of 5 years, beginning on the date of occupancy of the additional space. 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 and Related Shareholder Matters**

Beginning on February 4, 1997 our common stock was quoted on the Nasdaq National Market under the symbol "ASTM". Since June 11, 2002, our common stock has been quoted on the Nasdaq Capital Market (formerly the Nasdaq SmallCap 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 Capital Market:

Price Range of Common Stock

	<u>High</u>	<u>Low</u>
Year ended June 30, 2005:		
1st Quarter	\$.97	\$.63
2nd Quarter	1.66	.84
3rd Quarter	4.05	1.37
4th Quarter	3.13	1.90
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

As of August 31, 2006, there were approximately 591 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.

The following table sets forth information as of June 30, 2006 with respect to compensation plans (including individual compensation arrangements) under which equity securities are authorized for issuances:

	<u>Number of Securities to be Issued upon Exercise of Outstanding Options, Warrants and Rights</u>	<u>Weighted Average Exercise Price of Outstanding Options, Warrants and Rights</u>	<u>Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans</u>
Equity compensation plans approved by security holders (employees and directors)(1)	3,892,670	\$ 1.74	3,645,945
Equity compensation plans not approved by security holders (financings or services related)(2)	495,868	\$ 1.74	—
Balance, June 30, 2006	<u>4,388,538</u>	<u>\$ 1.74</u>	<u>3,645,945(1)</u>

(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.

Item 6. Selected Financial Data

The statement of operations data for the years ended June 30, 2004, 2005 and 2006 and for the period from March 24, 1989 (Inception) to June 30, 2006 and the balance sheet data at June 30, 2005 and 2006, 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, 2002 and 2003, and the balance sheet data at June 30, 2002, 2003 and 2004, are derived from audited consolidated financial statements not included herein. The data set forth below are qualified by reference to, and should be read in conjunction with, the consolidated financial statements and notes thereto and "Management's Discussion and Analysis of Financial Condition and Results of Operations."

	Year Ended June 30,					March 24, 1989
	2002	2003	2004	2005	2006	(Inception) to June 30, 2006
Statement of Operations Data:						
Revenues:						
Product sales and rentals	\$ 80,000	\$ 314,000	\$ 49,000	\$ 387,000	\$ 159,000	\$ 1,277,000
Research and development agreements	—	10,000	75,000	—	—	2,105,000
Grants	797,000	520,000	1,178,000	522,000	704,000	8,752,000
Total revenues	877,000	844,000	1,302,000	909,000	863,000	12,134,000
Costs and expenses:						
Cost of product sales and rentals(1)	202,000	893,000	280,000	148,000	11,000	2,804,000
Research and development	5,428,000	5,647,000	6,289,000	7,206,000	9,484,000	110,127,000
Selling, general and administrative	3,528,000	4,017,000	5,390,000	5,972,000	9,101,000	48,590,000
Total costs and expenses	9,158,000	10,557,000	11,959,000	13,326,000	18,596,000	161,521,000
Loss from operations	(8,281,000)	(9,713,000)	(10,657,000)	(12,417,000)	(17,733,000)	(149,387,000)
Other income (expense):						
Other income	—	—	—	12,000	—	1,249,000
Interest income	342,000	134,000	169,000	594,000	1,258,000	7,223,000
Interest expense	—	—	—	—	—	(267,000)
Net loss	\$ (7,939,000)	\$ (9,579,000)	\$ (10,488,000)	\$ (11,811,000)	\$ (16,475,000)	\$ (141,182,000)
Net loss applicable to common shares	\$ (7,939,000)	\$ (9,579,000)	\$ (10,488,000)	\$ (11,811,000)	\$ (16,475,000)	\$ (141,182,000)
Net loss per common share (basic and diluted)	\$ (.19)	\$ (.19)	\$ (.14)	\$ (.13)	\$ (.15)	\$ (.15)
Weighted average number of common shares outstanding (basic and diluted)	42,121,000	50,984,000	73,703,000	93,541,000	106,314,000	

	June 30,				
	2002	2003	2004	2005	2006
Balance Sheet Data:					
Cash, cash equivalents and short-term investments	\$ 9,605,000	\$ 10,512,000	\$ 16,926,000	\$ 32,414,000	\$ 42,997,000
Working capital	10,597,000	11,273,000	17,274,000	32,275,000	41,126,000
Total assets	11,553,000	12,155,000	18,166,000	33,897,000	44,881,000
Deficit accumulated during the development stage	(93,797,000)	(103,376,000)	(113,864,000)	(125,675,000)	(142,150,000)
Total shareholders' equity	10,803,000	11,575,000	17,608,000	33,028,000	42,342,000

(1) Cost of product sales and rentals for the years ended June 30, 2003, June 30, 2004 and June 30, 2005 include a charge of \$748,000, \$253,000, and \$9,000 for excess inventories, respectively.

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

Overview

We are a development stage company focused on the development of autologous cell products for use in regenerative medicine. Our pre-clinical and clinical product development programs utilize patient-derived bone marrow stem and progenitor cell populations, and are being investigated for their ability to aid in the regeneration of tissues such as vascular, bone, cardiac and neural.

Our platform TRC technology is based on 1) our cell products which are a unique cell mixture containing large numbers of stromal, stem and progenitor cells, produced outside of the body from a small amount of bone marrow taken from the patient, and 2) the means to produce these products in an automated process. TRC-based products have been used in over 225 patients, and are currently in active clinical trials for bone regeneration (long bone fractures and spine fusion) and vascular regeneration (diabetic patients with critical limb ischemia) applications. We have reported positive interim clinical trial results for TRCs suggesting both the clinical safety and the ability of TRCs to induce tissue regeneration in long bone fractures and jaw bone reconstruction. Recently, our proprietary TRC cell product received an Orphan Drug Designation from the FDA for use in the treatment of osteonecrosis of the femoral head. In addition, we are developing plans for a TRC-based therapy for cardiac regeneration.

Our primary business is to develop our TRC-based products for use in multiple therapeutic areas. Currently, we intend to pursue TRC-based cell products for the following therapeutic areas:

- Vascular tissue regeneration
- Bone tissue regeneration
- Cardiac tissue regeneration
- Neural tissue regeneration

We have developed a patented manufacturing system to produce human cells for clinical use. This automated cell manufacturing system enables our "single-pass perfusion" cell culture process. Single-pass perfusion is our patented technology for growing large quantities of human cells. These cells include adult stromal, stem and progenitor cell populations, which are considered to be required in the formation of tissues such as vascular, bone, cardiac and neural, as well as the hematopoietic system.

Since our inception, we have been in the development stage and engaged in research and product development, conducted principally on our own behalf, but also in connection with various collaborative research and development agreements with others. Our initial business plan was to pursue the bone marrow transplantation markets. At approximately the same time (late fiscal year 1999) that we intended to commence our initial pilot-scale product launch in the EU of our cell manufacturing system, the AastromReplicell System, with the SC-I kit, data was released at international meetings that resulted in the majority of the patients who would otherwise have been candidates for the SC-I product, to no longer require the use of the product. This loss of market for the SC-I caused us to reorganize our operations and suspend all external activities in October 1999, pending the receipt of additional funding and the completion of the reorganization process. We expanded the capabilities of the AastromReplicell System to include dendritic cell production and initiated pilot marketing activities for the DC-I, DCV-I and the DCV-II products. However, only minimal and intermittent revenue has been generated from these products, and as a result it is no longer a priority area for us. Therefore, we have eliminated our marketing efforts promoting the AastromReplicell System as a stand-alone product. Rather our current focus is on utilizing our TRC technology in our cell manufacturing facilities to support various development programs for tissue regeneration. 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 product sales commence. Until that time, we expect that our revenue sources will consist of only minor sales of our cell products such as TRCs, and our dendritic cell and T-cell kits to academic research centers, grant revenue and research funding, and potential licensing fees or other financial support from potential future corporate collaborators.

We do not have the sales and/or marketing resources that will be needed to fully commercialize our therapeutic products. We intend to seek commercialization partnerships with other companies who have these capabilities, as well as to develop our own ability to either support these relationships and, if necessary, to complete some pilot level of sales and marketing activity ourselves.

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, 2006, we have accumulated a net loss of approximately \$141 million. We cannot provide any assurance that we will be able to achieve profitability on a sustained basis, if at all, obtain the required funding, obtain the required regulatory approvals, or complete additional corporate partnering or acquisition transactions.

Critical Accounting Policies

There are several accounting policies that we believe are significant to the presentation of our consolidated financial statements. Note 1 to our consolidated financial statements "Overview and Summary of Significant Accounting Policies" summarizes each of our significant accounting policies. The most significant accounting policies include those related to revenue recognition, accounts receivable and inventories.

Revenue recognition — We generate revenue from grants and research agreements, collaborative agreements, product sales and licensing arrangements. Revenue from grants and research agreements is recognized on a cost reimbursement basis consistent with the performance requirements of the related agreements. Revenue from collaborative agreements is recognized when the scientific or clinical results stipulated in the agreement have been met and there are no other ongoing obligations on our part. We recognize revenue from product sales when title to the product transfers and there are no remaining obligations that will affect the customer's final acceptance of the sale. If there are remaining obligations, including training and installation, we do not recognize revenue until completion of these obligations. We recognize revenue from licensing fees under licensing agreements and rental revenue when there are no future performance obligations remaining with respect to such fees. Payments received before all obligations are fulfilled are classified as deferred revenue.

Revenues include rental revenue of \$37,000, \$0, \$0 and \$93,000, for the years ended June 30, 2004, 2005, 2006 and for the period from Inception to June 30, 2006, respectively. This revenue was generated from AastromReplicell System rental agreements that have since expired or have been terminated. Based upon our current business strategy we do not expect to generate rental revenues in future periods.

Accounts receivable — We make estimates evaluating collectibility of accounts receivable. We continuously monitor collections and payments from our customers and maintain an allowance for estimated credit losses based on any specific customer collection issues we have identified. While such credit issues have not been significant, there can be no assurance that we will continue to experience the same level of credit losses in the future. As of June 30, 2006, our allowance for doubtful accounts was \$55,000.

Inventories — We value our inventories that consist primarily of our cell manufacturing system, the AastromReplicell 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. We regularly review inventory quantities on hand and record a provision to write down excess inventories to their estimated net realizable value.

- *AastromReplicell System (ARS) Inventories* — Based upon market conditions and our historical experience with the ARS product line, the carrying value of our aggregate ARS inventories were reduced if such inventories were held in excess of twelve months without sale because the probability-weighted selling price of the aggregate inventories declines after inventory has been on-hand for more than twelve months. We continued to reduce the aggregate carrying value of ARS inventories over the ensuing six months if the inventories were not sold. The carrying value of ARS inventories under evaluation at potential customer sites were not reduced so long as the estimated selling price (less selling costs) exceeded the carrying value of the inventories under evaluation. Pursuant to this accounting policy we recorded provisions to reduce the

carrying value of the ARS inventories by \$253,000 and \$9,000 in fiscal years ending June 30, 2004 and 2005, respectively. Additionally, in fiscal year 2005, we recorded a charge of \$90,000 to research and development expense for excess ARS inventories that were re-deployed for clinical use. As of June 30, 2005, the carrying value of our ARS inventories was reduced to zero. We did not acquire any additional ARS inventory in subsequent periods. Based upon our current business strategy, we do not expect to generate revenues from the sale of ARS inventories in future periods.

- *Cell Cassette and Base Medium Inventories* — We maintain cell cassette and base medium inventories for sale to existing customers and use at production sites. We evaluate the net realizable value of these inventories considering expected future sales quantities, prices and timing, and considering the limited shelf life of these inventories.

Stock-Based Compensation Expense — 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 stock-based 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 our adoption of SFAS 123R, we accounted for share-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 its historical volatility. We estimate the expected life of options granted based on 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 we use different assumptions, our 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 our actual forfeiture rate is different from our estimate, we would report the effect of any change in estimated forfeiture rate in the period of change.

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 \$863,000 in 2006, \$909,000 in 2005, and \$1,302,000 in 2004. Product sales and rentals revenues decreased to \$159,000 in 2006 from \$387,000 in 2005 and increased from \$49,000 in 2004. Total revenues decreased in 2006 from 2005 primarily from the reduced volume of therapy kit sales for clinical trials and research by others, and revenue in 2005 included \$120,000 from the sale of an AastromReplicell System. The increase in product sales and rentals revenues from 2004 to 2005 is primarily the result of increased therapy kit sales for clinical trials and research by others. Revenues include rentals revenue of \$37,000, \$0, \$0 and \$93,000, for the years ended June 30, 2004, 2005, 2006 and for the period from Inception to June 30, 2006, respectively. These revenues were generated from AastromReplicell System rental agreements that have since expired or have been terminated. Based upon our current business strategy, we are not marketing the AastromReplicell System as a stand-alone product. Our current focus is on utilizing our TRC technology in cell manufacturing facilities to support our tissue regeneration development programs. At such time as we satisfy applicable regulatory approval requirements, we expect the sales of our TRC and our related cell-based products will constitute nearly all of our product sales revenues.

Revenues for 2004 also include \$75,000 in research and development agreements. This revenue is the result of a \$50,000 fee from our sublicense agreement with Corning Inc. and a fee of \$25,000 from a development agreement

with a European institution. No revenue was generated from research and development agreements in 2005 and 2006.

Grant revenues increased to \$704,000 in 2006 from \$522,000 in 2005 and decreased from \$1,178,000 in 2004. Grant revenues in 2006 increased from 2005 as a result of increased activity on grants from the National Institutes of Health. Grant revenues in 2005 decreased from 2004 due to fewer grants, resulting in less grant activity. Grant revenues accounted for 82% of total revenues for 2006, 57% for 2005 and 90% for 2004 and are recorded on a cost-reimbursement basis. Grant revenues may vary in any period based on timing of grant awards, grant-funded activities, level of grant funding and number of grants awarded.

Total costs and expenses were \$18,596,000 in 2006, \$13,326,000 in 2005 and \$11,959,000 in 2004. The increase in costs and expenses during the periods reflect the continued expansion of our research and development activities including additional clinical trial costs; the adoption of SFAS 123R; the implementation of a bonus performance plan; and certain costs associated with the resignation of our former Chief Executive Officer.

Cost of product sales and rentals were \$11,000 in 2006, \$139,000 in 2005 and \$27,000 in 2004. The fluctuation in cost of product sales and rentals is due to the changes in the volume of product sales. The non-cash provision for excess AastromReplicell System inventories was \$0 in 2006, \$9,000 in 2005 and \$253,000 in 2004. As of June 30, 2005, the carrying value of our AastromReplicell System inventories was reduced to zero and we purchased no new ARS inventories. Based upon our current business strategy, we do not expect to generate revenues from the sale of AastromReplicell System inventories in future periods.

Costs and expenses include an increase in research and development expenses to \$9,484,000 in 2006 from \$7,206,000 in 2005 and \$6,289,000 in 2004. These increases reflect the continued expansion of our research and development activities, including additional staffing requirements, to support future regulatory submissions, on-going and planned tissue regeneration clinical trials in the U.S. and EU and the development of facilities for product manufacturing and distribution processes. Research and development expenses for 2006 also include a non-cash charge of \$300,000 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 increased in 2006 to \$9,101,000 from \$5,972,000 in 2005 and \$5,390,000 in 2004. The increase from 2005 to 2006 is due to additional employee costs of approximately \$1,873,000 that include: salaries and fringe benefits for additional staffing requirements, bonuses paid to certain employees, an accrual for the management performance bonus plan, an accrual for payments relating to the former Chief Executive Officer's revised employment agreement, and recruitment expenses relating to Board of Director members, the European Marketing Director and the search for the new Chief Executive Officer. The amount of compensation expense in 2006 resulting from our former CEO's revised employment agreement was \$589,000, and the accrual for our management performance bonus plan was \$600,000. This increase also reflects additional consulting and marketing activities and increased legal costs associated with patent protection. This increase also includes a non-cash charge of \$734,000 relating to stock-based compensation recognized in accordance with SFAS 123R. The increase in selling, general and administrative expenses from 2004 to 2005 is due to additional consulting, pre-marketing activities and costs required for financial internal controls compliance and certification. Salary and related employee benefits also increased in 2005 as a result of hiring an additional executive. Additionally, in 2005 there was a non-cash charge of \$59,000 related to a stock option grant. These increases were partially offset by decreased legal expenses. Selling, general and administrative costs in 2004 also includes a non-cash charge of \$53,000 relating to certain warrants issued for public and investor relations services and a \$372,000 non-cash charge related to an employee performance-based stock option that vested.

Interest income was \$1,258,000 in 2006, \$594,000 in 2005 and \$169,000 in 2004. 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 improving yields from our investments.

Our net loss was \$16,475,000, or \$.15 per common share in 2006, \$11,811,000, or \$.13 per common share in 2005, and \$10,488,000, or \$.14 per common share in 2004. These increases in net loss are primarily the result of

increased costs and expenses as discussed above offset on per share basis by an increase in the weighted average number of common shares outstanding resulting from additional equity financings described in the "Liquidity and Capital Resources" discussion below. 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 our autologous cell products — TRC-based products — for use in regenerative medicine. Our pre-clinical and clinical product development programs utilize patient-derived bone marrow stem and progenitor cell populations, and are being investigated for their ability to aid in the regeneration of tissues such as vascular, bone, cardiac and neural. We are also completing other research and development activities to improve TRC functionality for certain clinical indications, to improve shelf life, and to decrease the cost of manufacturing our TRC products. Research and development expenses outside of the TRC program 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, 2006:

R&D Project	Year Ended June 30,		
	2004	2005	2006
TRCs	\$ 4,133,000	\$ 5,916,000	\$ 8,347,000
Other	2,156,000	1,290,000	1,137,000
Total	<u>\$ 6,289,000</u>	<u>\$ 7,206,000</u>	<u>\$ 9,484,000</u>

Because of the uncertainties of clinical trials and the evolving regulatory requirements applicable to TRCs, estimating the completion dates or cost to complete our major research and development program would be highly speculative and subjective. The risks and uncertainties associated with developing our products, including significant and changing governmental regulation and the uncertainty of future clinical study results, are discussed in greater detail in the "Any changes in the governmental regulatory classifications of our products could prevent, limit or delay our ability to market and develop our products," "Our inability to complete our product development activities successfully would severely limit our ability to operate or finance operations," and "We must successfully complete our clinical trials to be able to market certain of our products," sections under the heading "Risk Factors" following Item 1 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, 2006, we have generated cumulative Federal tax net operating loss and tax credit carryforwards of, \$69,000,000 and \$935,000, 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, 2006, have totaled approximately \$184 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 \$42,997,000 at June 30, 2006, an increase of \$10,583,000 from June 30, 2005. During the year ended June 30, 2006, the primary source of cash, cash equivalents and short-term investments was from equity transactions, with net proceeds of \$24,755,000, of which \$23,886,000 was raised in April 2006, in a registered direct placement of 15,943,750 shares of common stock to a select group of institutional investors at a price of \$1.60 per share. These shares are registered pursuant to a registration statement that we filed with the U.S. Securities and Exchange Commission. The remaining equity financing was obtained under multiple transactions in which we sold our common shares in connection with option and warrant exercises and through our stock option plans and Direct Stock Purchase Plan. 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 for cell manufacturing and laboratory equipment.

Our combined cash, cash equivalents and short-term investments totaled \$32,414,000 at June 30, 2005, an increase of \$15,488,000 from June 30, 2004. During the year ended June 30, 2005, we raised net proceeds of \$27,071,000 through the sale of our equity securities. The primary uses of cash, cash equivalents and short-term investments during the year ended June 30, 2005 included \$11,065,000 to finance our operations and working capital requirements, and \$586,000 in capital equipment additions.

We expect that our total capital expenditures for the fiscal year ending June 30, 2007 to be approximately \$1,292,000. The primary purpose of these expenditures will be for the construction of a core cell manufacturing facility, located in Ann Arbor, Michigan, and the acquisition of cell manufacturing and laboratory equipment. We expect our monthly cash utilization to average approximately \$1.8 million per month during fiscal year 2007.

Our future cash requirements will depend on many factors, including continued scientific progress in our research and development programs, the scope and results of clinical trials, the time and costs involved in obtaining regulatory approvals, the costs involved in filing, prosecuting and enforcing patents, competing technological and market developments and the cost of product commercialization. We do not expect to generate a positive cash flow from operations for at least the next several years due to the expected spending for research and development programs and the cost of commercializing our product candidates. We intend to seek additional funding through research and development agreements or grants, distribution and marketing agreements and through public or private 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 currently planned activities at least through the end of fiscal year 2007 (ending June 30, 2007). 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", included herein. In order to grow and expand our business, and to introduce our product candidates into the marketplace, we will need to raise additional funds. We will also need additional funds or a collaborative partner, or both, to finance the research and development activities of our product candidates for the expansion of additional cell types. 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 adequate funds are not available, we may be required to delay, reduce the scope of, or eliminate one or more of our research and development programs, which may have a material adverse affect on our business. See "Risk Factors" and "Notes to Consolidated Financial Statements" included herein.

Long-Term Contractual Obligations and Commitments

The following table sets forth Aastrom's contractual obligations along with cash payments due each period.

Contractual Obligations	Total	Payments Due by Period			
		Less than 1 Year	1—3 Years	3—5 Years	More than 5 Years
Purchase order commitments	\$ 398,000	\$ 398,000	\$ —	\$ —	\$ —
Total	\$ 398,000	\$ 398,000	\$ —	\$ —	\$ —

As of July 20, 2006, the Company renegotiated its lease with Domino's Farms Office Park, LLC, increasing the leased space to 30,230 square feet. This new lease covers a period of five years, beginning on the date of occupancy of the additional space, which we anticipate will be in March 2007. The aggregate minimum rent commitment under the new five year lease is approximately \$4,878,000. This commitment which did not exist as of June 30, 2006 is excluded from the above table.

New Accounting Standards

In June 2006, the Financial Accounting Standards Board (FASB) issued FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109," ("FIN 48"). FIN 48 clarifies the accounting for uncertainties in income taxes recognized in a company's financial statements in accordance with Statement 109 and prescribes a recognition threshold and measurement attributable for financial disclosure of tax positions taken or expected to be taken on a tax return. Additionally, Interpretation 48 provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. Interpretation 48 is effective for fiscal years beginning after December 15, 2006. Because we have not reported any income tax expense, we do not expect adoption will materially impact our financial position, results of operations, or cash flows.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

As of June 30, 2006, 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.

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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.:

We have completed integrated audits of Aastrom Biosciences, Inc.'s 2006 and 2005 consolidated financial statements and of its internal control over financial reporting as of June 30, 2006 and an audit of its 2004 consolidated financial statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Our opinions, based on our audits, are presented below.

Consolidated Financial Statements and Financial Statement Schedule

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, 2006 and 2005, and the results of their operations and their cash flows for each of the three years in the period ended June 30, 2006, and for the period from March 24, 1989 (Inception) to June 30, 2006, in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedule listed in the accompanying index presents fairly, in all material respects, the information set forth therein when read in conjunction with the related consolidated financial statements. These financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and financial statement schedule based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit of financial statements includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

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

Internal Control Over Financial Reporting

Also, in our opinion, Management's Assessment, included in Management's Report on Internal Control over Financial Reporting appearing under Item 9A, that the Company maintained effective internal control over financial reporting as of June 30, 2006 based on criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), is fairly stated, in all material respects, based on those criteria. Furthermore, in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of June 30, 2006, based on criteria established in *Internal Control — Integrated Framework* issued by the COSO. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express opinions on management's assessment and on the effectiveness of the Company's internal control over financial reporting based on our audit. We conducted our audit of internal control over financial reporting in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. An audit of internal control over financial reporting includes obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we consider necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinions.

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

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

/s/ PRICEWATERHOUSECOOPERS LLP
Minneapolis, Minnesota
September 13, 2006

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

	June 30,	
	2005	2006
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 14,408,000	\$ 9,034,000
Short-term investments	18,006,000	33,963,000
Receivables, net	193,000	139,000
Inventories	116,000	1,000
Other current assets	421,000	528,000
Total current assets	33,144,000	43,665,000
PROPERTY AND EQUIPMENT, NET	753,000	1,216,000
Total assets	\$ 33,897,000	\$ 44,881,000
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	\$ 533,000	\$ 1,084,000
Accrued employee benefits	336,000	1,455,000
Total current liabilities	869,000	2,539,000
COMMITMENTS AND CONTINGENCIES (Notes 5 and 6)		
SHAREHOLDERS' EQUITY:		
Common Stock, no par value; shares authorized — 250,000,000; shares issued and outstanding — 102,328,785 and 119,439,612, respectively	158,703,000	184,492,000
Deficit accumulated during the development stage	(125,675,000)	(142,150,000)
Total shareholders' equity	33,028,000	42,342,000
Total liabilities and shareholders' equity	\$ 33,897,000	\$ 44,881,000

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

AASTROM BIOSCIENCES, INC.
(a development stage company)

CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended June 30,			March 24, 1989
	2004	2005	2006	(Inception) to June 30, 2006
REVENUES:				
Product sales and rentals	\$ 49,000	\$ 387,000	\$ 159,000	\$ 1,277,000
Research and development agreements	75,000	—	—	2,105,000
Grants	1,178,000	522,000	704,000	8,752,000
Total revenues	1,302,000	909,000	863,000	12,134,000
COSTS AND EXPENSES:				
Cost of product sales and rentals	27,000	139,000	11,000	565,000
Cost of product sales and rentals — provision for excess inventories	253,000	9,000	—	2,239,000
Research and development	6,289,000	7,206,000	9,484,000	110,127,000
Selling, general and administrative	5,390,000	5,972,000	9,101,000	48,590,000
Total costs and expenses	11,959,000	13,326,000	18,596,000	161,521,000
LOSS FROM OPERATIONS	(10,657,000)	(12,417,000)	(17,733,000)	(149,387,000)
OTHER INCOME (EXPENSE):				
Other income	—	12,000	—	1,249,000
Interest income	169,000	594,000	1,258,000	7,223,000
Interest expense	—	—	—	(267,000)
Total other income	169,000	606,000	1,258,000	8,205,000
NET LOSS	\$ (10,488,000)	\$ (11,811,000)	\$ (16,475,000)	\$ (141,182,000)
NET LOSS PER SHARE (Basic and Diluted)	\$ (.14)	\$ (.13)	\$ (.15)	
Weighted average number of common shares outstanding (Basic and Diluted)	73,703,000	93,541,000	106,314,000	

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

AASTROM BIOSCIENCES, INC.
(a development stage company)

CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY AND COMPREHENSIVE LOSS

	Preferred Stock		Common Stock		Deficit Accumulated During the Development Stage	Total Shareholders' Equity
	Shares	Amount	Shares	Amount		
BALANCE, MARCH 24, 1989 (Inception)	—	\$ —	—	\$ —	\$ —	\$ —
Net loss and comprehensive loss					(102,408,000)	(102,408,000)
Issuance of common stock for cash, services and license rights			1,195,124	2,336,000		2,336,000
Issuance of Series A through Series E Preferred Stock for cash, net of issuance costs of \$342,000	9,451,766	34,218,000				34,218,000
Issuance of Series E Preferred Stock at \$17.00 per share	205,882	3,500,000		(3,500,000)		
Exercise of stock options and warrants, and issuance of stock under Employee Stock Purchase Plan			3,027,983	942,000		942,000
Issuance of Stock Purchase Rights for cash in September 1995 and March 1996				3,500,000		3,500,000
Principal payment received under shareholder note receivable				31,000		31,000
Initial public offering of common stock at \$7.00 per share, net of issuance costs of \$2,865,000			3,250,000	19,885,000		19,885,000
Conversion of preferred stock	(11,865,648)	(55,374,000)	21,753,709	55,374,000		19,885,000
Compensation expense related to stock options and warrants granted				989,000		989,000
Issuance of 5.5% Convertible Preferred Stock at \$5.00 per share, net of issuance costs of \$1,070,000	2,200,000	9,930,000		9,930,000		9,930,000
Issuance of 1998 Series I Convertible Preferred Stock at \$1,000 per share, net of issuance costs of \$460,000	5,000	4,540,000	40,404	149,000		4,689,000
Issuance of 1999 Series III Convertible Preferred Stock at \$1,000 per share, net of issuance costs of \$280,000	3,000	2,720,000	49,994	90,000		2,810,000
Issuance of common stock, net of issuance costs of \$600,000			35,378,811	34,726,000		34,726,000
Dividends and yields on preferred stock		466,000		148,568	(968,000)	
Repurchase and retirement of Common Shares outstanding				(73,000)		(73,000)
BALANCE, JUNE 30, 2003	—	—	64,812,422	114,951,000	(103,376,000)	11,575,000
Net loss and comprehensive loss					(10,488,000)	(10,488,000)
Exercise of stock purchase warrants			236,534	121,000		121,000
Exercise of stock options and issuance of stock under Employee Stock Purchase Plan			45,919	24,000		24,000
Issuance of stock under Direct Stock Purchase Plan			5,453	5,000		5,000
Compensation expense related to stock options and warrants granted				425,000		425,000
Issuance of common stock, net of issuance costs of \$1,294,000			16,272,863	15,946,000		15,946,000
BALANCE, JUNE 30, 2004	—	—	81,373,191	131,472,000	(113,864,000)	17,608,000
Net loss and comprehensive loss					(11,811,000)	(11,811,000)
Exercise of stock purchase warrants			2,043,826	2,873,000		2,873,000
Exercise of stock options and issuance of stock under Employee Stock Purchase Plan			1,593,442	897,000		897,000
Issuance of stock under Direct Stock Purchase Plan			23,452	38,000		38,000
Compensation expense related to stock options granted				160,000		160,000
Issuance of common stock, net of issuance costs of \$5,629,000			17,294,874	23,263,000		23,263,000
BALANCE, JUNE 30, 2005	—	—	102,328,785	158,703,000	(125,675,000)	33,028,000
Net loss and comprehensive loss					(16,475,000)	(16,475,000)
Exercise of stock purchase warrants			205,883	253,000		253,000
Exercise of stock options			528,083	473,000		473,000
Issuance of restricted stock			342,817			
Issuance of stock under Direct Stock Purchase Plan			90,294	143,000		143,000
Compensation expense related to stock options and restricted stock awards and units granted				1,034,000		1,034,000
Issuance of common stock, net of issuance costs of \$1,624,000			15,943,750	23,886,000		23,886,000
BALANCE, JUNE 30, 2006	—	\$ —	119,439,612	\$ 184,492,000	\$ (142,150,000)	\$ 42,342,000

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

AASTROM BIOSCIENCES, INC.
(a development stage company)
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended June 30,			March 24, 1989
	2004	2005	2006	(Inception) to June 30, 2006
OPERATING ACTIVITIES:				
Net loss	\$ (10,488,000)	\$ (11,811,000)	\$ (16,475,000)	\$ (141,182,000)
Adjustments to reconcile net loss to net cash used for operating activities:				
Depreciation and amortization	125,000	167,000	326,000	4,064,000
Loss on property held for resale	—	—	—	110,000
Amortization of discounts and premiums on investments	—	(68,000)	(135,000)	(746,000)
Stock compensation expense	425,000	160,000	1,034,000	2,618,000
Inventories write downs and reserves	253,000	9,000	—	2,239,000
Stock issued pursuant to license agreement	—	—	—	3,300,000
Provision for losses on accounts receivable	4,000	9,000	39,000	204,000
Changes in assets and liabilities:				
Receivables	100,000	42,000	15,000	(388,000)
Inventories	164,000	264,000	115,000	(2,336,000)
Other current assets	(86,000)	(148,000)	(107,000)	(507,000)
Accounts payable and accrued expenses	(24,000)	151,000	551,000	1,084,000
Accrued employee benefits	2,000	160,000	1,119,000	1,455,000
Net cash used for operating activities	<u>(9,525,000)</u>	<u>(11,065,000)</u>	<u>(13,518,000)</u>	<u>(130,085,000)</u>
INVESTING ACTIVITIES:				
Organizational costs	—	—	—	(73,000)
Purchase of short-term investments	—	(25,938,000)	(43,900,000)	(131,962,000)
Maturities of short-term investments	—	8,000,000	28,078,000	98,745,000
Property and equipment purchases	(157,000)	(586,000)	(789,000)	(4,447,000)
Proceeds from sale of property held for resale	—	—	—	400,000
Net cash used for investing activities	<u>(157,000)</u>	<u>(18,524,000)</u>	<u>(16,611,000)</u>	<u>(37,337,000)</u>
FINANCING ACTIVITIES:				
Net proceeds from issuance of preferred stock	—	—	—	51,647,000
Net proceeds from issuance of common stock	16,096,000	27,071,000	24,755,000	122,501,000
Repurchase of common stock	—	—	—	(49,000)
Payments received for stock purchase rights	—	—	—	3,500,000
Payments received under shareholder notes	—	—	—	31,000
Principal payments under capital lease obligations	—	—	—	(1,174,000)
Net cash provided by financing activities	<u>16,096,000</u>	<u>27,071,000</u>	<u>24,755,000</u>	<u>176,456,000</u>
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	6,414,000	(2,518,000)	(5,374,000)	9,034,000
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	10,512,000	16,926,000	14,408,000	—
CASH AND CASH EQUIVALENTS AT END OF PERIOD	\$ 16,926,000	\$ 14,408,000	\$ 9,034,000	\$ 9,034,000
SUPPLEMENTAL CASH FLOW INFORMATION:				
Interest paid	\$ —	\$ —	\$ —	\$ 267,000
Equipment acquired under capital lease obligations	\$ —	\$ —	\$ —	\$ 1,174,000

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

AASTROM BIOSCIENCES, INC.
(a development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Summary of Significant Accounting Policies

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

Successful future operations are subject to several technical and risk factors, including satisfactory product development, obtaining regulatory approval and market acceptance for the Company's products and the Company's continued ability to obtain future funding.

The Company is subject to certain risks related to the operation of its business and development of its products and product candidates. While management believes available cash, cash equivalents and short-term investments are adequate to finance currently planned activities at least until the end of fiscal year 2007 (ending June 30, 2007), 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 product candidates. The Company cannot be certain that such funding will be available on favorable terms, if at all. Some of the factors that will impact the Company's ability to raise additional capital and its overall success include: the rate and degree of progress for its product development, the rate of regulatory approval to proceed with clinical trial programs, the requirements for marketing authorization from regulatory bodies in the U.S., 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 negatively impact the Company's business, financial condition and results of operations.

Significant Revenue Relationships — One collaborator accounted for 15% of total revenues for the period from Inception to June 30, 2006. However, for the fiscal year ended June 30, 2006, there was no revenue recognized from this source. Grant revenues consist of grants received from federal and state agencies.

Suppliers — Some of the key components used to manufacture the Company's Tissue Repair Cell-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, 2006, 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 and Restricted Investments — Short-term investments consist of highly rated corporate debt securities with original maturities of over three months and less than one year. Short-term investments are classified as available-for-sale, and are presented at market value, with unrealized gains and losses on investments reflected as a component of 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 as interest income. The Company has not experienced unrealized gains or losses on its investments.

Included in other current assets at both June 30, 2005 and June 30, 2006 are \$91,000, of bank certificates of deposit which serve as collateral for certain potential European Value Added Taxes.

AASTROM BIOSCIENCES, INC.
(a development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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.

Accounts Receivable — The Company makes estimates evaluating collectibility of accounts receivable. The Company continuously monitors collections and payments from its customers and maintains an allowance for estimated credit losses based on any specific customer collection issues that are identified. While such credit issues have not been significant, there can be no assurance that the Company will continue to experience the same level of credit losses in the future. The allowance for doubtful accounts was \$16,000 and \$55,000 at June 30, 2005 and 2006, respectively.

Inventories — The Company values its inventories that consist primarily of our cell manufacturing system, the AastromReplicell 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 records a provision to write down excess inventories to their estimated net realizable value.

- *AastromReplicell System (ARS) Inventories* — Based upon market conditions and the Company's historical experience with the ARS product line, the carrying value of its aggregate ARS inventories was reduced if such inventories were held in excess of twelve months without sale because the probability-weighted selling price of the aggregate inventories declines after inventory has been on-hand for more than twelve months. The Company continued to reduce the aggregate carrying value of ARS inventories over the ensuing six months if the inventories were not sold. The carrying value of ARS inventories under evaluation at potential customer sites were not reduced so long as the estimated selling price (less selling costs) exceeded the carrying value of the inventories under evaluation. Pursuant to this accounting policy the Company recorded provisions to reduce the carrying value of the ARS inventories by \$253,000 and \$9,000 in fiscal years ending June 30, 2004 and 2005, respectively. Additionally, in fiscal year 2005, the Company recorded a charge of \$90,000 to research and development expense for excess ARS inventories that were re-deployed for clinical use. As of June 30, 2005, the carrying value of the Company's ARS inventories was reduced to zero and the Company did not acquire any additional ARS inventories in subsequent periods. Based upon our current business strategy, the Company does not expect to generate revenues from the sale of ARS inventories in future periods.
- *Cell Cassette and Base Medium Inventories* — The Company maintains cell cassette and base medium inventories for sale to existing customers and use at production sites. The Company evaluates the net realizable value of these inventories considering expected future sales quantities, prices and timing, and considering the limited shelf life of these inventories.

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 \$125,000, \$167,000, \$326,000 and \$4,064,000 for the years ended June 30, 2004, 2005, 2006 and for the period from Inception to June 30, 2006, respectively. During 2005 the Company acquired equipment that it intends to use in the future in a specialized facility under the Company's control, for the production of human cells. The cost of this equipment was \$111,000 and is included in property and equipment as equipment in process at June 30, 2006. The equipment will be depreciated over its useful life beginning when the equipment is placed into service. 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 — Revenue is generated from grants and research agreements, collaborative agreements, product sales and rentals. Revenue from grants and research agreements is recognized on a cost

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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.

Revenues include rental revenue of \$37,000, \$0, \$0 and \$93,000, for the years ended June 30, 2004, 2005, 2006 and for the period from Inception to June 30, 2006, respectively. This revenue was generated from AastromReplicell System rental agreements that have since expired or have been terminated. Based upon the Company's current business strategy we do not expect to generate rental revenues in future periods.

Research and Development Costs — Research and development costs are expensed as incurred. Such costs and expenses related to programs under collaborative agreements with other companies totaled \$418,000 and \$527,000 for the years ended June 30, 2004 and 2005, respectively and \$2,590,000 for the period from Inception to June 30, 2006. There were no such costs and expenses for the year ended June 30, 2006.

Stock Compensation — On July 1, 2005, the Company adopted the provisions of Financial Accounting Standards Board Statement No. 123R, "Share-Based Payment" (SFAS 123R). SFAS 123R revised SFAS 123, "Accounting for Stock Based Compensation" and supersedes APB Opinion No. 25, "Accounting for Stock Issued to Employees." SFAS 123R requires companies to measure and recognize compensation expense for all employee stock-based payments at fair value over the service period underlying the arrangement. Therefore, the Company is now required to record the grant-date fair value of its graded vesting employee stock-based payments (i.e., stock options and other equity-based compensation) in the statement of operations. The Company adopted FAS 123R using the "modified prospective" method, whereby the fair value of all previously-granted employee stock-based arrangements that remained unvested at July 1, 2005 and all grants made on or after July 1, 2005 have been included in the Company's determination of stock-based compensation expense for the year ended June 30, 2006. The compensation costs charged as operating expense for grants under the plan were approximately \$1,034,000 for the year ended June 30, 2006. No tax benefit was recognized related to share-based compensation expense since the Company has never reported taxable income and has established a full valuation allowance to offset all of the potential tax benefits associated with our deferred tax assets. In addition, no amounts of share-based compensation cost were capitalized as part of fixed assets or inventories for the periods presented.

During fiscal year 2004 and 2005 the Company recorded and reported its employee stock-based compensation pursuant to APB 25 and its related interpretations, pursuant to which stock-based compensation was recorded for grants of performance-based equity awards to certain employees but no compensation expense was recorded for most grants because the awards provided for time-based vesting and the exercise price equaled the fair value of the underlying common stock on the date of grant. The Company has not restated its operating results for the years ended June 30, 2004 and 2005 to reflect charges for the fair value of employee stock-based arrangements. See Note 3.

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.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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, 2004, 2005 and 2006 is approximately 10,104,000, 9,340,000 and 8,939,000, respectively.

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

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

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

New Accounting Standards — In June 2006, the Financial Accounting Standards Board (FASB) issued FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109," ("FIN 48"). FIN 48 clarifies the accounting for uncertainties in income taxes recognized in a company's financial statements in accordance with Statement 109 and prescribes a recognition threshold and measurement attributable for financial disclosure of tax positions taken or expected to be taken on a tax return. Additionally, Interpretation 48 provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. Interpretation 48 is effective for fiscal years beginning after December 15, 2006. Because the Company has not reported any income tax expense it does not expect adoption will materially impact its financial position, results of operations or cash flows.

2. Selected Balance Sheet Information

Receivables — Receivables consist of amounts due to the Company for product sales and rentals and research services provided under terms of government grants, and are presented net of allowances for doubtful accounts of \$16,000 and \$55,000 at June 30, 2005 and 2006, respectively.

Restricted Investments — Included in other current assets at both June 30, 2005 and 2006 are \$91,000 of bank certificates of deposit which serve as collateral for certain potential European Value Added Taxes.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Property and Equipment — Property and equipment consists of the following:

	June 30,	
	2005	2006
Machinery and equipment	\$ 1,405,000	\$ 1,957,000
Office equipment	807,000	1,029,000
Leasehold improvements	622,000	622,000
Equipment in process	111,000	111,000
	2,945,000	3,719,000
Less accumulated depreciation and amortization	(2,192,000)	(2,503,000)
	<u>\$ 753,000</u>	<u>\$ 1,216,000</u>

Accounts Payable and Accrued Expenses — Accounts payable and accrued expenses consists of the following:

	June 30,	
	2005	2006
Accounts payable	\$ 216,000	\$ 356,000
Accrued expenses:		
Clinical studies	48,000	169,000
Manufacturing and engineering	53,000	273,000
Professional services	124,000	98,000
Other	92,000	188,000
	<u>\$ 533,000</u>	<u>\$ 1,084,000</u>

Accrued Employee Benefits — Accrued employee benefits consists of the following:

	June 30,	
	2005	2006
Accrued vacation pay	\$ 210,000	\$ 251,000
Relocation expenses	104,000	—
Performance bonuses	—	600,000
Payment to stay to former CEO	—	589,000
Other	22,000	15,000
	<u>\$ 336,000</u>	<u>\$ 1,455,000</u>

3. Shareholders' Equity

Employee Stock-Based Compensation

Stock Option and Equity Incentive Plans — The Company has various stock option plans (Option Plans) and agreements that provide for the issuance of nonqualified and incentive stock options to acquire up to 3,645,945 shares of common stock. Such options 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 generally become exercisable ratably over a four-year period following the date of grant.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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. Any shares that are issuable upon expiration or cancellation of options previously granted under the 1992 Stock Option Plan or the 1996 Outside Director Stock Option Plan will not be available for future grants.

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 2001 Stock Option Plan. However, any shares that are issuable upon expiration or cancellation of options previously granted under the 2001 Stock Option Plan will be available for future grants under the 2004 Plan.

On November 1, 2005, a new equity compensation policy for outside directors was approved. Each non-employee director will receive periodic grants of stock options and restricted stock awards. A stock option grant to purchase 30,000 shares will be made at the start of an elected three year term with an exercise price equal to the fair market value of the common stock on the date of grant, and will vest in equal annual increments over a period of three years. New non-employee directors appointed to less than a three year term will receive a grant for a pro rated amount of the 30,000 shares, reflecting the period of time until they are expected to be subject to election by the shareholders. Each non-employee director will also receive an annual grant of shares of restricted common stock with an aggregate value of \$15,000, with the number of shares being computed based on the price of the common stock ten days prior to the date of grant. The restricted shares vest one year after the date of grant.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

The following table summarizes the combined activity under the equity incentive plans for the indicated periods:

	<u>Options Outstanding</u>	<u>Awards Available for Grant</u>	<u>Weighted Average Exercise Price Per Share</u>	<u>Options Exercisable at Period End</u>
March 24, 1989 (Inception)				
Options authorized	—	8,049,927		
Options terminated with approval of 2001 Plan	—	(1,062,286)		
Options canceled	(2,947,074)	2,847,074	\$ 3.48	
Options granted	9,144,615	(9,044,615)	\$ 1.80	
Options exercised	(1,851,782)	—	\$.44	
Balance, June 30, 2003	<u>4,345,759</u>	<u>790,100</u>	\$ 1.58	1,925,884
Options authorized	—	2,000,000		
Options terminated with approval of 2001 Plan	—	(3,333)		
Options canceled	(203,333)	203,333	\$.41	
Options granted	819,000	(819,000)	\$ 1.60	
Options exercised	(5,000)	—	\$ 1.20	
Balance, June 30, 2004	<u>4,956,426</u>	<u>2,171,100</u>	\$ 1.33	3,118,094
Options authorized	—	3,000,000		
Options abandoned with approval of 2004 Plan	—	(734,425)		
Options canceled	(727,159)	296,612	\$ 1.16	
Options granted	1,410,750	(676,325)	\$ 1.33	
Options exercised	(1,554,064)	—	\$.84	
Balance, June 30, 2005	<u>4,085,953</u>	<u>4,056,962</u>	\$ 1.55	1,782,871
Options abandoned due to approval of 2004 Plan	—	(77,217)		
Options canceled	(323,217)	323,217	\$ 2.17	
Options granted	289,900	(289,900)	\$ 2.55	
Restricted stock awards and units granted	—	(374,217)		
Restricted stock awards and units canceled	—	7,100		
Options exercised	(528,083)	—	\$.90	
Balance, June 30, 2006	<u>3,524,553</u>	<u>3,645,945</u>	\$ 1.67	2,361,707

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

The following table summarizes information about stock option plans as of June 30, 2006:

Range of Exercise Prices	Number of Options Outstanding	Remaining Contractual Life — Years	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price of Exercisable Options
\$.31 - \$.99	929,939	7.4	\$.66	535,936	\$.64
\$1.05 - \$2.27	1,609,206	6.9	\$ 1.42	970,199	\$ 1.26
\$2.44 - \$2.95	780,000	5.0	\$ 2.92	698,289	\$ 2.92
\$3.19 - \$3.65	205,408	6.6	\$ 3.19	157,283	\$ 3.20
	<u>3,524,553</u>		<u>\$ 1.67</u>	<u>2,361,707</u>	<u>\$ 1.72</u>

2006 Employee Stock-Based Compensation Expense

As described in Note 1, effective July 1, 2005, we adopted FAS 123R and began recognizing compensation expense for the fair value of equity grants to employees and directors.

The fair value of each employee and director grant of options to purchase common stock is estimated on the date of the grant using the Black-Scholes option-pricing model with the following weighted-average assumptions used for grants for the year ended June 30, 2006: 1) risk-free interest rate of 4.3%; 2) expected dividend yield of 0%; 3) expected holding period of 6.6 years based on the simplified method provided for in Securities and Exchange Commission Staff Accounting Bulletin No. 107 for “plain vanilla options”; 4) expected volatility of 106%. The fair value of restricted stock award and unit grants is measured based upon the quoted market price of the Company’s common stock on the date of grant. Stock-compensation expense related to options and restricted stock awards and units is reported net of estimated forfeitures of 10%.

The estimated 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 the Company’s historical rate. The Company estimates the expected life of options granted based on the simplified method provided for in the Securities and Exchange Commission Staff Accounting Bulletin No. 107 for “plain vanilla options.” The Company estimates the volatility of its common stock at the date of grant based on historical volatility. The Company estimates the forfeiture rate based on historical experience of its stock-based awards.

Compensation costs reported as operating expense for the option grants under the 2004 Plan were approximately \$724,000 for the year ended June 30, 2006.

During the year ended June 30, 2006 we granted 374,217 shares of restricted stock awards and units and 289,900 options to purchase common stock, to directors of the Company and to employees. Restricted stock awards are granted to U.S. employees, while restricted stock units, which entitle the recipient to receive common stock upon vesting, are granted to international employees. Restricted stock awards and units are treated the same with respect to stock-based compensation expense. The weighted average grant-date fair value of shares of restricted stock awards and units granted during the year ended June 30, 2006 was \$2.35. As of June 30, 2006, 7,100 shares of restricted stock awards and units were forfeited and no shares have vested. The compensation costs charged as operating expenses for restricted stock for the year ended June 30, 2006 were \$310,000.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

A summary of option activity under the plan as of June 30, 2006, and changes during the year then ended are presented below:

Options	Shares	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		
Forfeited or expired	(323,217)	\$ 2.17		
Outstanding at June 30, 2006	<u>3,524,553</u>	<u>\$ 1.67</u>	<u>6.5</u>	<u>\$ 860,000</u>
Exercisable at June 30, 2006	<u>2,361,707</u>	<u>\$ 1.72</u>	<u>5.6</u>	<u>\$ 564,000</u>

A summary of the status of the Company's non-vested shares as of June 30, 2006 is presented below:

Non-Vested Options	Shares	Weighted Average Grant Date Fair Value
Non-vested at July 1, 2005	1,890,071	\$ 1.29
Granted	289,900	\$ 2.55
Vested	(812,473)	\$ 1.18
Forfeited	(204,652)	\$ 1.77
Non-vested at June 30, 2006	<u>1,162,846</u>	<u>\$ 1.59</u>

As of June 30, 2006 there was approximately \$892,000 of total unrecognized compensation cost related to non-vested share-based compensation arrangements granted under the plan. That cost is expected to be recognized over a weighted-average period of 2.5 years.

2005 and 2004 Employee Stock-Based Compensation Expense

During fiscal year 2004 and 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 years ended June 30, 2004 and 2005:

	June 30,	
	2004	2005
Reported net loss	\$ (10,488,000)	\$ (11,811,000)
Add: Stock-based employee compensation expense included in reported net loss	372,000	160,000
Deduct: Stock-based employee compensation expense determined under fair value based method for all awards	(1,352,000)	(721,000)
Pro forma net loss	<u>\$ (11,468,000)</u>	<u>\$ (12,372,000)</u>
Earnings per share:		
As reported	\$ (.14)	\$ (.13)
Pro forma	<u>\$ (.16)</u>	<u>\$ (.13)</u>

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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,	
	2004	2005
Dividend rate	None	None
Expected stock price volatility	60%	72%
Risk-free interest rate	3.1% — 3.9%	3.5% — 3.9%
Expected life of options	5 years	5 years

The weighted average fair value of options granted during the years ended June 30, 2004 and 2005 was \$1.60 and \$1.33 per share, respectively.

During fiscal year 2001, pursuant to Financial Accounting Standards Board Interpretation Number 44 to APB 25 (Interpretation No. 44) as it related to an effective re-pricing of options to purchase 759,000 shares of common stock issued by the Company in December 1999 to certain employees. Under this rule, a charge to expense was required for subsequent increases in the market price of the Company's common stock above \$2.41 per share. Such charges continued until such options were exercised, forfeited or otherwise expired. During fiscal year 2004, there was no charge to expense because the Company's common stock price did not exceed \$2.41 per share. During fiscal year 2005, the Company recorded a \$59,000 charge to selling, general and administrative expenses related to these options. These options were exercised during fiscal year 2005.

Employee Stock Purchase Plan — The Company had an employee stock purchase plan under which eligible employees could purchase common stock, at a discount to the market price, through payroll deductions of up to 10% of the employee's base compensation, subject to certain limitations, during sequential 24-month offering periods. Each offering period was divided into four consecutive six-month purchase periods beginning on March 1 and September 1 of each year. Unless otherwise provided by the Board of Directors prior to the commencement of an offering period, the price at which stock was purchased under the plan for such offering period was equal to 85% of the lesser of the fair market value of the common stock on the first day of such offering period or the last day of the purchase period of such offering period. During the years ended June 30, 2004 and 2005, 40,919 shares and 39,017 shares, respectively, of common stock were purchased under this plan. From Inception to June 30, 2006, 231,491 shares were purchased under this plan. The Employee Stock Purchase plan was terminated effective March 1, 2005.

Non-Employee Stock-Based Compensation Expense

Stock Purchase Warrants Issued for Services — In August 2003, the Company issued warrants to two individuals who performed public and investor relations services. Under the terms of this agreement, the holders were entitled to purchase up to 100,000 shares of common stock for \$0.50 through August 4, 2004. As a result of this agreement the Company recorded \$53,000 in selling, general and administrative expenses during the year ended June 30, 2004 which represented the fair value of the warrants. At June 30, 2006 and 2005, none of these warrants were outstanding.

The fair value of all warrants issued in fiscal year 2004 were determined at the date of grant using the Black-Scholes option-pricing model at an expected stock price volatility of 120% and a risk-free interest rate of 1.26%. These warrants were issued in private transactions.

Stock Purchase Warrants — In July 2003, the Company issued 5,058,824 shares of common stock to multiple private placement investors, for gross proceeds of approximately \$4,300,000. As part of this transaction, the Company issued warrants to the private placement investors, exercisable for 4 years, or until July 9, 2007, to purchase up to 1,264,706 shares of common stock at \$1.23, as well as warrants to purchase up to 1,011,765 shares of

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

common stock at \$1.50 per share prior to October 31, 2003. These later warrants expired unexercised. In addition, warrants to purchase 303,529 shares of common stock were issued to a private placement agent, exercisable for 4 years, or until July 9, 2007, at a price of \$1.23. At June 30, 2006, warrants to purchase up to 808,824 shares of common stock pursuant to these warrant agreements remained outstanding.

In April 2004, the Company issued 8,000,000 shares of common stock through a registered direct offering to institutional investors, for gross proceeds of approximately \$9,100,000. As part of this transaction, the Company issued warrants to the institutional investors, 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 2.4 million shares of common stock at an exercise price of \$1.65 per share. In addition, the Company issued warrants to the 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, 2005, to purchase up to 560,000 shares of common stock at an exercise price of \$1.65 per share. At June 30, 2006, warrants to purchase up to 2.4 million shares of common stock pursuant to these warrant agreements remained outstanding.

In October 2004, the Company issued 8,264,463 shares of common stock through a registered direct offering to institutional investors, for aggregate gross cash proceeds of approximately \$10,000,000. As part of this transaction, the Company issued warrants to the institutional investors, exercisable from April 28, 2005 through October 27, 2008, to purchase up to 2,066,116 shares of common stock at an exercise price of \$1.74 per share. In addition, the Company issued warrants to the placement agent, exercisable from April 28, 2005 through October 27, 2008, to purchase up to 495,868 shares of common stock at an exercise price of \$1.74 per share. At June 30, 2006, warrants to purchase up to 1,838,843 shares of common stock pursuant to these warrant agreements remained outstanding.

Common Shares Reserved — As of June 30, 2006, the Company has reserved shares of common stock for future issuance as follows:

Issuance under stock option and stock purchase plans	13,530,216
Issuance under stock purchase warrants	5,047,667
	18,577,883

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

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:

	Year Ended June 30,		
	2004	2005	2006
Loss before income taxes	\$ 10,488,000	\$ 11,811,000	\$ 16,475,000
Federal statutory rate	34%	34%	34%
Taxes computed at federal statutory rate	(3,566,000)	(4,015,000)	(5,600,000)
State taxes, net of federal taxes	—	(354,000)	—
Increase (decrease) in taxes from:			
Stock compensation	145,000	(80,000)	110,000
Other, net	5,000	(85,000)	10,000
Valuation allowance	3,416,000	4,534,000	5,480,000
Reported income taxes	\$ —	\$ —	\$ —

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Deferred tax assets consist of the following:

	June 30,	
	2005	2006
Net operating loss carryforwards	\$ 21,200,000	\$ 25,500,000
Research and development credit carryforwards	685,000	935,000
Inventories	435,000	435,000
Property and equipment	130,000	120,000
Employee benefits	—	550,000
Other, net	100,000	190,000
Total deferred tax assets	22,550,000	27,730,000
Valuation allowance	(22,550,000)	(27,730,000)
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, 2006 the Company estimates the maximum Federal tax net operating loss and tax credit carryforwards, which could be utilized, were \$69,000,000 and \$935,000, respectively, which will expire from 2007 through 2027, if not utilized. The Company's ability to utilize its net operating loss and tax credit carryforwards may become subject to further annual limitation in the event of future change in ownership events.

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 \$5,000 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. The sublicense agreement also provided for the Company to receive an up-front fee of \$10,000 and a one-time fee of \$50,000 due thirty days after the one-year anniversary of the effective date of the agreement. The upfront fee was received in fiscal year 2003 and the anniversary fee was received in fiscal year 2004. These fees were recorded as research and development agreements revenue. 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.

Musculoskeletal Transplant Foundation — In June 2003, the Company entered into a strategic alliance with Musculoskeletal Transplant Foundation (MTF) to jointly develop and commercialize innovative treatments for the regeneration of tissues such as bone and cartilage. Under the terms of the alliance, the companies will develop products that are based on combinations of MTF's matrices and Aastrom's TRCs.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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 effect on the Company's business.

6. Operating Lease and Purchase Order Commitments

As of June 30, 2006, the Company leases its office and research facility under a month-to-month operating lease. Rent expense for the years ended June 30, 2004, 2005 and 2006, was \$616,000, \$626,000 and \$626,000, respectively, and \$6,331,000 for the period from Inception to June 30, 2006.

As of July 20, 2006, the Company renegotiated its lease with Domino's Farms Office Park, LLC, increasing the leased space to 30,230 square feet. This new lease covers a period of five years, beginning on the date of occupancy of the additional space, which the Company anticipates will be in March 2007. The aggregate minimum rent commitment under the new five year lease is approximately \$4,878,000.

As of June 30, 2006, the Company had open purchase order commitments totaling \$398,000.

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 \$121,000, \$137,000 and \$160,000 for the years ended June 30, 2004, 2005 and 2006, respectively and \$673,000 for the period from Inception to June 30, 2006.

8. Quarterly Financial Data (Unaudited)

Year Ended June 30, 2006	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Fiscal Year
Revenues	\$ 180,000	\$ 117,000	\$ 238,000	\$ 328,000	\$ 863,000
Loss from operations	(3,974,000)	(4,339,000)	(4,799,000)	(4,801,000)	(17,733,000)
Net loss	(3,488,000)	(4,142,000)	(4,549,000)	(4,296,000)	(16,475,000)
Net loss per common share	(.03)	(.04)	(.04)	(.04)	(.15)
Year Ended June 30, 2005	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Fiscal Year
Revenues	\$ 187,000	\$ 374,000	\$ 252,000	\$ 96,000	\$ 909,000
Loss from operations	(2,709,000)	(2,550,000)	(3,553,000)	(3,605,000)	(12,417,000)
Net loss	(2,649,000)	(2,453,000)	(3,349,000)	(3,360,000)	(11,811,000)
Net loss per common share	(.03)	(.03)	(.03)	(.03)	(.13)

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.

9. Subsequent Event

On July 17, 2006, Aastrom announced that George W. Dunbar had joined the Company as Chief Executive Officer, President and a Director to replace Dr. R. Douglas Armstrong, who will continue as Chairman of the Board for the remainder of his term. Pursuant to Dr. Armstrong's revised employment agreement, he is entitled to \$638,000 as payment to stay, including the \$589,000 that is reported as an operating expense for the year ended June 30, 2006. In July 2006, Dr. Armstrong also entered into a consulting agreement, pursuant to which he is entitled to approximately \$42,000, unless the agreement is extended.

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 13(a) — 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 using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control — Integrated Framework. Management, under the supervision and with the participation of the Company's Chief Executive Officer and Chief Financial Officer, assessed the effectiveness of our internal control over financial reporting as of June 30, 2006 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 and management's assessment of the effectiveness of our internal control over financial reporting as of June 30, 2006, and has expressed unqualified opinions thereon in their report which appears under Item 8.

Changes in Internal Control over Financial Reporting

During our fourth quarter of fiscal 2006 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 2006 Annual Meeting of Shareholders to be held on November 2, 2006.

Item 10. Directors and Executive Officers of the Registrant

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 Aastron."

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 and Related Transactions

The information relating to certain relationships and related 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 certain relationships and related transactions is incorporated by reference to the Proxy Statement under the caption "Ratification of Appointment of Independent Registered Public Accounting Firm".

PART IV

Item 15. Exhibits and Financial Statement Schedule

(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, 2006

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below on September 13, 2006 by the following persons in the capacities indicated.

<u>Signature</u>	<u>Title</u>
_____ /s/ GEORGE W. DUNBAR George W. Dunbar	Chief Executive Officer, President and Director <i>(Principal Executive Officer)</i>
_____ /s/ GERALD D. BRENNAN, JR. Gerald D. Brennan, Jr.	Vice President Administrative and Financial Operations and Chief Financial Officer <i>(Principal Financial and Accounting Officer)</i>
_____ /s/ R. DOUGLAS ARMSTRONG, PH.D. R. Douglas Armstrong, Ph.D.	Chairman
_____ /s/ SUSAN L. WYANT, PHARM. D Susan L. Wyant, Pharm. D	Lead 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/ STEPHEN G. SUDOVAR Stephen G. Sudovar	Director
_____ /s/ ROBERT L. ZERBE, M.D. Robert L. Zerbe, M.D.	Director

EXHIBIT INDEX

Number	Notes
3.1	Restated Articles of Incorporation of Aastrom, as amended.
3.2	H Bylaws, as amended.
10.1#	A Form of Indemnification Agreement.
10.2#	A Amended and Restated 1992 Incentive and Non-Qualified Stock Option Plan and forms of agreements thereunder.
10.3#	A 1996 Outside Directors Stock Option Plan and forms of agreements thereunder.
10.20#	A Form of Employment Agreement.
10.21	A 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	A 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#	A Employee Proprietary Information and Invention Agreement, effective June 1, 1991, between Aastrom and R. Douglas Armstrong.
10.72#	B Aastrom Biosciences 2001 Stock Option Plan.
10.76	C 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.
10.79#	F Employment Agreement with Janet Hock dated September 1, 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#	H Form of Option and Restricted Stock Award Agreements for Grants under 2004 Equity Incentive Plan.
10.85	H Employee Compensation Guidelines.
10.86#	H Employment Agreement with Gerald D. Brennan, Jr. dated June 10, 2005.
10.87	H 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.
21	Subsidiaries of Registrant.
23.1	Consent of Independent Registered Public Accounting Firm.
31	Rules 13a-14(a) and 14d-14(a) Certifications.
32	Section 1350 Certifications.

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 Annual Report on Form 10-K for the year ended June 30, 2005.

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

SCHEDULE II
VALUATION AND QUALIFYING ACCOUNTS

	Years Ended June 30,		
	2004	2005	2006
Allowance for Doubtful Accounts:			
Balance at beginning of year	\$ 31,000	\$ 7,000	\$ 16,000
Additions charged to income	4,000	9,000	39,000
Write-offs, net of recoveries	(28,000)	—	—
Balance at end of year	<u>\$ 7,000</u>	<u>\$ 16,000</u>	<u>\$ 55,000</u>

	Years Ended June 30,		
	2004	2005	2006
Reserve for Obsolescence and Excess Inventories:			
Balance at beginning of year	\$ 950,000	\$ 1,203,000	\$ 1,173,000
Additions charged to income	253,000	9,000	—
Reductions(1)	—	(39,000)	—
Balance at end of year	<u>\$ 1,203,000</u>	<u>\$ 1,173,000</u>	<u>\$ 1,173,000</u>

(1) Reflects the elimination of reserve upon the sale of the related inventories.

**RESTATED ARTICLES OF INCORPORATION
FOR USE BY DOMESTIC PROFIT CORPORATIONS**

1. The present name of the corporation is:
Aastrom Biosciences, Inc.
2. The identification number assigned by the Bureau is:
529-456
3. All former names of the corporation are:
Ann Arbor Stromal, Inc.
4. The date of filing the original Articles of Incorporation was:
March 24, 1989

The following Restated Articles of Incorporation supersede the Articles of Incorporation as amended and shall be the Articles of Incorporation for the corporation:

ARTICLE I:

The name of the corporation is:
Aastrom Biosciences, Inc.

ARTICLE II:

The purpose or purposes for which the corporation is formed are:
To engage in any activity within the purpose for which corporations may be organized under the Michigan Corporation Act.

ARTICLE III:

The total authorized shares:

Common Shares 200,000,000 Preferred Shares 5,000,000

A statement of all or any of the relative rights, preferences and limitations of the shares of each class is as follows:
See Rider attached hereto and made a part hereof.

ARTICLE IV:

1. The address of the registered office is:

Domino's Farms Lobby L, 24 Frank Lloyd Wright Drive, Ann Arbor, Michigan 48105.

2. The mailing address of the registered office, if different than above:

P.O. Box 376, Ann Arbor, Michigan 48106.

3. The name of the resident agent:

Michael Durski

ARTICLE V:

(OPTIONAL. DELETE IF NOT APPLICABLE)

ARTICLE VI:

(OPTIONAL. DELETE IF NOT APPLICABLE)

ARTICLE VII:

(ADDITIONAL PROVISIONS, IF ANY, MAY BE INSERTED HERE; ATTACH ADDITIONAL PAGES IF NEEDED.)

See Rider attached hereto and made a part hereof.

RIDER TO ARTICLE III

PART A: COMMON STOCK

Section 1. Voting Rights.

a. One Vote Per Share. The holders of shares of Common Stock shall be entitled to one vote for each share so held with respect to all matters voted on by the holders of shares of Common Stock of the Corporation.

b. Two-Thirds Consent. Consent of the holders of a least two-thirds (2/3) of the outstanding shares of Common Stock shall be required for (i) any action which results in a consolidation or merger which would be treated as a liquidation, dissolution or winding up of the Corporation under Section 2 of this Part A of this Article III, or which results in the liquidation, sale or assignment of all or substantially all of the assets of the Corporation; (ii) any amendment to these Articles of Incorporation; or (iii) any amendment by the shareholders of the Corporation of the Bylaws of the Corporation (the Board of Directors of the Corporation, as provided in Section 3 of Article VII, shall have the authority to amend the Bylaws of the Corporation without the consent of the shareholders of the Corporation).

Section 2. Liquidation Rights. Subject to preferences applicable to any outstanding shares of Preferred Stock, all distributions made or funds paid to the holders of Common Stock upon the occurrence of any voluntary or involuntary liquidation, dissolution or winding up of the affairs of the Corporation shall be made on the basis of the number of shares of Common Stock held by each of them. A consolidation or merger of the Corporation with or into another corporation or entity shall be regarded as a liquidation, dissolution or winding up of the Corporation within the meaning of this Section 2 unless such consolidation or merger is not intended to effect a change in the ownership or control of the Corporation or of its assets and is not intended to alter materially the business or assets of the Corporation, including, by way of example and without limiting the generality of the foregoing: (i) a consolidation or merger which merely changes the identity, form or place of organization of the Corporation, or which is between or among the Corporation and any of its direct or indirect subsidiaries, or (ii) following such merger or consolidation, shareholders of the Corporation immediately prior to such event own not less than 51% of the voting power of such corporation immediately after such merger or consolidation on a pro rata basis.

Section 3. Dividends. Dividends may be paid on the Common Stock as and when declared by the Board of Directors, subject to preferences applicable to any outstanding shares of Preferred Stock.

PART B. PREFERRED STOCK

The Preferred Stock may be issued from time to time in one or more series. The Board of Directors of the Corporation is hereby authorized, within the limitations and restrictions stated in these Restated Articles of Incorporation, to fix or alter the dividend rights, dividend rate, conversion rights, voting rights, rights and terms of redemption (including sinking fund provisions), the redemption price or prices, and the liquidation preferences of any wholly unissued series of Preferred Stock, and the number of shares constituting any such series and the designation thereof, or any of them, and to increase or decrease the number of shares of any series subsequent to the issue of shares of that series but not below the number of shares of such series then outstanding. In case the number of shares of any series shall be so decreased, the shares constituting such decrease shall resume the status which they had prior to the adoption of the resolution originally fixing the number of shares of such series.

RIDER TO ARTICLE VII

1. Director Liability. A director of the Corporation shall not be personally liable to the Corporation or its shareholders for monetary damages for breach of fiduciary duty as a director. However, this provision does not eliminate or limit the liability of a director for any of the following:

- (a) any breach of the director's duty of loyalty to the Corporation or its shareholders;
- (b) any acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;

(c) a violation of Section 551(1) of the Michigan Business Corporation Act, as amended (the “MBCA”);

(d) a transaction from which the director derived an improper personal benefit; or

(e) an act or omission occurring before the date these Articles of Incorporation became effective in accordance with the pertinent provisions of the MBCA.

Any repeal, amendment or other modification of this Article VII shall not adversely affect any right or protection of a director of the Corporation existing at the time of such repeal, amendment or other modification.

If the MBCA is amended, after this Article becomes effective, to authorize corporate action further eliminating or limiting personal liability of directors, then the liability of directors shall be eliminated or limited to the fullest extent permitted by the MBCA as so amended.

2. Control Share Acquisitions. Chapter 7B of the MBCA, known as the “Stacy, Bennett, and Randall shareholder equity act,” does not apply to control share acquisitions of shares of the Corporation.

3. Amendment of Bylaws. In furtherance and not in limitation of the powers conferred by statute, the Board of Directors of the Corporation is expressly authorized to make, alter or repeal the Bylaws of the Corporation.

SUBSIDIARIES OF REGISTRANT

Astrom Biosciences, Ltd.
Astrom Biosciences GmbH
Astrom Biosciences SL

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 and 333-25021) and Form S-3 (Nos. 333-123570, 333-108963, 333-108989, 333-108964 and 333-107579) of Aastron Biosciences, Inc. (a development stage company) of our report dated September 13, 2006, relating to the financial statements, financial statement schedule, management's assessment of the effectiveness of internal control over financial reporting and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP
Minneapolis, Minnesota
September 13, 2006

CERTIFICATION

I, George W. Dunbar, 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.
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: September 13, 2006

/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.
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: September 13, 2006

/s/ GERALD D. BRENNAN, JR.

Gerald D. Brennan, Jr.
Vice President Administrative and 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, 2006, 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:

- (1) The Report fully complies with the requirements of section 13(a) of the Securities Exchange Act of 1934 (15 U.S.C. 78m); and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: September 13, 2006

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

**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, 2006, 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:

- (1) The Report fully complies with the requirements of section 13(a) of the Securities Exchange Act of 1934 (15 U.S.C. 78m); and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: September 13, 2006

/s/GERALD D. BRENNAN, JR.
Gerald D. Brennan, Jr.
*Vice President Administrative and Financial
Operations and Chief Financial Officer*