

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

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

For the fiscal year ended June 30, 2004

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:

None

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

Common Stock, no par value

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 75 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 an accelerated filer (as defined in Rule 12b-2 of the 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 SmallCap Market) on December 31, 2003 was approximately \$94 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, 2004, 83,076,168 shares of Common Stock, no par value, were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Document

Form 10-K Reference

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

		<u>Page No.</u>
<u>PART I</u>		
<u>Item 1.</u>	<u>Business</u>	2
<u>Item 2.</u>	<u>Properties</u>	16
<u>Item 3.</u>	<u>Legal Proceedings</u>	17
<u>Item 4.</u>	<u>Submission of Matters to a Vote of Security Holders</u>	17
<u>PART II</u>		
<u>Item 5.</u>	<u>Market for Registrant’s Common Equity and Related Shareholder Matters</u>	18
<u>Item 6.</u>	<u>Selected Financial Data</u>	19
<u>Item 7.</u>	<u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	20
<u>Item 7A.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	24
<u>Item 8.</u>	<u>Financial Statements and Supplementary Data</u>	32
<u>Item 9.</u>	<u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	48
<u>Item 9A.</u>	<u>Controls and Procedures</u>	48
<u>Item 9B.</u>	<u>Other Information</u>	48
<u>PART III</u>		
<u>Item 10.</u>	<u>Directors and Executive Officers of the Registrant</u>	49
<u>Item 11.</u>	<u>Executive Compensation</u>	49
<u>Item 12.</u>	<u>Security Ownership of Certain Beneficial Owners and Management</u>	49
<u>Item 13.</u>	<u>Certain Relationships and Related Transactions</u>	49
<u>Item 14.</u>	<u>Principal Accountant Fees and Services</u>	49
<u>PART IV</u>		
<u>Item 15.</u>	<u>Exhibits and Financial Statement Schedule</u>	50
<u>Signatures</u>		51
<u>EXHIBIT 10.77</u>		
<u>EXHIBIT 21</u>		
<u>EXHIBIT 23.1</u>		
<u>EXHIBIT 31</u>		
<u>EXHIBIT 32</u>		

Table of Contents

Except for the historical information presented, the matters discussed in this Report, including our product development and commercialization goals and expectations, revenue expectations, potential market opportunities, our plans and anticipated results of clinical development activities and the potential advantage 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 "Business Risks" 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 late-stage development company focused on the development of processes and products for the *ex vivo* production and sale of human cell products for use in cell therapy and regenerative medicine. Our pre-clinical and clinical product development programs utilize adult bone marrow stem and progenitor cells for forming solid tissues such as bone, vascular tissue, cartilage, and blood and immune system cells.

Cell therapy is the use of living cells in the treatment of medical disorders. These cells can either be used in conjunction with, or as a replacement for, traditional therapies. Cell therapy began with simple, but very effective, blood and platelet transfusions, expanding later to include specialized procedures including hematopoietic stem cell transplants obtained from the marrow or from the blood stream after stem cell mobilization. In hematopoietic procedures, stem cells are transplanted into patients to restore blood and immune system function that is damaged or destroyed by aggressive chemotherapy and/or radiation therapy used to treat the cancer. In immunologic cell therapy, T-cells and dendritic cells are administered to stimulate an immune response in patients with various forms of cancers and infectious diseases, such as viral infections. In recent years, pre-clinical and clinical observations appear to extend the potential use of bone marrow-derived stem cells to regenerate multiple tissues including bone, blood vessels, cartilage, cardiac tissue, and nerves.

While these forms of cell therapy are emerging as potential new treatment options for several diseases and medical disorders, the success of cellular therapy is based, in part, on the need for care providers to be able to access therapeutic quantities of biologically active cells necessary for patient treatment, cost-effectively and in compliance with regulatory requirements. Our patented AastromReplicell® System and single-pass perfusion technology are intended to enable the manufacturing of patient specific cell products for clinical use.

In the expanding field of cell therapy, we develop proprietary Prescription Cell Products (PCP) for the regenerative repair of damaged human tissues and other medical disorders, the first of which is now in the clinical stage. Our lead PCP products are Tissue Repair Cells (TRCs), which are a unique mixture of bone marrow-derived stem and progenitor cells, produced *ex vivo*. In previous multi-center clinical trials involving over 160 patients, our TRCs have been demonstrated to be safe and reliable, and to regenerate certain normal healthy human tissues.

We have also developed our proprietary AastromReplicell System, which is a patented, integrated system of instrumentation and single-use consumable kits for the commercial production of human cells. The AastromReplicell System was developed to provide a manufacturing platform for our proprietary cell products, such as our TRCs. The AastromReplicell System technology has recently been expanded for the production of dendritic cells and dendritic cell vaccines, and is the basis of our Cell Production Products (CPP) business. The clinical use of dendritic cell vaccines is minimal at this time, and as such the market is only just developing. We are currently exploring the market for our CPP dendritic cell vaccine products in the European Union (EU) and in the United States by targeting academic and other third party therapeutic cell developers requiring automated cell production with GMP compliance.

Table of Contents

Our commercial production pathway for our Prescription Cell Products is enabled through the AastromReplicell System platform. This proprietary and automated clinical cell production system combines patented GMP-compliant automated cell production with patented “single-pass perfusion.” Single-pass perfusion is our technology for growing large quantities of highly robust human cells outside the body. These cells include adult stem and progenitor cell mixtures — cells required for forming solid tissues such as bone, vascular tissue, cartilage, and blood and immune system cells.

Stem cells are human cells that have the capability to form many or all of an individual’s tissues and organs. Our PCP cell therapy programs currently utilize bone marrow-derived stem cells, a class of adult stem cells that is found in every individual’s bone marrow. Access to adult stem cells is obtained through a recognized procedure, without controversy, and these cells have successfully grown to the increased number of cells required for certain clinical applications, using the patented technology embodied in the AastromReplicell System. Our programs have used bone marrow, cord blood and blood cells as starting sources of cells. As such, federal support or other factors relating to embryonic stem cell research have no direct impact on our current product programs.

Our primary business model utilizes patented core technology and processes for the manufacturing and distribution of TRC cell products for use in multiple medical markets. Initially, we will pursue TRCs for the following two therapeutic areas:

- Local bone regeneration in fractures, spinal fusion and jaw bone reconstruction for dental implants
- Vascular (blood vessel) regeneration in limb ischemia resulting from diabetes and other diseases

In the future, we may develop, and/or support third party development of TRC products for other areas such as cartilage regeneration and cardiac tissue regeneration.

In the EU, our business and marketing activities are directed through Zellera AG, our wholly-owned subsidiary located in Berlin, Germany

Prescription Cell Products

We are leveraging our *ex vivo* cell production technology for a growing Prescription Cell Product pipeline by focusing on our Tissue Repair Cells (TRCs) for stem cell-derived tissue repair and regeneration.

Tissue Repair Cells

The clinical trial direction of our development effort has been influenced by observations that our bone marrow cell products (TRCs) may be suitable as a treatment for bone and vascular regeneration, each of which may represent a substantial market opportunity. In reviewing the pre-clinical and clinical data for our bone marrow cell products in various Aastrom-supported trials and research, we have noted that the cells produced contain a substantial increase in the cell types that can generate connective tissues including bone and cartilage. In addition, our bone marrow cell product has been given to one patient, on a compassionate-use basis approved by the FDA, with a congenital genetic defect (hypophosphatasia) resulting in a lethal condition of abnormal bone and cartilage formation. The results of this compassionate-use treatment, now published in the *Journal of Bone and Mineral Research*, demonstrated bone formation in the child.

Using the AastromReplicell System, TRCs are grown from a small sample of a patient’s bone marrow. Once administered back to the patient, the cells are intended to generate normal healthy tissues. The primary TRC application we are initially pursuing is bone grafting (large bone fractures, spine fusions or jaw bone reconstruction). In August 2003, the FDA approved our Investigational New Drug (IND) application to begin a multi-center Phase I/II clinical trial for bone grafting in severe leg fractures. Our bone grafting clinical trials have recently been initiated in the U.S. and EU for the treatment of tibial non-union fractures, and we expect to announce additional clinical sites for this application. The initiation of the EU clinical studies for jawbone reconstruction needed for dental implants are pending the finalization of applicable cell production licensing requirements. Once sufficient data is obtained to show the safety and bone-forming

Table of Contents

capability of TRCs in the fracture or jaw areas, we expect to initiate a clinical plan for the use of TRCs in spine fusion applications.

Under normal circumstances, bone has the ability to maintain its integrity and repair itself when fractured or damaged, due to its capacity to regenerate. Bone grafting is the procedure of locally applying cells or other material to a bone site to either build or repair needed bone tissue when the clinical situation is such that the natural bone generation process is either too slow or unable to occur. Through scientific advances, it is now widely known that bone grafting can accelerate the regenerative process.

There are different approaches to bone graft procedures, and each carries with it certain disadvantages. Traditionally, autograft material is surgically taken from the patient's iliac crest (hip bone) and implanted where it is needed. Sometimes "extenders" are added to this material. There are a number of issues with this autograft procedure, including:

- Potential infection at the bone harvest site
- Very painful harvest procedure and painful after-effects at the collection site
- Chronic pain at the harvest site
- Limited supply of autograft material
- Additional time in surgery to collect the autograft material and additional time in the hospital to recover

As a substitute to traditional autograft, allograft, synthetic, and osteoinductive (e.g. bone morphogenic proteins) materials have recently been introduced to address some of these market issues, and are now included in approximately 50% of bone graft procedures in the U.S. However, some of these substitute materials have not been able to produce the same level of clinical efficacy as traditional autograft (e.g. the tempo of formation and the quality of bone), and their use has some other limitations. Additionally, the matrix products (allograft and synthetics) are almost always combined with some biological material, either as an extender of autograft material, in combination with blood or plasma material, or with bone marrow (typically less than 100 ml).

Our TRCs are being developed as an alternative to the autograft harvest process. First, a physician collects a small starting sample of a patient's bone marrow with a needle aspiration in a simple outpatient procedure. Then our TRCs are produced in the AastromReplicell System in about 12 days. The TRCs, containing an expanded amount of bone-forming stem and progenitor cells, are mixed with a matrix (allograft or synthetic), and may provide a viable alternative to autograft without the painful after-effects. The total served market for such a product is believed to be more than 1 million procedures annually in the U.S., EU and Japan.

Additionally, published results from other clinical studies have suggested that large volumes of a patient's own bone marrow may be concentrated and injected into the vascular tissue area of patients with limb ischemia. Degenerated vascular tissue has a high occurrence in diabetic patients, and can result in immobility, severe ulcerations, and amputation. Bone marrow cells may rebuild this vascular tissue and offer therapeutic benefit; therefore, we are pursuing research to explore the capability of TRCs for vascular regeneration.

We also believe that the stem and progenitor cell components of our TRCs may be useful for other medical indications, including the regeneration of cardiac tissue and cartilage.

Cell Production Products

Our Cell Production Products (CPP) operation seeks to market and sell the AastromReplicell System and DC-I (dendritic cells for fusion and transfection), DCV-I (complex antigen-loaded dendritic cells) and DCV-II (peptide-loaded dendritic cells) cell production kits to academic researchers and companies that are developing dendritic cell-based cancer vaccines. We expect that the recent collaborations with users of these products may generate very modest amounts of revenues at irregular intervals, although we are not yet able to project the market size, potential revenues or revenue growth for these products. The EU has recently issued

[Table of Contents](#)

new directives that affect the manufacturing of cell products and clinical trials. These changes have delayed and in many cases temporarily halted dendritic cell vaccine clinical trials in EU, which has reduced the number of customer opportunities and adversely affected our progress in our CPP business.

Aastrom's Proprietary Core Technologies

Our technology platform consists of two components: (i) proprietary processes, "single-pass perfusion", and culture devices to enable certain types of stem cells and other types of human cells to be produced with superior biological capabilities as compared with standard cell culture approaches, and (ii) the AastromReplicell System, a clinical cell production platform that is designed to standardize and enable an effective GMP-compliant commercialization pathway for bringing therapeutic cell production to medical practice. The AastromReplicell System consists of an instrumentation platform, to be integrated within the hospital or other centralized facilities, that can operate a variety of single-use cell production kits that are specific to the desired medical application. Through this product configuration, we intend either to directly provide cells for therapeutic use, or to enable customers or potential collaborators with the capability to produce cells for therapeutic applications through sale of the AastromReplicell System product line and cell therapy products. This approach is intended to provide a product pathway for each cell therapy that is equivalent to a biological product including regulatory approval, reimbursement, marketing and pricing. We believe that the product design of the AastromReplicell System will allow us to develop additional cell therapy products to provide standardization for a number of emerging cell therapies being developed by other researchers.

Aastrom's Single-Pass Perfusion for Human Cell Growth

We have developed proprietary processes and patented technologies for *ex vivo* production of therapeutic stem and progenitor cells as well as other key cells found in human bone marrow. This proprietary process is called "single-pass perfusion" and provides a cell culture environment that attempts to mimic the biology and physiology of natural bone marrow outside of the body. This process enables the production of stem and early- and late-stage progenitor cells needed for an effective bone marrow stem cell therapy procedure. When this process is applied to other cell types, the resulting cell product appears to have enhanced biologic function as compared to cells produced through standard static culture processes. In pre-clinical studies performed at Aastrom, T-cells produced using our proprietary processes appear to have a significantly higher replicative capability. Further, dendritic cells produced using this process appear to have an enhanced ability to present antigen to the immune system. We believe that these benefits can improve the overall clinical effectiveness of these procedures.

Growth factors can be added to stimulate specific cell lineages to grow cells, or to increase cell growth, to meet a particular therapeutic objective. We believe the stem cell growth process can best be completed with little or no additional stem cell selection or purification procedures. This stem cell replication process can also enable or augment the genetic modification of cells by providing the cell division step needed for new genes to integrate into the stem cell DNA. Other currently available cell culture methods tend to result in a loss of stem cells, either through death or through differentiation into mature cells. When compared with cells grown using standard cell culture techniques, the perfusion approach enables stem cells to grow, and improves the biological features of other types of human cells as well. We have exclusive rights to several issued U.S. patents that cover these processes and cell compositions.

We have developed a proprietary cell culture chamber to implement our process technology. The culture chamber can produce cells on a clinical-scale and allows for recovery of the cells for therapeutic use. Our pre-clinical and clinical data indicate that our cell culture chamber may be used for growing various types of human therapeutic cells, such as stem cells, T-cells and dendritic cells used for immunotherapies, chondrocytes for cartilage replacement, and mesenchymal cells for bone and cartilage replacement. We hold exclusive rights to issued U.S. patents and additional applications for our cell culture chamber device technology.

The AastromReplicell System

The AastromReplicell System is our proprietary clinical-scale cell production platform to enable the large scale *ex vivo* production of a variety of therapeutic cells at healthcare facilities, independent laboratories, transplant centers, blood banks, and centralized cell production facilities. It has been designed to implement our stem cell growth process as well as processes for the production of certain other cell types. The AastromReplicell System is comprised of several components, including microprocessor-controlled instruments and single-use cell production kits such as the TRC-I (for the production of our TRC cell products), DC-I, DCV-I and DCV-II kits (for the production of cells used in our CPP operation for sale to third parties). The single-use cell production kits include an AastromReplicell System Cell Cassette cartridge containing our proprietary cell culture chamber, supply and waste reservoirs, and harvest bag along with process specific software which provides the cell production processing parameters to the AastromReplicell System instruments. The microprocessor-controlled instruments include the AastromReplicell System Incubator which controls the culture conditions for the production of cells within the Cell Cassette, and the AastromReplicell System Processor which automates the procedure sequences such as the inoculation of cells into, and harvesting of the cells from, the Cell Cassette. The AastromReplicell System Manager provides user interface software that monitors the cell production process in multiple Incubators, records relevant process variables and operator actions, and automatically generates cell production batch records.

The AastromReplicell System is designed to be operated with minimal operator activity by a qualified cell production or cell processing technician to implement clinical-scale cell production. The endpoint of the AastromReplicell System process is a blood-bag containing the specific cell product. The control and documentation features of the AastromReplicell System have been designed to meet GMP requirements for the production of cells for clinical use. The System can be scaled-up producing simultaneous multiple independent cell batches and is suitable for installation in a regional or centralized cell production facility. This is intended to provide a product pathway for each cell therapy that is similar to a biological product including regulatory approval, reimbursement, marketing and pricing. We believe that the design of the AastromReplicell System may allow us to develop additional cell production kits to provide a commercialization pathway for a number of emerging cell therapies being developed by other researchers.

The typical industry approach to growing human cells has largely used manual research laboratory methods, requiring substantial time and technical expertise. The AastromReplicell System is designed to provide closed-system, automated cell production capabilities in compliance with regulatory standards, with high process reliability and reduced requirements for specialized facilities and staffing.

Product Development

Prescription Cell Products

Our initial development efforts were focused on the development of the SC-I kit for the production of bone marrow stem cells for use in bone marrow transplantation. A decreased market opportunity for the SC-I product led to the discontinuance of further product development in this area. Our current product development efforts are focused on the development of bone marrow-derived stem and progenitor cells — Tissue Repair Cells (TRCs) — for use in orthopedic indications (bone grafting, spine fusion and jaw bone reconstruction) and for use in vascular system regeneration. These cells and processes are very similar to those produced with the SC-I process which have been introduced into human patients in previous trials. (See “Clinical Development.”) Clinical trials are underway to demonstrate bone formation in patients with large bone fractures, and clinical protocols are in development for spine fusions and jaw bone reconstruction, and for treating limb ischemia resulting from peripheral vascular disease. All of these products use Aastrom’s proprietary process and device technologies. We believe that additional products may be developed for use in a variety of other emerging cell therapies.

Our research programs are currently developing new variations of TRCs that are intended to improve either the functionality for certain clinical indications, improve storage and shelf life, or to decrease the cost of the manufacturing of the TRC products. Programs are also exploring the capability of TRCs to generate different types of human tissues, such as bone, vascular, cartilage and cardiac tissues.

Cell Production Products

The AastromReplicell System has the potential to supplant current manual cell culture methods to produce therapeutic quantities of cell types such as T-cells, dendritic cells, cell-based cancer vaccines, chondrocytes, mesenchymal stem cells, keratinocytes and neuronal cells. For example, Aastrom developed the DC-I, DCV-I, and DCV-II kits for dendritic cell production. Other than a limited application of chondrocyte therapy, novel cell therapies are still in early stages of development by third parties, and such other cell therapies may not be successfully developed. Potential advantages of the AastromReplicell System in these therapies may include: (i) reducing labor and capital costs; (ii) enhancing process reliability; (iii) automating quality assurance and process record keeping; (iv) reducing the need for specialized, environmentally controlled facilities; (v) providing greater accessibility of these procedures to care providers and patients; and, (vi) providing a more biologically active cell product.

Modification of such processes and application of our products to the expansion of other cell types will require additional development of specialized cell culture capabilities that may need to be incorporated within our existing product platform. Such modifications may require us to raise substantial additional funds, or to seek additional collaborative partners, or both. We may not be able to successfully modify or develop existing or future products to enable such additional cell production processes. See "Clinical Development" and "Business Risks."

Research and development expenses for the fiscal years ended June 30, 2002, 2003 and 2004 were \$5,428,000, \$5,647,000 and \$6,289,000, respectively.

Clinical Development

Currently, our clinical trial direction is focused on the utilization of our TRCs in the areas of bone regeneration and vascular regeneration in limb ischemia resulting from diabetes and other diseases. Both of these therapeutic areas have substantial market opportunities. Our current studies were also influenced by the limited scope of hematopoietic stem cell transplantation.

Current Activities

In reviewing the pre-clinical and clinical data for our TRCs a substantial increase in the mesenchymal or stromal stem and progenitor cell content was observed. Mesenchymal stromal cells are integral for bone marrow to generate non-hematopoietic tissues such as bone and cartilage. Our TRCs have been administered to one patient under a compassionate use request approved by the FDA, who had a congenital bone disease called hypophosphatasia, which results in a typically lethal condition of abnormal bone and cartilage formation. This compassionate use treatment, now published in the *Journal of Bone and Mineral Research* (April 2003, Vol. 18, page 264), resulted in long-term systemic bone formation in the child. Subsequently, we demonstrated in the laboratory, and in mice, that our TRC product is capable of forming bone lineage tissue.

Based on these and other pre-clinical and clinical observations, we are currently enrolling patients in U.S. and EU clinical trials for bone regeneration in patients with severe limb fractures. The U.S. trial is being conducted under an FDA approved Investigational New Drug (IND) application, including up to three participating centers and as many as 20 patients. The EU trials are now underway at centers in Spain and Germany, under Ethical Committee approvals. We are developing a protocol and an IND submission for a clinical trial to evaluate TRCs in spine fusions. We expect to have clinical result data from the first five treatments in Spain during the quarter ended December 31, 2004. We are also planning to evaluate TRCs to augment jaw bone reconstruction as a method to improve the well-being of patients needing dental implants, and intend to initiate these studies and provide proof of concept during fiscal year 2005 in the EU.

In addition to bone and hematopoietic tissues, TRCs have been demonstrated in the laboratory to contain the stem and progenitor cells capable of forming vascular tissue or blood vessel growth. Based on clinical observations of the efficacy obtained using large volumes of unexpanded bone marrow cells, we are developing clinical protocols that will evaluate our TRCs for the treatment of limb ischemia, such as occurs in diabetes and other peripheral vascular diseases.

Table of Contents

The preliminary results of our pre-pivotal trials may not be indicative of results that will be obtained from subsequent patients in the trials or from more extensive trials. Further, our pre-pivotal or pivotal trials may not be successful, and we may not be able to obtain the required biologic license application (BLA) registration or required foreign regulatory approvals for the AastromReplicell System in a timely fashion, or at all. See “Business Risks.”

Previous Activities

The AastromReplicell System, and certain cell products produced using our system, have been evaluated in multi-site clinical trials in the U.S. under an Investigational Device Exemption (IDE) from the FDA.

Results from these studies demonstrated the ability of the AastromReplicell System to safely and reliably produce stem and progenitor cells (called “SC-I cells”) that engraft and restore blood system function in breast cancer patients who had undergone very aggressive chemotherapy. Further, the small volume aspirate, along with a purging of contaminated tumor cells during the stem cell production, indicated a way to offer patients a transplant with a lower risk of receiving back tumor cells.

Based on positive results from the feasibility stage trials, we had initiated a randomized Phase III U.S. clinical trial evaluating the SC-I cells produced with the AastromReplicell System to compliment traditional therapies by augmenting stem cells collected from a single Peripheral Blood Stem Cell (PBSC) apheresis procedure. The objectives of this study were to demonstrate that an optimal hematopoietic recovery could be achieved using the SC-I cells with a sub-optimal PBSC dose that otherwise would not provide this desired outcome.

However, during the course of the Phase III clinical trial of the SC-I cells, medical developments occurred that have influenced our strategy. These developments included:

- The demonstration that high-dose cytotoxic therapy requiring stem cell support did not result in increased survival benefit for patients with carcinoma of the breast compared with standard, less toxic chemotherapy, thus eliminating this medical approach
- The demonstration that bone marrow stem cells collected from the PBSC after mobilization by cytokine(s) and/or chemotherapy resulted in more rapid hematopoietic engraftment compared to stem cells collected directly from the bone marrow
- The demonstration that only a fraction of patients would be unable to be successfully mobilized for the collection of PBSC using a combination of chemotherapy with augmented dose hematopoietic cytokines
- The demonstration that dose-dense chemotherapy followed by cytokine supported hematopoietic recovery may be an alternative to PBSC transplantation for patients with carcinoma of the breast
- A change in the policy of the FDA that the AastromReplicell System cell products will now require a Biologics License Application (BLA) for product registration, which was not originally expected or planned

The results of these medical market developments substantially reduced the ability to accrue patients in the Phase III trial we had started. Further, these observations indicated to us that the market value of the product studied by the current clinical hematopoietic studies was becoming markedly constrained and much reduced from estimates performed before trial initiation. Given the limited market opportunity, the newly added regulatory requirements, and our available resources, we are no longer pursuing that Phase III trial. With the greatly reduced market size for the SC-I cells, we successfully obtained Orphan Product Designation.

We have also conducted clinical feasibility trials to evaluate umbilical cord blood (CB) cells produced in the AastromReplicell System to improve recoveries of pediatric and adult patients requiring donor-derived (or allogeneic) stem cell transplants. Results of the pediatric transplants indicated that AastromReplicell System-produced cells were safe and well tolerated by the patients. Results from our adult cord blood trial may suggest that the AastromReplicell System could increase the quantity of cord blood cells available but do not

[Table of Contents](#)

significantly affect the rate of hematopoietic recovery. We had extended these trials into a comparative adult trial with concurrent controls. Recently, the clinical enthusiasm for the use of CB for the treatment of adults has diminished with the identification of increased morbidity and mortality when compared to pediatric patients receiving CB transplantation. The increased morbidity was due to delayed hematopoietic and immunological recovery. The waning enthusiasm for CB transplants for adults has caused Aastrom to halt its CB comparative trial due to the very diminished market opportunity. Our research has identified alternative approaches with our technology using stromal cells for *ex-vivo* production of CB cells. We may later pursue a clinical evaluation of one or more of these approaches.

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 will coordinate and fund the development of products that are based on combinations of MTF's allograft matrices and our Tissue Repair Cells (TRCs). The companies will both contribute in certain development and clinical trial expenses of these treatment approaches and products, and intend to adopt a coordinated promotion and marketing strategy for future products.

Manufacturing

We have established relationships with third party manufacturers that are FDA registered as suppliers of medical products to manufacture various components of the AastromReplicell System.

In March 2003, we signed a three-year master supply agreement with Astro Instrumentation, L.L.C., to manufacture our products, component parts, subassemblies and associated spare parts, used in the instrumentation platform of our AastromReplicell System. We retain all proprietary rights to our intellectual property that is utilized by Astro pursuant to this agreement.

In March 1996, we entered into a License and Supply Agreement with Immunex Corporation, now a wholly owned subsidiary of Amgen Corporation, for an initial five-year term to purchase and resell certain cytokines and ancillary materials for use in conjunction with the AastromReplicell System. Subsequently, this license agreement was extended through March 2003. We are currently negotiating a new agreement with Amgen. In the event that Amgen elects to cease to supply to us cytokines and ancillary materials or is prevented from supplying such materials to us, there is no assurance that we could successfully manufacture the compounds ourselves or identify others that could manufacture these compounds to acceptable quality standards and costs, if at all. However, we are currently conducting pre-clinical research to evaluate the elimination of these components.

In February 2004, we entered into a five-year agreement continuing Moll Industries as our supplier of Cell Cassettes. Under this agreement, Moll will perform commercial manufacturing and assembly of our Cell Cassette, the main single-use component of the AastromReplicell System. We retain all proprietary 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 "Business Risks."

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

Table of Contents

to one other issued U.S. patent. These patents present claims to: i) certain methods for *ex vivo* stem cell division as well as *ex vivo* human hematopoietic stem cell stable genetic transformation and expanding and harvesting a human hematopoietic stem cell pool; (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. 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. These patents are due to expire beginning in 2008. In addition, we and our exclusive licensors have filed applications for patents in the United States 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 the AastromReplicell 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 United States are maintained in secrecy until shortly before patents issue, 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, board of directors, technical review board 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, devices, designs, products, processes or other subject matter are claimed under other existing United States 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

Table of Contents

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 United States are to be manufactured substantially in the United States, 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 affect 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 from Corning.

Government Regulation

Our research and development activities and the manufacturing and marketing of our products are subject to the laws and regulations of governmental authorities in the United States and other countries in which our products will be marketed. Specifically, in the United States, 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 United States, 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. 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 the cells produced in the AastromReplicell System as a licensed biologic through the Center for Biologics Evaluation and Research. However, there can be no assurance that the FDA will ultimately regulate the AastromReplicell System in this manner.

As current regulations exist, the FDA will require regulatory approval for certain human cellular or tissue based products, including cells produced in the AastromReplicell System, through a biologic license application (BLA).

The FDA has published regulations which require registration of certain facilities, which may include our customers, and is in the process of publishing regulations for the manufacture or manipulation of human cellular or tissue based products which may impact our customers. We believe that the fixed validated process in a sterile disposable provided by our products will assist our customers in meeting these requirements, but the regulations may change prior to final release.

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, 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 order to obtain FDA approval of a new medical product, sponsors must generally submit proof of safety and efficacy. In some cases, such proof entails extensive pre-clinical and clinical laboratory 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 are not maintained or if problems occur following initial marketing. 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 the product will have to file an Investigational Device Exemption (IDE) or Investigational New Drug (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 IDE or 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 IDEs and INDs for the AastromReplicell System, and have conducted clinical studies under these IDEs and INDs.

Table of Contents

We believe that the cells produced in the AastromReplicell System 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. The FDA categorizes human cell or tissue based products as either minimally manipulated or more than minimally manipulated, and has proposed that more than minimally manipulated products be regulated through a “tiered approach intended to regulate human cellular and tissue based products only to the extent necessary to protect public health.” 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 or IDE application which must be effective 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 biologic license application (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.

Pre-clinical testing covers laboratory evaluation of product chemistry and formulation as well as animal studies to assess the safety and efficacy of the product. The results of these tests are submitted to the FDA as part of the IND. Following the submission of an 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 30-day period, clinical trials may be initiated. Clinical trials are typically conducted in three sequential phases. Phase I represents the initial administration of the drug or biologic to a small group of humans, either healthy volunteers or patients, to test for safety and other relevant factors. Phase II involves studies in a small number of patients to assess the efficacy of the product, to ascertain dose tolerance and the optimal dose range and to gather additional data relating to safety and potential adverse affects. Once an investigational drug is found to have some efficacy and an acceptable safety profile in the targeted patient population, multi-center Phase III studies are initiated to establish safety and efficacy in an expanded patient population and multiple clinical study sites. The FDA reviews both the clinical plans and the results of the trials and may request us to discontinue the trials at any time if there are significant safety issues.

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 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 affects, which can involve significant expense.

Under current requirements, facilities manufacturing biological products must be licensed. To accomplish this, a BLA must be filed with the FDA. In addition to the pre-clinical and clinical tests, the BLA includes a description of the facilities, equipment and personnel involved in the manufacturing process. An establishment license is granted on the basis of inspections of the applicant’s facilities in which the primary focus is on compliance with GMPs 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 AastromReplicell System instruments and disposables are currently being regulated in Europe as a Class I Sterile, Class IIb or Class III medical device, under the authority of the Medical Device Directive (MDD) implemented by EU member countries. These classifications apply to medical laboratory equipment and supplies including, among other products, many devices that are used for the collection and processing of blood for patient therapy. Certain ancillary products (e.g., biological reagents) used as part of the AastromReplicell System are treated as Class III medical devices.

Table of Contents

The MDD vests the authority to permit affixing of the CE Mark with various Notified Bodies. These are private and state organizations which operate under license from the Competent Authority of the member states within the EU to certify that appropriate quality assurance standards and compliance procedures are followed by developers and manufacturers of medical device products or, alternatively, that a manufactured medical product meets a more limited set of requirements. Notified Bodies are also given the responsibility for determination of the appropriate standards to apply to a medical product. Receipt of permission to affix the CE Mark enables a company to sell a medical device in all EU member countries. Other registration requirements may also need to be satisfied in certain countries.

We have received permission from our Notified Body (The British Standards Institute) to affix the CE Mark to the AastromReplicell System instrumentation and components for the SC-I kit, CB-I kit, DC-I kit, DCV-I kit and DCV-II kit. This has allowed us to market these products in the EU. There can be no assurance that the AastromReplicell System will continue to be regulated under its current status, any change in which would affect our ability to sell the product and adversely affect our business, financial condition and results of operations.

New directives (laws) have recently become effective in the EU that may affect the manufacturing of cell products and clinical trials. These changes have delayed or in some cases temporarily halted dendritic cell clinical trials in the EU, which has reduced the number of customer opportunities and affected our progress in our Cell Production Products business. The recent changes to the European Union Medicinal Products Prime Directive shifted patient-derived cells to the medicinal products category. These new laws may delay some of our current planned clinical trials in the EU.

Competitive Environment

The biotechnology and medical device industries are characterized by rapidly evolving technology and intense competition. Aastrom's competitors include major multinational medical device companies, pharmaceutical companies, specialty biotechnology companies and chemical and medical products companies operating in the fields of tissue engineering, tissue regeneration, orthopedics and in a small number of instances, cell-based therapies. Many of these companies are well-established and possess technical, research and development, financial, and sales and marketing resources significantly greater than Aastrom. In addition, many smaller biotech and specialty medical products companies 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 product areas currently being pursued by Aastrom. 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 Aastrom. 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 Aastrom.

Aastrom's 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, Aastrom faces primary competition from existing devices and products. Some of Aastrom's competitors in orthopedic device and tissue engineered orthopedic applications have longer operating histories and substantially greater resources. These include Stryker Corp., Medtronic, Wright Medical, Smith & Nephew, Biomet, Osteotech, J&J/ DePuy, Zimmer and Synthes/ Mathys Medical. Other well-established competitors, such as CONMED, Arthrex and Implex Corporation compete in orthopedics with a variety of other tissue substitution products. A number of other companies have developed tissue-derived products for these markets, including Regeneration Technologies, Allosource, Lifecell Corporation, NovaBone, IsoTis Orthobiologics, Co.don and OrthoVita.

In the general area of cell-based therapies, including orthopedics and other tissue regeneration applications, Aastrom competes with a variety of companies, most of whom are specialty medical products or biotechnology companies. Some of these, such as Genzyme Corporation and Fidia SA are well-established and have substantial technical and financial resources compared to Aastrom. However, as cell-based products are only just emerging as viable medical therapies, many of Aastrom's direct competitors are smaller

Table of Contents

biotechnology and specialty medical products companies. These include Orthologic/ Chrysalis Biotechnologies, Biosyntech, Inc., Osiris Therapeutics, Isto Technologies, Interface Biologics, MacroPore Biosurgery and Raymedica.

Domestic product sales and rentals for the fiscal years ended June 30, 2002, 2003 and 2004 were \$0, \$0 and \$10,000, respectively. Foreign product sales and rentals for the fiscal years ended June 30, 2002, 2003 and 2004 were \$80,000, \$314,000 and \$39,000, respectively.

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 at irregular intervals from our CPP business to academic and commercial research centers, grant revenue, research funding and licensing fees from potential future corporate collaborators, and potentially the sale of TRCs in certain non-U.S. countries. 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 "Business Risks".

Employees

As of August 31, 2004, we employed approximately 50 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, 2004, are as follows:

<u>Name</u>	<u>Age</u>	<u>Position</u>
R. Douglas Armstrong, Ph.D.	51	Chief Executive Officer and Chairman of the Board of Directors
James A. Cour	48	President and Chief Operating Officer
Brian S. Hampson	47	Vice President Product Development
Alan M. Wright	59	Senior Vice President Administrative and Financial Operations and Chief Financial Officer

R. Douglas Armstrong, Ph.D. joined Aastrom in June 1991 as its President and Chief Executive Officer, and as a Director. In 1999, Dr. Armstrong was elected Chairman of Aastrom's Board of Directors. In July 2004, the duties and responsibilities of President were transferred to the Company's new Chief Operating Officer, allowing Dr. Armstrong, as CEO, to increase focus on strategic activities and issues, investor relations, the Board of Directors, and Aastrom's European subsidiary, Zellera AG, for which he is also Chairman of the Supervisory Board. From 1987 to 1991, Dr. Armstrong served as Executive Vice President and Trustee at the La Jolla Cancer Research Foundation (LJCRF), now named the Burnham Institute, a scientific research institute located in San Diego, CA. Prior to joining the Burnham Institute, Dr. Armstrong held various faculty and staff positions at the Yale University School of Medicine, University of California, San Francisco, LJCRF and the University of Michigan. Dr. Armstrong received a Bachelor's of Arts degree in Chemistry from the University of Richmond in Richmond, VA, and completed his Doctorate in Pharmacology and Toxicology from the Medical College of Virginia. Additionally, Dr. Armstrong was a participant in the formation of Telios Pharmaceuticals, Inc., has served on the boards of both biotechnology and venture capital organizations, and currently serves as the Chairman of the Board for the Center for Cell Therapy.

Table of Contents

James A. Cour joined Aastrom in July 2004 as its President and Chief Operating Officer. Prior to joining Aastrom Mr. Cour held executive level management positions with several companies, including Baxter International, Windsor VanGelder Limited and Cytomedix. Mr. Cour brings to Aastrom over twenty years of business success and accomplishments, ranging from strong expertise in operations and business development to strategic planning and international business. His broad range of experiences includes the management of major multinational healthcare operations, as well as a biotech/medical device company. Mr. Cour is skilled in the areas of medical products, biologic pharmaceuticals, business development, strategic alliances, analysis of new technologies and licensing. Mr. Cour received a Bachelor of Business Administration, with honors, from the University of Notre Dame, and an MBA from the University of Chicago, with concentrations in Marketing and International Business, with a specialization in Finance. He was also licensed as a Certified Public Accountant.

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.

Alan M. Wright joined Aastrom in September 2000 as a member of the Board of Directors until August 2002 when he joined the Company's management team as Senior Vice President Administrative and Financial Operations and Chief Financial Officer. From 1991 to 2002, Mr. Wright held several executive positions at CMS Energy and its principal subsidiary, Consumers Energy, most recently as its Executive Vice President, Chief Financial Officer and Chief Administrative Officer, where he was responsible for raising \$17 billion in capital during his tenure. Prior to joining CMS Energy, Mr. Wright held various financial management positions at Entergy Corporation, including Vice President of Finance. He served on the Finance Committee and the Finance and Regulation Executive Advisory Committee of the Edison Electric Institute (EEI), the Conference Board Council of CFOs, the Committee on Corporate Reporting of the Financial Executives Institute, and on Jenkins' Special Committee to the Financial Accounting Standards Board. Mr. Wright earned a Bachelor of Science degree in Economics from Cornell University under a General Motors national scholarship. He has also completed Stanford University's Executive Program, the EEI Executive Leadership Program and post-graduate studies in Accounting at the University of West Florida. In addition, Mr. Wright serves on the Board of Directors of Ensure Technologies, a privately held company.

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.

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 expiring in December 2004. We are currently negotiating an extension to our current lease and expect to complete this negotiation prior to its expiration. 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 European Operations, Zellera AG.

[Table of Contents](#)

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 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 SmallCap Market:

Price Range of Common Stock

	<u>High</u>	<u>Low</u>
Year ended June 30, 2003:		
1st Quarter	\$.46	\$.27
2nd Quarter	.66	.23
3rd Quarter	.53	.25
4th Quarter	1.45	.30
Year ended June 30, 2004:		
1st Quarter	1.83	.79
2nd Quarter	1.66	1.25
3rd Quarter	1.76	1.27
4th Quarter	1.36	.80

As of August 31, 2004, there were approximately 594 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, 2004 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)	4,956,426	\$1.33	2,228,626
Equity compensation plans not approved by security holders (financings or services related)	1,483,529	\$1.18	—
Balance, June 30, 2004	<u>6,439,955</u>	\$1.30	<u>2,228,626(1)</u>

(1) Includes shares issuable under the 2001 Stock Option Plan and the 1996 Employee Stock Purchase Plan.

[Table of Contents](#)

Item 6. Selected Financial Data

The statement of operations data for the years ended June 30, 2002, 2003 and 2004 and for the period from March 24, 1989 (Inception) to June 30, 2004 and the balance sheet data at June 30, 2003 and 2004, 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, 2000 and 2001, and the balance sheet data at June 30, 2000, 2001 and 2002, are derived from audited consolidated financial statements not included herein. The data set forth below are qualified by reference to, and should be read in conjunction with, the consolidated financial statements and notes thereto and "Management's Discussion and Analysis of Financial Condition and Results of Operations."

	Year Ended June 30,					March 24, 1989 (Inception) to June 30, 2004
	2000	2001	2002	2003	2004	
Statement of Operations Data:						
Revenues:						
Product sales and rentals	\$ 169,000	\$ 85,000	\$ 80,000	\$ 314,000	\$ 49,000	\$ 731,000
Research and development agreements	—	—	—	10,000	75,000	2,105,000
Grants	981,000	814,000	797,000	520,000	1,178,000	7,526,000
Total revenues	1,150,000	899,000	877,000	844,000	1,302,000	10,362,000
Costs and expenses:						
Cost of product sales and rentals(1)	1,251,000	13,000	202,000	893,000	280,000	2,645,000
Research and development	6,289,000	4,983,000	5,428,000	5,647,000	6,289,000	93,437,000
Selling, general and administrative	3,364,000	2,482,000	3,528,000	4,017,000	5,390,000	33,517,000
Total costs and expenses	10,904,000	7,478,000	9,158,000	10,557,000	11,959,000	129,599,000
Loss from operations	(9,754,000)	(6,579,000)	(8,281,000)	(9,713,000)	(10,657,000)	(119,237,000)
Other income (expense):						
Other income	—	—	—	—	—	1,237,000
Interest income	364,000	653,000	342,000	134,000	169,000	5,371,000
Interest expense	—	—	—	—	—	(267,000)
Net loss	\$ (9,390,000)	\$ (5,926,000)	\$ (7,939,000)	\$ (9,579,000)	\$ (10,488,000)	\$ (112,896,000)
Net loss applicable to common shares	\$ (9,598,000)	\$ (5,926,000)	\$ (7,939,000)	\$ (9,579,000)	\$ (10,488,000)	
Net loss per common share (basic and diluted)	\$ (.41)	\$ (.17)	\$ (.19)	\$ (.19)	\$ (.14)	
Weighted average number of common shares outstanding (basic and diluted)	23,344,000	34,030,000	42,121,000	50,984,000	73,703,000	
June 30,						
	2000	2001	2002	2003	2004	

Balance Sheet Data:

Cash, cash equivalents and short-term investments	\$ 12,745,000	\$ 10,659,000	\$ 9,605,000	\$ 10,512,000	\$ 16,926,000
Working capital	12,143,000	10,715,000	10,597,000	11,273,000	17,274,000
Total assets	13,437,000	11,905,000	11,553,000	12,155,000	18,166,000
Deficit accumulated during the development stage	(79,932,000)	(85,858,000)	(93,797,000)	(103,376,000)	(113,864,000)
Total shareholders' equity	12,435,000	10,894,000	10,803,000	11,575,000	17,608,000

(1) Cost of product sales and rentals for the year ended June 30, 2000 includes an inventory write off of \$1,027,000 and for the years ended June 30, 2002, June 30, 2003 and June 30, 2004 includes a charge of \$202,000, \$748,000 and \$253,000 for obsolete and excess inventory, respectively.

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

Overview

We are a late-stage development company focused on the development of processes and products for the *ex vivo* production and sale of human cell products for use in cell therapy and regenerative medicine. Our pre-clinical and clinical product development programs utilize adult bone marrow stem and progenitor cells for forming solid tissues such as bone, vascular tissue, cartilage, and blood and immune system cells. We currently operate our business in one reportable segment — research and product development, conducted both on our own behalf and in connection with various collaborative research and development agreements with others, involving the development and sale of processes and products for the *ex vivo* production of human cells for use in cell therapy.

While cell therapies are emerging as potential new treatment options for several diseases and medical disorders, the success of cellular therapy is based, in part, on the need for care providers to be able to access therapeutic quantities of biologically active cells necessary for patient treatment, cost-effectively and in compliance with regulatory requirements. Our patented AastromReplicell System and single-pass perfusion technology are intended to enable the manufacturing of patient specific cell products for clinical use.

In the expanding field of cell therapy, we develop proprietary Prescription Cell Products (PCP) for the regenerative repair of damaged human tissues and other medical disorders, the first of which is now in the clinical stage. Our lead PCP products are Tissue Repair Cells (TRCs), which are a unique mixture of bone marrow-derived stem and progenitor cells, produced *ex vivo*. In previous multi-center clinical trials involving over 160 patients, our TRCs have been demonstrated to be safe and reliable, and to regenerate certain normal healthy human tissues.

We have also developed our proprietary AastromReplicell System, which is a patented, integrated system of instrumentation and single-use consumable kits for the commercial production of human cells. The AastromReplicell System was developed to provide a manufacturing platform for our proprietary cell products, such as our TRCs. The AastromReplicell System technology has recently been expanded for the production of dendritic cells and dendritic cell vaccines, and is the basis of our Cell Production Products (CPP) business. The clinical use of dendritic cell vaccines is minimal at this time, and as such the market is only just developing. We are currently exploring the market for our CPP dendritic cell vaccine products in the EU and in the United States by targeting academic and other third party therapeutic cell developers requiring automated cell production with GMP compliance.

Our commercial production pathway for our Prescription Cell Products is enabled through the AastromReplicell System platform. This proprietary and automated clinical cell production system combines patented GMP-compliant automated cell production with patented “single-pass perfusion.” Single-pass perfusion is our technology for growing large quantities of highly robust human cells outside the body. These cells include adult stem and progenitor cell mixtures — cells required for forming solid tissues such as bone, vascular tissue, cartilage, and immune system cells.

Our primary business model utilizes a core infrastructure for the manufacturing and distribution of TRC cell products for use in multiple medical markets. Initially, we will pursue TRCs for the following two therapeutic areas:

- Local bone regeneration in fractures, spinal fusion and jaw bone reconstruction, and
- Vascular (blood vessel) regeneration in limb ischemia resulting from diabetes and other diseases.

In the future, we may develop, and/or support the development by third parties, TRC products for other areas such as cartilage regeneration and cardiac tissue regeneration.

In the EU, our business and marketing activities are directed through Zellera AG, our wholly-owned subsidiary located in Berlin, Germany.

Since our inception, we have been in the development stage and engaged in research and product development, conducted principally on our own behalf, but also in connection with various collaborative

Table of Contents

research and development agreements with others. We commenced our initial pilot-scale product launch in the EU of the AastromReplicellSystem with the SC-I kit in April 1999. At approximately this same time, 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 marketing activities in October 1999, pending the receipt of additional financing and the completion of the reorganization process. While we have initiated marketing activities in the EU for the CE Marked SC-I, DC-I, DCV-I and the DCV-II products, we do not expect to generate positive cash flows from our consolidated operations for at least the next several years and then only if more significant product sales commence. Until that time, we expect that our revenue sources will consist of sales from our Cell Production Product operation to academic and commercial research centers, grant revenue and research funding and licensing fees 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. As a development-stage company, we have never been profitable and do not anticipate having net income unless and until significant product sales commence, which is unlikely to occur until we obtain significant additional funding and complete the required clinical trials for regulatory approvals. Through June 30, 2004, we have accumulated losses of approximately \$114 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 inventory, revenue recognition and accounts receivable.

Revenue recognition. We generate revenue from grants and research agreements, collaborative agreements, product sales and rentals and licensing arrangements. Revenue from grants and research agreements is recognized on a cost reimbursement basis consistent with the performance requirements of the related agreements. Revenue from collaborative agreements is recognized when the scientific or clinical results stipulated in the agreement have been met and there are no other ongoing obligations on our part. We recognize revenue from product sales when title to the product transfers and there are no remaining obligations that will affect the customer's final acceptance of the sale. If there are remaining obligations, including training and installation (which we believe to be significant), we recognize revenue upon completion of these obligations. We recognize revenue from licensing fees under licensing agreements 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.

Accounts receivable. We make estimates evaluating collectibility of accounts receivable. We continuously monitor collections and payments from our customers and maintain an allowance for estimated credit losses based on any specific customer collection issues we have identified. While such credit issues have not been significant, there is no assurance that we will continue to experience the same credit losses in the future. As of June 30, 2004, our allowance for doubtful accounts was \$7,000.

Inventory. We value our inventory that consists primarily of finished components of our lead product, the AastromReplicell System and our disposable cell production cassettes, at the lower of cost (specific identification using first in, first out) or market. We regularly review inventory quantities on hand and record a provision to write down obsolete and excess inventory to its estimated net realizable value. Based on the aging of inventory at each period end, we utilize a systematic approach to determine our reserve for obsolete and excess inventory. Under this systematic approach, AastromReplicell System inventory that is less than twelve months old, based on the receipt date, will be carried at full value. Inventory quantities in excess of twelve months old are reserved over a six-month period, until the items are either sold or fully reserved. We review cell production cassette inventory relative to its age and our expected sales and, where quantities exceed expected sales utilization, we reduce the recorded value of cell cassette inventory. We feel this approach is appropriate given our limited product sales history and the risk associated with our ability to recover the

Table of Contents

inventory as we are still in the process of establishing our product market. Future technological changes, new product development and actual sales could result in additional obsolete and excess inventory on hand. This could have a significant impact on the value of our inventory and our reported operating results.

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 \$1,302,000 in 2004, \$844,000 in 2003, and \$877,000 in 2002. Grant revenues increased to \$1,178,000 in 2004 from \$520,000 in 2003 and from \$797,000 in 2002. Grant revenues in 2004 have increased from prior years as a result of increased activity on the collaborative grant with the Defense Advanced Research Projects Agency (DARPA) and additional grant awards from the National Institutes of Health. Grant revenues accounted for 90% of total revenues for the year ended June 30, 2004 and 62% for the year ended June 30, 2003 and 91% for the year ended June 30, 2002 and are recorded on a cost-reimbursement basis. Product sales and rentals decreased to \$49,000 in 2004 from \$314,000 in 2003 and \$80,000 in 2002. This decrease is primarily the result of extended internal evaluations at potential customer sites that have delayed sales of our instrumentation and cell production kits for the year ended June 30, 2004. Revenues for the year ended June 30, 2004, also include \$75,000 in research and development agreements compared to \$10,000 for year ended June 30, 2003 and none for the year ended June 30, 2002. This increase is the result of a \$50,000 fee from our sublicense agreement with Corning Inc. compared to a \$10,000 fee for the year ended June 30, 2003, and an additional fee of \$25,000 from a development agreement with a European institution.

Total costs and expenses were \$11,959,000 in 2004, \$10,557,000 in 2003 and \$9,158,000 in 2002. The increase in costs and expenses is primarily the result of increased selling, general and administrative expenses to \$5,390,000 in 2004 from \$4,017,000 in 2003 and \$3,528,000 in 2002, reflecting the continued expansion of marketing activities in the EU to further our commercialization efforts and additional capital raising costs not related to specific transactions. Selling, general and administrative expenses for the fiscal year ended June 30, 2004 also includes a non-cash charge of \$53,000 relating to certain warrants issued in August 2003 for public and investor relations services and a \$372,000 non-cash charge related to an employee performance-based stock option that vested in September 2003. Research and development expenses increased to \$6,289,000 in 2004 from \$5,647,000 in 2003 and \$5,428,000 in 2002, reflecting increased research and product development activities in the area of tissue regeneration and our on-going and planned bone grafting clinical trials in the United States and the EU. Research and development expenses in 2004 include \$256,000 of cell cassettes allocated for use in clinical trials, research and product development studies. Cost of product sales and rentals were \$27,000 in 2004, \$145,000 in 2003 and none in 2002. This decrease is due to the decline in the volume of product sales. The non-cash provision for obsolete and excess AastromReplicell System inventory was \$253,000 in 2004, \$748,000 in 2003 and \$202,000 in 2002. The decrease in 2004 is the result of the carrying value of our AastromReplicell System inventory that was written down to zero by September 30, 2003.

Interest income was \$169,000 in 2004, \$134,000 in 2003 and \$342,000 in 2002. The fluctuations in interest income are due primarily to corresponding changes in the levels of cash, cash equivalents and short-term investments and decreasing yields from our investments during the periods.

Our net loss was \$10,488,000, or \$.14 per common share in 2004, \$9,579,000, or \$.19 per common share in 2003, and \$7,939,000, or \$.19 per common share in 2002. These increases in net loss are primarily the result of increased costs and expenses as the result of expanded research and marketing activities and, for the purposes of computing per share amounts, were offset by an increase in the weighted average number of common shares outstanding resulting from additional equity financings. We expect to report additional significant net losses until such time as more substantial product sales 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 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

[Table of Contents](#)

significantly limited in future periods, even if we generate taxable income. At June 30, 2004, we have generated cumulative Federal tax net operating loss and tax credit carryforwards of, \$45,000,000 and \$500,000, respectively, which will expire in various periods between 2005 and 2025, 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 events.

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, 2003, have totaled approximately \$131 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 \$16,926,000 at June 30, 2004, an increase of \$6,414,000 from June 30, 2003. During the year ended June 30, 2004, we raised net proceeds of \$16,096,000 through the sale of our equity securities. The primary uses of cash, cash equivalents and short-term investments during the year ended June 30, 2004 included \$9,525,000 to finance our operations and working capital requirements, and \$157,000 in capital equipment additions.

Our combined cash, cash equivalents and short-term investments totaled \$10,512,000 at June 30, 2003, an increase of \$907,000 from June 30, 2002. During the year ended June 30, 2003, we raised net proceeds of \$10,016,000 through the sale of our equity securities. The primary uses of cash, cash equivalents and short-term investments during the year ended June 30, 2003 included \$8,990,000 to finance our operations and working capital requirements, and \$119,000 in capital equipment additions.

We expect that our capital expenditures for the fiscal year ended June 30, 2005 will be \$145,000, in total. The primary use of these expenditures will be for cell production equipment.

Our future cash requirements will depend on many factors, including continued scientific progress in our research and development programs, the scope and results of clinical trials, the time and costs involved in obtaining regulatory approvals, the costs involved in filing, prosecuting and enforcing patents, competing technological and market developments and the cost of product commercialization. We do not expect to generate a positive cash flow from operations for at least the next several years due to the expected spending for research and development programs and the cost of commercializing our product candidates. We intend to seek additional funding through research and development agreements or grants, distribution and marketing agreements and through public or private financing transactions. Successful future operations are subject to several technical and business risks, including our continued ability to obtain future funding, satisfactory product development, obtaining regulatory approval and market acceptance for our products. We expect that our available cash and expected interest income will be sufficient to finance currently planned activities at least through the end of fiscal year 2005 (ending June 30, 2005). These estimates are based on certain assumptions which could be negatively impacted by the matters discussed under this heading and under the caption "Business Risks", 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 debt or equity securities. There can be no assurance that such collaborative arrangements, or any public or private financing, will be available on acceptable terms, if at all, or can be sustained. Several factors will affect our ability to raise additional funding, including, but not limited to, market volatility of our common stock, continued stock market listing and economic conditions affecting the public markets generally or some portion or all of the technology sector. If our common stock is delisted from The Nasdaq SmallCap Market, the liquidity of our common stock could be impaired, and prices for the shares of our common stock could be lower than might otherwise prevail.

[Table of Contents](#)

On July 28, 2004, we received a letter from the Nasdaq Stock Market indicating that for 30 consecutive trading days the bid price for our common stock had closed below the \$1.00 minimum continued listing requirement established by Nasdaq Marketplace Rule 4310(c)(4). Pursuant to applicable Nasdaq rules, we have been provided a grace period until January 24, 2005, to regain compliance by having our stock price close at \$1.00 or more for a minimum of 10 consecutive business days. Under the current Nasdaq rules, if the stock price does not satisfy the minimum bid price requirement by January 24, 2005, we may also be granted at least one additional 180 day grace period to regain compliance if we meet the required initial listing criteria. Our most material initial listing requirement is the minimum shareholders' equity balance of \$5,000,000. As of June 30, 2004, our shareholders' equity balance was \$17,608,000.

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 "Business Risks" and "Notes to Consolidated Financial Statements" included herein.

Long-Term Contractual Obligations and Commitments

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

	Payments Due through Fiscal Year Ended June 30, 2005
Operating lease obligations	\$316,000
Purchase order commitments	579,000
Total obligations and commitment	\$895,000

New Accounting Standards

In December 2003, the FASB issued a revision of FIN 46 (FIN 46R), which clarified certain complexities of FIN 46 and generally requires the adoption of all special-purpose entities that qualify as variable interest entities no later than the end of the first reporting period ending after December 15, 2003 and to all non special-purpose entities that qualify as variable interest entities no later than the end of the first reporting period ending after March 15, 2004. At June 30, 2004, Aastrom did not have any entities that require disclosure or new consolidation as a result of adopting the provisions of FIN 46R.

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

As of June 30, 2004, our cash and cash equivalents included money market securities. 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 on our securities portfolio.

Our sales to customers in foreign countries are denominated in U.S. dollars. Accordingly, we are not directly exposed to 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 in connection with our internal controls and policies. We do not enter into hedging transactions and do not purchase derivative instruments.

BUSINESS RISKS

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, 2004, we have incurred cumulative net losses totaling approximately \$114 million. These losses have resulted principally from costs incurred in the research and development of our cell culture technologies and the AastromReplicell System, general and administrative expenses, and the prosecution of patent applications. We expect to incur significant operating losses until product sales increase, primarily owing to our research and development programs, including pre-clinical studies and clinical trials, and the establishment of marketing and distribution capabilities necessary to support commercialization efforts for our products. We cannot predict with any certainty the amount of future losses. Our ability to achieve profitability will depend, among other things, on successfully completing the development of our product candidates, obtaining regulatory approvals, establishing manufacturing, sales and marketing arrangements with third parties, and raising sufficient funds to finance our activities. We may not be able to achieve or sustain profitability.

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

We must obtain the approval of the FDA before commercial sales of our cell product candidates may commence in the United States, which we believe will ultimately be the largest market for our products. We may also be required to obtain additional approvals from foreign regulatory authorities to continue or increase our sales activities of cells and equipment in those jurisdictions. If we cannot demonstrate the safety, reliability and efficacy of our product candidates, or of the cells produced in such products, we may not be able to obtain required regulatory approvals. If we cannot demonstrate the safety or efficacy of our technologies and product candidates, including long-term sustained engraftment, or if one or more patients die or suffer severe complications, the FDA or other regulatory authorities could delay or withhold regulatory approval of our product candidates.

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

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

The FDA establishes regulatory requirements based on the classification of a product. Although the AastromReplicell System is considered to be unregulated manufacturing equipment in the U.S., the FDA may reconsider this and classify the System as a Class III medical device, or the FDA may ultimately choose to regulate the AastromReplicell System under another category. Because our product development programs are designed to satisfy the standards applicable to medical devices and biological licensure for our cellular products, any change in the regulatory classification or designation would affect our ability to obtain FDA approval of our products. The AastromReplicell System is used to produce different cell mixtures, and each of these cell mixtures will, under current regulations be regulated as biologic products, which require a biologic license application (BLA).

New directives (laws) have recently become effective in the EU that may affect the manufacturing of cell products and clinical trials. These changes have delayed or in some cases temporarily halted dendritic cell clinical trials in the EU, which has reduced the number of customer opportunities and affected our progress in our Cell Production Products business. The recent changes to the European Union Medicinal Products Prime

Directive shifted patient-derived cells to the medicinal products category. These new laws may delay some of our current planned clinical trials in the EU.

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

Commercialization in the United States of our cell product candidates will require substantial clinical trials. We may not be able to successfully complete development of our product candidates, or successfully market our technologies or product candidates. We, and any of our potential collaborators, may encounter problems and delays relating to research and development, regulatory approval and intellectual property rights of our technologies and product candidates. Our research and development programs may not be successful, and our cell culture technologies and product candidates may not facilitate the production of cells outside the human body with the expected result. Our technologies and product candidates may not prove to be safe and efficacious in clinical trials, and we may not obtain the requisite regulatory approvals for our technologies or product candidates and the cells produced in such products. If any of these events occur, we may not have adequate resources to continue operations for the period required to resolve the issue delaying commercialization and we may not be able to raise capital to finance our continued operation during the period required for resolution of that issue.

We 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. In October 1999, we were forced to reduce operations based on our declining level of capital resources and our limited financing alternatives available at that time. The previous reduction in our operating activities has delayed our product development programs. We expect that our available cash and financing will be sufficient to fund currently planned activities through our 2005 fiscal year (ending June 30, 2005). However, in order to grow and expand our business, and to introduce our new product candidates into the marketplace, we will need to raise additional funds. We will also need additional funds or a collaborative partner, or both, to finance the research and development activities of our product candidates for the expansion of additional cell types. Accordingly, we are continuing to pursue additional sources of financing.

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

- continued scientific progress in our research and development programs;
- costs and timing of conducting clinical trials and seeking regulatory approvals;
- competing technological and market developments;
- our ability to establish additional collaborative relationships; and
- the effect of commercialization activities and facility expansions if and as required.

Because of our long-term funding requirements, we are likely to access the public or private equity markets if and whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time. Further, we may enter into financing transactions at prices, which are at a substantial discount to market. 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 current market prices, such an equity issuance would cause a substantially larger number of shares to be outstanding and would dilute the ownership interest of existing stockholders.

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

The market price of shares of our common stock has been volatile, ranging in closing price between \$0.79 and \$1.83 during the twelve month period ended June 30, 2004. 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;
- reports by securities analysts; and
- status of the investment markets.

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

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

We are required to meet certain financial tests (including a minimum bid price for our common stock of \$1.00) to maintain the listing of our common stock on the Nasdaq Stock Market. Our common stock may be recommended for delisting (subject to any appeal we would file) if we do not maintain compliance with the Nasdaq requirements within specified periods and subject to permitted extensions. 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.

On July 28, 2004, we received a letter from the Nasdaq Stock Market indicating that for 30 consecutive trading days the bid price for our common stock had closed below the \$1.00 minimum continued listing requirement established by Nasdaq Marketplace Rule 4310(c)(4). Pursuant to applicable Nasdaq rules, we have been provided a grace period until January 24, 2005, to regain compliance by having our stock price close at \$1.00 or more for a minimum of 10 consecutive business days. Under the current Nasdaq rules, if the stock price does not satisfy the minimum bid price requirement by January 24, 2005, we may also be granted at least one additional 180 day grace period to regain compliance if we meet the required initial listing criteria. Our most material initial listing requirement is the minimum shareholders' equity balance of \$5,000,000. As of June 30, 2004, our shareholders' equity balance was \$17,608,000.

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

To be able to market Prescription Cell Products in the United States, we must demonstrate, through extensive preclinical studies and clinical trials, the safety and efficacy of our processes and product candidates, for application in the treatment of humans. If our clinical trials are not successful, our products may not be marketable.

Table of Contents

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.

Even if we obtain regulatory approvals to sell our products, lack of commercial acceptance could impair our business.

We are seeking to obtain regulatory approval to market stem cell tissue repair and regeneration treatments, and cancer and infectious disease treatments. Even if we obtain all required regulatory approvals, we cannot be certain that our products and processes will be adopted at a level that would allow us to operate profitably. Our tissue repair products will face competition from existing, and/or potential other new treatments in the future which could limit revenue potential. It may be necessary to increase the yield and/or cell type purity, for certain of our AastromReplicell System cell processes to gain commercial acceptance. Our technologies or product candidates may not be employed in all potential applications being investigated, and any reduction in applications would limit the market acceptance of our technologies and product candidates and our potential revenues.

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

Our ability to successfully commercialize our product candidates will depend on the extent to which government healthcare programs, such as Medicare and Medicaid, as well as private health insurers, health maintenance organizations and other third party payors will pay for our products and related treatments. Reimbursement by third party payors depends on a number of factors, including the payor's determination that use of the product is safe and effective, not experimental or investigational, medically necessary, appropriate for the specific patient and cost-effective. Reimbursement in the United States or foreign countries may not be available or maintained for any of our product candidates. If we do not obtain approvals for adequate third party reimbursements, we may not be able to establish or maintain price levels sufficient to realize an appropriate return on our investment in product development. Any limits on reimbursement available from third party payors may reduce the demand for, or negatively affect the price of, our products. For example, in the past, published studies have suggested that stem cell transplantation for breast cancer, 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 would negatively affect the marketability of our products.

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

We rely solely on third parties such as Astro, Moll, Cambrex and Amgen to manufacture our product candidates, component parts and growth factors and other materials used in the cell expansion process. We would not be able to obtain alternate sources of supply for many of these items on a short-term basis. If any of our key manufacturers or suppliers fail to perform their respective obligations or if our supply of growth factors, components or other materials is limited or interrupted, we would not be able to conduct clinical trials or market our product candidates on a timely and cost-competitive basis, if at all.

Finally, we may not be able to continue our present arrangements with our suppliers, supplement existing relationships, establish new relationships or be able to identify and obtain the ancillary materials that are necessary to develop our product candidates in the future. Our dependence upon third parties for the supply and manufacture of these items could adversely affect our ability to develop and deliver commercially feasible products on a timely and competitive basis.

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

Some of the compounds we use in our current bone marrow or cord blood cell expansion processes involve the use of animal-derived products. Suppliers or regulatory authorities may limit or restrict the availability of such compounds for clinical and commercial use. Any restrictions on these compounds would impose a potential competitive disadvantage for our products. Regulatory authorities in the EU are reviewing the safety issues related to the use of animal derived materials which we currently use in our production process. It is unknown at this time what actions, if any, the authority 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.

Given our limited internal sales and marketing capabilities, we need to develop increased internal capability or collaborative relationships to sell, market and distribute our products.

While we have commenced marketing on a limited basis of the AastromReplicell System and SC-I, DC-I, DCV-I and DCV-II cell production kits in the EU and domestically for research and industrial use, we have only limited internal sales, marketing and distribution capabilities. We intend to get assistance to market our products through collaborative relationships with companies with established sales, marketing and distribution capabilities. While we have entered into such arrangements with respect to Switzerland, Turkey and Italy, we will need to establish additional relationships to be able to achieve the market coverage we desire. 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.

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 market for our products is very competitive, is subject to rapid technological changes and varies 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 chemo-therapy, 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 a substantial decline in the market for the AastromReplicell System with our SC-I kit.

Our products are designed to improve and automate the processes for producing cells used in therapeutic procedures. Even if we are able to demonstrate improved or equivalent results, the cost or process of treatment and other factors may cause researchers and practitioners to not use our products and we will suffer a competitive disadvantage. As a result, we may be unable to recover the net book value of our inventory. Finally, to the extent that others develop new technologies that address the targeted application for our products, our business will suffer.

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

Our success depends 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 separate occasions. As a result of these and other factors, we may not be successful in hiring or retaining key personnel. The Company has a key man life insurance policy for R. Douglas Armstrong, Chief Executive Officer and Chairman of Aastrom. Our inability to replace any other lost key employee could harm our operations.

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

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

Intellectual property litigation could harm our business.

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

The government maintains certain rights in technology that we 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 certain rights in the technology developed with the grant. These rights include a non-exclusive, paid-up, world-wide license to use the technology for any governmental purpose. In addition, the government has the right to require us to grant an exclusive license to use the developed technology to a third party if the government determines that:

- we have not taken adequate steps to commercialize such technology;
- such action is necessary to meet public health or safety needs; or
- such action is necessary to meet requirements for public use under federal regulations.

In these instances, we would not receive revenues on the products we developed. Additionally, technology that was partially funded by a federal research grant is subject to the following government rights:

- products using the technology which are sold in the United States are to be manufactured substantially in the United States, unless a waiver is obtained;
- the government may force the granting of a license to a third party who will make and sell the needed product if we do not pursue reasonable commercialization of a needed product using the technology; and
- the U.S. Government may use the technology for its own needs.

[Table of Contents](#)

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 during research and development efforts, including clinical trials, or after commercialization results in adverse affects. As a result, we may incur significant product liability exposure, which could exceed existing insurance coverage. We may not be able to maintain adequate levels of insurance at reasonable cost and/ or reasonable terms. Excessive insurance costs or uninsured claims would increase our operating loss and affect our financial condition.

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

Our Board of Directors has the authority, without shareholder approval, to issue additional shares of preferred stock 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.

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;
- product development and marketing plan;
- clinical trial plans and anticipated results;
- anticipation of future losses;
- replacement of manufacturing sources;
- commercialization plans; and
- revenue expectations and operating results.

These statements are subject to risks and uncertainties, including those set forth in this Business Risks 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 reason why actual results might differ.

[Table of Contents](#)

Item 8. Financial Statements and Supplementary Data

	Page
Report of Independent Registered Public Accounting Firm	33
Consolidated Balance Sheets as of June 30, 2003 and 2004	34
Consolidated Statements of Operations for the years ended June 30, 2002, 2003 and 2004 and for the Period from March 24, 1989 (Inception) to June 30, 2004	35
Consolidated Statements of Shareholders' Equity from March 24, 1989 (Inception) to June 30, 2004	36
Consolidated Statements of Cash Flows for the years ended June 30, 2002, 2003 and 2004 and for the Period from March 24, 1989 (Inception) to June 30, 2004	37
Notes to Consolidated Financial Statements	38
Schedule II Valuation and Qualifying Accounts	

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of

Aastrom Biosciences, Inc.

In our opinion, the consolidated financial statements listed in the accompanying index present fairly, in all material respects, the financial position of Aastrom Biosciences, Inc. and its subsidiaries (a development stage company) at June 30, 2003 and 2004, and the results of their operations and their cash flows for each of the three years in the period ended June 30, 2004, and for the period from March 24, 1989 (Inception) to June 30, 2004 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 present 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 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 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.

PRICEWATERHOUSECOOPERS LLP

Minneapolis, MN

August 6, 2004

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

	June 30,	
	2003	2004
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 10,512,000	\$ 16,926,000
Receivables, net	350,000	246,000
Inventory	806,000	389,000
Other current assets	185,000	271,000
	<u>11,853,000</u>	<u>17,832,000</u>
PROPERTY AND EQUIPMENT, NET	302,000	334,000
	<u>12,155,000</u>	<u>18,166,000</u>
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	\$ 406,000	\$ 382,000
Accrued employee benefits	174,000	176,000
	<u>580,000</u>	<u>558,000</u>
COMMITMENTS AND CONTINGENCIES (Note 5 and 6)		
SHAREHOLDERS' EQUITY:		
Common Stock, no par value; shares authorized — 150,000,000; shares issued and outstanding — 64,812,422 and 81,373,191, respectively	114,951,000	131,472,000
Deficit accumulated during the development stage	(103,376,000)	(113,864,000)
	<u>11,575,000</u>	<u>17,608,000</u>
Total liabilities and shareholders' equity	<u>\$ 12,155,000</u>	<u>\$ 18,166,000</u>

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
	2002	2003	2004	(Inception) to June 30, 2004
REVENUES:				
Product sales and rentals	\$ 80,000	\$ 314,000	\$ 49,000	\$ 731,000
Research and development agreements	—	10,000	75,000	2,105,000
Grants	797,000	520,000	1,178,000	7,526,000
Total revenues	877,000	844,000	1,302,000	10,362,000
COSTS AND EXPENSES:				
Cost of product sales and rentals	—	145,000	27,000	415,000
Cost of product sales and rentals — provision for obsolete and excess inventory	202,000	748,000	253,000	2,230,000
Research and development	5,428,000	5,647,000	6,289,000	93,437,000
Selling, general and administrative	3,528,000	4,017,000	5,390,000	33,517,000
Total costs and expenses	9,158,000	10,557,000	11,959,000	129,599,000
LOSS FROM OPERATIONS	(8,281,000)	(9,713,000)	(10,657,000)	(119,237,000)
OTHER INCOME (EXPENSE):				
Other income	—	—	—	1,237,000
Interest income	342,000	134,000	169,000	5,371,000
Interest expense	—	—	—	(267,000)
Total other income	342,000	134,000	169,000	6,341,000
NET LOSS	\$ (7,939,000)	\$ (9,579,000)	\$ (10,488,000)	\$ (112,896,000)
NET LOSS PER SHARE (Basic and Diluted)	\$ (.19)	\$ (.19)	\$ (.14)	
Weighted average number of common shares Outstanding (Basic and Diluted)	42,121,000	50,984,000	73,703,000	

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

AASTROM BIOSCIENCES, INC.

(a development stage company)

CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY

	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					(84,890,000)	(84,890,000)
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			2,947,185	893,000		893,000
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		—
Compensation expense related to stock options granted				654,000		654,000
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
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 \$239,000			8,328,422	16,911,000		16,911,000
Dividends and yields on preferred stock		466,000	148,568	502,000	(968,000)	—
Repurchase and retirement of Common Shares Outstanding			(32,171)	(73,000)		(73,000)
BALANCE, JUNE 30, 2001	—	—	37,681,235	96,752,000	(85,858,000)	10,894,000
Net loss and comprehensive loss					(7,939,000)	(7,939,000)
Exercise of stock options and issuance of stock under Employee Stock Purchase Plan			42,075	34,000		34,000
Issuance of common stock, net of issuance costs of \$19,000			6,003,247	7,814,000		7,814,000
BALANCE, JUNE 30, 2002	—	—	43,726,557	104,600,000	(93,797,000)	10,803,000
Net loss and comprehensive loss					(9,579,000)	(9,579,000)
Exercise of stock options and issuance of stock under Employee Stock Purchase Plan			38,723	15,000		15,000
Compensation expense related to stock warrants granted				335,000		335,000
Issuance of common stock, net of issuance costs of \$342,000			21,047,142	10,001,000		10,001,000
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

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
	2002	2003	2004	(Inception) to June 30, 2004
OPERATING ACTIVITIES:				
Net loss	\$ (7,939,000)	\$ (9,579,000)	\$ (10,488,000)	\$ (112,896,000)
Adjustments to reconcile net loss to net cash used for operating activities:				
Depreciation and amortization	126,000	119,000	125,000	3,571,000
Loss on property held for resale	—	—	—	110,000
Amortization of discounts and premiums on investments	—	—	—	(543,000)
Stock compensation expense	—	335,000	425,000	1,424,000
Inventory write downs and reserves	202,000	748,000	253,000	2,230,000
Stock issued pursuant to license agreement	—	—	—	3,300,000
Provision for losses on accounts receivable	—	—	4,000	156,000
Changes in assets and liabilities:				
Receivables	9,000	(230,000)	100,000	(426,000)
Inventory	(874,000)	(253,000)	164,000	(2,715,000)
Other current assets	(12,000)	40,000	(86,000)	(271,000)
Accounts payable and accrued expenses	(267,000)	(183,000)	(24,000)	382,000
Accrued employee benefits	6,000	13,000	2,000	176,000
Net cash used for operating activities	(8,749,000)	(8,990,000)	(9,525,000)	(105,502,000)
INVESTING ACTIVITIES:				
Organizational costs	—	—	—	(73,000)
Purchase of short-term investments	(5,500,000)	—	—	(62,124,000)
Maturities of short-term investments	4,500,000	1,000,000	—	62,667,000
Property and equipment purchases	(153,000)	(119,000)	(157,000)	(3,072,000)
Proceeds from sale of property held for resale	—	—	—	400,000
Net cash provided by (used for) investing activities	(1,153,000)	881,000	(157,000)	(2,202,000)
FINANCING ACTIVITIES:				
Net proceeds from issuance of preferred stock	—	—	—	51,647,000
Net proceeds from issuance of common stock	7,848,000	10,016,000	16,096,000	70,675,000
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	7,848,000	10,016,000	16,096,000	124,630,000
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(2,054,000)	1,907,000	6,414,000	16,926,000
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	10,659,000	8,605,000	10,512,000	—
CASH AND CASH EQUIVALENTS AT END OF PERIOD	\$ 8,605,000	\$ 10,512,000	\$ 16,926,000	\$ 16,926,000
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, conducted both on its own behalf and in connection with various collaborative research and development agreements with others, involving the development and sale of processes and products for the *ex vivo* production of human cells for use in cell therapy.

Successful future operations are subject to several technical and business risks, including satisfactory product development, obtaining regulatory approval and market acceptance for its 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 available cash and investments are expected to finance currently planned activities at least through the end of fiscal year 2005, it will need to raise additional funds in order to complete its product development programs and commercialize its first 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 includes, the rate and degree of progress for its product development programs, the liquidity and volatility of its equity securities, regulatory and manufacturing requirements and uncertainties, technological developments by competitors and other factors. If the Company cannot raise such funds, it may not be able to develop or enhance products, take advantage of future opportunities, or respond to competitive pressures or unanticipated requirements, which would negatively impact its business, financial condition and results of operations.

Significant Revenue Relationships — One collaborator accounted for 17% of total revenues for the period from Inception to June 30, 2004. However, for the fiscal year ended June 30, 2004, there was no revenue recognized from this source. Grant revenues consist of grants received from federal and state agencies.

Suppliers — The Company is dependent on a single contract manufacturer and some of the key components in the Company's 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 subsidiary, Zellera AG (Zellera) which is located in Berlin, Germany, (collectively, the Company). All significant inter-company transactions and accounts have been eliminated in consolidation. As of June 30, 2004, Zellera has only limited operations and is 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 or original maturities of three months or less at the time of purchase.

Short-Term Investments — Short-term investments consist of U.S. government securities and commercial paper 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 fair value, with unrealized gains and losses on investments reflected as a component of accumulated other comprehensive income within shareholders' equity. Through June 30, 2004, the Company has not experienced unrealized gains or losses on its investments.

Diversity of Credit Risk — The Company invests its excess cash in U.S. government securities and commercial paper, maintained in U.S. financial institutions, 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 realized losses on its cash equivalents or short-term investments.

AASTROM BIOSCIENCES, INC.
(a development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Inventory — The Company values its inventory that consists primarily of finished components, the AastromReplicell System and our disposable cell production cassettes, at the lower of cost (specific identification using first in, first out) or market. We regularly review inventory quantities on hand and record a provision to write down obsolete and excess inventory to its estimated net realizable value. Based on the aging of inventory at each period end, we utilize a systematic approach to determine our reserve for obsolete and excess inventory. Under this systematic approach, AastromReplicell System inventory that is less than twelve months old, based on the receipt date, will be carried at full value. Inventory quantities in excess of twelve months old are reserved over a six-month period, until the items are either sold or fully reserved. We review cell production cassette inventory relative to its age and our expected sales and, where quantities exceed expected sales utilization, we reduce the recorded value of cell cassette inventory. We feel this approach is appropriate given our limited product sales history and the risk associated with our ability to recover the inventory as we are still in the process of establishing our product market. Future technological changes, new product development and actual sales results could result in additional obsolete and excess inventory on hand. This could have a significant impact on the value of our inventory and our reported operating results. The Company charged \$748,000 and \$253,000, for the years, ended June 30, 2003 and 2004, respectively to cost of product sales and rentals — provision for obsolete and excess inventory.

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 lease term, whichever is shorter. Depreciation expense was \$126,000, \$119,000, \$125,000 and \$3,571,000 for the years ended June 30, 2002, 2003, 2004 and for the period from Inception to June 30, 2004, respectively. When assets are disposed of, the cost and accumulated depreciation are removed from the accounts. Repairs and maintenance are charged to expense as incurred.

Revenue Recognition — Revenue from grants and research agreements is recognized on a cost reimbursement basis consistent with the performance requirements of the related agreement. Revenue from product sales is recognized when title to the product transfers to customers 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, revenue is recognized upon completion of these obligations. Revenue from achievement of milestone events, which to date has not been material, is recognized when the funding party agrees that the scientific or clinical results stipulated in the agreement have been met and there are no other ongoing obligations on the Company's part. Revenue from licensing fees under licensing agreements is recognized as revenue when there are no future performance obligations remaining with respect to such fees.

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 for the year ended June 30, 2004 and \$2,063,000 for the period from Inception to June 30, 2004. There were no such costs and expenses for years ended June 30, 2002 and 2003.

Stock Compensation — The Company has adopted the disclosure provisions of Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation" (SFAS 123) applicable to stock-based compensation. As permitted by SFAS 123, the Company continues to apply Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees," (APB 25) and related interpretations and does not recognize compensation expense for its employee stock-based compensation plans as allowed by SFAS 123.

AASTROM BIOSCIENCES, INC.
(a development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

If Aastrom had elected to recognize compensation cost based on the fair value of the options granted to employees as prescribed by SFAS No. 123, the following proforma operating results would have occurred using the Black-Scholes option-pricing model to determine the fair value of the options:

	Year Ended June 30,		
	2002	2003	2004
Reported net loss	\$(7,939,000)	\$ (9,579,000)	\$(10,488,000)
Add: Stock-based employee compensation expense included in reported net loss	—	—	372,000
Deduct: Stock-based employee compensation expense determined under fair value based method for all awards	(1,253,000)	(829,000)	(1,352,000)
Pro forma net loss	\$(9,192,000)	\$(10,408,000)	\$(11,468,000)
Earnings per share:			
As reported	\$ (.19)	\$ (.19)	\$ (.14)
Pro forma	\$ (.22)	\$ (.20)	\$ (.16)

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

	Year Ended June 30,		
	2002	2003	2004
Dividend rate	None	None	None
Expected stock price volatility	100%	120%	60%
Risk-free interest rate	4.0% - 4.8%	2.5% - 3.3%	3.1% - 3.9%
Expected life of options	5 years	5 years	5 years

The weighted average fair value of options granted during the years ended June 30, 2002, 2003 and 2004 was \$.80, \$.28 and \$1.60 per share, respectively.

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, or the application of SFAS 109 does not permit management to conclude thereunder that it is more likely than not that some portion or all of the deferred tax assets will be realized.

Net Loss Per Share — Net loss per common share is computed using the weighted-average number of common shares outstanding during the period. Common equivalent shares are not included in the per share calculation where the effect of their inclusion would be anti-dilutive. The aggregate number of common equivalent shares that have been excluded from the computations of net loss per common share for the periods ended June 30, 2002, 2003 and 2004 is approximately 6,143,000, 5,144,000 and 10,104,661, 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.

AASTROM BIOSCIENCES, INC.
(a development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Financial Instruments — The Company's financial instruments include cash equivalents, 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 December 2003, the FASB issued a revision of FIN 46 (FIN 46R), which clarified certain complexities of FIN 46 and generally requires the adoption of all special-purpose entities that qualify as variable interest entities no later than the end of the first reporting period ending after December 15, 2003 and to all non special-purpose entities that qualify as variable interest entities no later than the end of the first reporting period ending after March 15, 2004. At June 30, 2004, the Company did not have any entities that require disclosure or new consolidation as a result of adopting the provisions of FIN 46R.

2. Selected Balance Sheet Information

Receivables — Receivables are presented, net of allowance for doubtful accounts of \$31,000 and \$7,000 at June 30, 2003 and 2004, respectively.

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

	June 30,	
	2003	2004
Machinery and equipment	\$ 1,538,000	\$ 1,610,000
Office equipment	965,000	1,050,000
Leasehold improvements	622,000	622,000
Equipment under lease to third parties	217,000	217,000
	<u>3,342,000</u>	<u>3,499,000</u>
Less accumulated depreciation and amortization	(3,040,000)	(3,165,000)
	<u>\$ 302,000</u>	<u>\$ 334,000</u>

AASTROM BIOSCIENCES, INC.
(a development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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

	June 30,	
	2003	2004
Accounts payable	\$251,000	\$186,000
Accrued expenses:		
Clinical studies	13,000	8,000
Professional services	71,000	87,000
Manufacturing and engineering	5,000	47,000
Deferred revenue	9,000	42,000
Other	57,000	12,000
	\$406,000	\$382,000

3. Shareholders' Equity

Stock Option 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 9,963,615 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. The exercise price of incentive stock options shall not be less than the fair market value of the shares on the date of grant. In the case of individuals who are also holders of 10% or more of the outstanding shares of common stock, the exercise price of incentive stock options shall not be less than 110% of the fair market value of the shares on the date of grant. The exercise price of non-qualified stock options shall not be less than 85% of the fair market value on the date of grant. 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. The Company also grants non-qualified options to purchase 10,000 shares of common stock to each outside director on the day following the Annual Shareholders' meeting or upon their appointment as a director. These options generally vest over a one-year period and expire ten years after the date of grant.

Following shareholder approval of the 2001 Stock Option Plan the Company agreed that it would not grant additional options under the 1992 Stock Option Plan or the 1996 Outside Director Stock Option Plan. 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 under those plans or the 2001 Stock Option Plan.

The following table summarizes option activity:

	Options Outstanding	Options Available for Grant Under Option Plans	Weighted Average Exercise Price Per Share	Options Exercisable at Period End
March 24, 1989 (Inception)				
Options authorized	—	5,949,927		
Options canceled	(2,131,920)	2,031,920	\$4.25	
Options granted	6,027,401	(5,927,401)	\$2.33	
Options exercised	(1,847,619)	—	\$.43	
Balance, June 30, 2001	2,047,862	2,054,446	\$2.03	880,171

AASTROM BIOSCIENCES, INC.
(a development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

	Options Outstanding	Options Available for Grant Under Option Plans	Weighted Average Exercise Price Per Share	Options Exercisable at Period End
Options authorized	—	2,100,000		
Options terminated with approval of 2001 Plan	—	(808,206)		
Options canceled	(412,324)	412,324	\$1.41	
Options granted	1,893,564	(1,893,564)	\$1.05	
Balance, June 30, 2002	3,529,102	1,865,000	\$1.58	1,331,815
Options authorized	—	—		
Options terminated with approval of 2001 Plan	—	(254,080)		
Options canceled	(402,830)	402,830	\$1.56	
Options granted	1,223,650	(1,223,650)	\$.38	
Options exercised	(4,163)	—	\$1.15	
Balance, June 30, 2003	4,345,759	790,100	\$1.24	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	4,956,426	2,171,100	\$1.33	3,118,094

The following table summarizes information about stock-based compensation plans as of June 30, 2004:

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	1,669,050	7.5	\$.56	1,219,180	\$.58
\$1.05 - \$1.91	2,443,776	7.8	\$1.29	1,093,339	\$1.15
\$2.44 - \$2.94	676,400	6.2	\$2.91	638,375	\$2.91
\$3.20 - \$4.75	167,200	5.4	\$3.24	167,200	\$3.24
	4,956,426		\$1.33	3,118,094	\$1.41

Effective July 1, 2000, the Company adopted Financial Accounting Standards Board Interpretation Number 44 to APB 25 (Interpretation No. 44) as it related to 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 is recorded for subsequent increases in the market price of the Company's common stock above \$2.41. This charge continues until such options have been exercised, forfeited or otherwise expire. During fiscal years 2002, 2003 and 2004, there was no charge to expense because the Company's stock price did not exceed \$2.41. At June 30, 2004, options to purchase 317,000 of these shares remain outstanding.

Employee Stock Purchase Plan — The Company has an employee stock purchase plan under which eligible employees may purchase common stock, at a discount to the market price, through payroll deductions

AASTROM BIOSCIENCES, INC.
(a development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

of up to 10% of the employee's base compensation, subject to certain limitations, during sequential 24-month offering periods. Each offering period is 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 may be purchased under the plan for such offering period is 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, 2002, 2003 and 2004, 42,075 shares, 34,560 shares and 40,919 shares, respectively, of common stock were purchased under this plan. From inception to June 30, 2004, 192,474 shares were purchased under this plan.

Stock Purchase Warrants Issued for Services — In August 2003, the Company issued warrants to two individuals who performed public and investor relation's services. Under the terms of this agreement, the holders are entitled to purchase 100,000 shares of common stock at \$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 represents the fair value of the warrants.

In August 2002, the Company issued a warrant to SBI USA, LLC for investment banking services. The warrant entitled the holder to purchase 2,000,000 shares of common stock at \$0.75 per share through August 23, 2003. As a result of the issuance of this warrant we recorded \$159,000 in selling, general and administrative expenses which represents the fair value of the warrants. Subsequently, in February 2003, by mutual agreement of both parties this warrant was canceled. The Company has also agreed to issue warrants in connection with two separate agreements for public and investor relation's services. Under the terms of these agreements one holder is entitled to purchase 600,000 shares of common stock at \$0.75 per share through December 19, 2004, and the other holder is entitled to purchase 100,000 shares of common stock at \$0.50 through February 4, 2004. As a result of these agreements the Company recorded \$176,000 in selling, general and administrative expenses during the year ended June 30, 2003 which represents the fair value of the warrants. In addition, the Company agreed, subject to a placement agreement to issue a warrant to purchase 97,595 shares of common stock at \$0.91 through June 6, 2005. A placement was completed in June 2003. The estimated fair value of these warrants was \$54,000 and they were recorded as common stock issuance costs for the year ended June 30, 2003.

The fair value of all warrants issued in fiscal year 2003 were determined at the date of grant using the Black-Scholes option-pricing model at an expected stock price volatility of 120% and risk-free interest rates that ranged from 1.25% to 1.87%. 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 are issued in private transactions to investors who agreed to acquire the warrants for investment purposes, such that the transactions were exempt from shareholder approval and registration pursuant to Section 4(2) of the Securities Act.

Stock Purchase Warrants — In September 2003, we issued 5,058,824 shares of our common stock to multiple private placement investors, for gross proceeds of approximately \$4,300,000. As part of this transaction, we 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 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.

In April 2004, we issued 8,000,000 shares of our common stock through a registered direct offering to institutional investors, for gross proceeds of approximately \$9,100,000. As part of this transaction, we issued warrants to the institutional investors, exercisable for 5 years, or until April 5, 2009, subject to mandatory exercise at our option, in certain circumstances of stock price escalation after April 5, 2006, to purchase up to

AASTROM BIOSCIENCES, INC.
(a development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

2.4 million shares of common stock at an exercise price of \$1.65 per share. In addition, we issued warrants to the placement agent, exercisable for 5 years, or until April 5, 2009, subject to mandatory exercise at our 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.

Common Shares Reserved — As of June 30, 2004, the Company has reserved shares of common stock for future issuance as follows:

Issuance under stock option and stock purchase plans	30,657,707
Issuance under stock purchase warrants	5,148,235
	<u>35,805,942</u>

No cash dividends have ever been declared or paid.

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,		
	2002	2003	2004
Loss before income taxes	\$ 7,939,000	\$ 9,579,000	\$10,488,000
Federal statutory rate	34%	34%	34%
Taxes computed at federal statutory rate	(2,699,000)	(3,257,000)	(3,566,000)
State taxes, net of federal taxes	—	—	—
Increase (decrease) in taxes from:			
Stock compensation	—	114,000	145,000
Other, net	5,000	5,000	5,000
Valuation allowance	2,694,000	3,138,000	3,416,000
Reported income taxes	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>

Deferred tax assets consist of the following:

	June 30,	
	2003	2004
Net operating loss carryforwards	\$ 18,500,000	\$ 16,650,000
Research and development credit carryforwards	320,000	485,000
Inventory	368,000	451,000
Property and equipment	(180,000)	(145,000)
Other, net	(88,000)	(84,000)
Net deferred tax assets	<u>18,920,000</u>	<u>17,357,000</u>
Valuation allowance	(18,920,000)	(17,357,000)
Net deferred tax asset	<u>\$ —</u>	<u>\$ —</u>

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

AASTROM BIOSCIENCES, INC.
(a development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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 due to the multiple ownership changes, which have occurred. At June 30, 2004 the Company estimates the maximum Federal tax net operating loss and tax credit carryforwards, which could be utilized were \$45,000,000 and \$500,000, respectively, which will expire from 2005 through 2025, 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 \$1,300 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, we do 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 treatments for the regeneration of tissues such as bone and cartilage. Under the terms of the alliance, the companies will provide each other with rights to their technologies for treatments and products that are based on combinations of MTF's matrices and Aastrom's Tissue Repair Cells. The companies will share in development and clinical trial expenses for these treatment approach products, and will adopt a coordinated promotion and marketing strategy for future products.

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. Pursuant to one such agreement, the Company made annual renewal payments of \$1,000,000, due in advance, in March of each year during the initial term of the agreement, which ended in 2001. The license agreement was extended through March 2003, with no additional annual renewal fees due. If the manufacturing or supply agreements expire or otherwise terminated, we may not be able to identify and obtain ancillary materials that are necessary to develop our product and as such would have a material affect on our business.

AASTROM BIOSCIENCES, INC.
(a development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

6. Operating Lease

The Company leases its office and research facility under an operating lease that expires December 31, 2004. Future minimum lease payments due under the non-cancelable operating leases are as follows:

Year Ending June 30,	Operating Leases
2005	\$316,000

Rent expense for the years ended June 30, 2002, 2003 and 2004, was \$547,000, \$602,000 and \$616,000, respectively, and \$5,079,000 for the period from Inception to June 30, 2004.

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 \$146,000, \$109,000 and \$121,000 for the years ended June 30, 2002, 2003 and 2004, respectively and \$376,000 for the period Inception to June 30, 2004.

8. Quarterly Financial Data (Unaudited)

Year Ended June 30, 2004	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Fiscal Year
Revenues	\$ 300,000	\$ 376,000	\$ 416,000	\$ 210,000	\$ 1,302,000
Loss from operations	(2,886,000)	(2,440,000)	(2,528,000)	(2,803,000)	(10,657,000)
Net loss	(2,838,000)	(2,403,000)	(2,500,000)	(2,747,000)	(10,488,000)
Net loss per common share	(.04)	(.03)	(.03)	(.03)	(.14)
Year Ended June 30, 2003	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Fiscal Year
Revenues	\$ 93,000	\$ 296,000	\$ 280,000	\$ 175,000	\$ 844,000
Loss from operations	(2,493,000)	(2,320,000)	(2,132,000)	(2,768,000)	(9,713,000)
Net loss	(2,452,000)	(2,287,000)	(2,102,000)	(2,738,000)	(9,579,000)
Net loss per common share	(.05)	(.05)	(.04)	(.05)	(.19)

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.

[Table of Contents](#)

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

There are none to report.

Item 9A. *Controls and Procedures*

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chairman, and our Senior Vice President Administrative and Financial Operations and Chief Financial Officer, we evaluated the effectiveness of our disclosure controls and procedures, as such term is defined in Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934, as amended. Based on this evaluation, our Chief Executive Officer and Chairman, and our Senior Vice President Administrative and Financial Operations and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this annual report. During the fourth quarter ended June 30, 2004, there has been no change in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) that has materially affected or is 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 2004 Annual Meeting of Shareholders to be held on November 10, 2004.

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 Aastrom.”

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

Item 11. *Executive Compensation*

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

Item 12. *Security Ownership of Certain Beneficial Owners and Management*

The information relating to ownership of our equity securities by certain beneficial owners and management is incorporated by reference to the Proxy Statement as set forth under the caption “General Information — 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.”

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.

EXHIBIT INDEX

Number	Notes
3.1	H Restated Articles of Incorporation of Aastrom, as amended
3.2	A 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.
10.4#	A 1996 Employee Stock Purchase Plan and form of agreement 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.
10.24+	A License and Supply Agreement, dated April 1, 1996, between Immunex Corporation and Aastrom.
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, Ph.D.
10.40	B Amendment to License and Supply Agreement, dated August 25, 1997, between Immunex Corporation and Aastrom.
10.46#	C Executive Retention and Severance Agreement, dated February 2, 1999, between Aastrom and R. Douglas Armstrong.
10.55#	D Pay to Stay Severance Agreement between R. Douglas Armstrong, Ph.D. and Aastrom dated October 15, 1999.
10.63#	E Agreement Regarding Pay-to-Stay, by and between Aastrom and R. Douglas Armstrong, Ph.D. dated April 28, 2000.
10.65#	E Agreement Regarding Pay-to-Stay, by and between Aastrom and Brian S. Hampson dated April 28, 2000.
10.66#	E Form of Retention Bonus Agreement, by and between Aastrom and Brian S. Hampson
10.67#	E Form of Relocation Bonus Agreement, by and between Aastrom and Brian S. Hampson
10.70	F Seventh Amendment to Office Lease.
10.72#	F Aastrom Biosciences 2001 Stock Option Plan.
10.73#	G Employment Agreement with Alan Wright
10.74#	G Retention Bonus Agreement with Alan Wright
10.76	G Master Supply Agreement with Astro Instrumentation, LLC
10.77	Supply Agreement between Aastrom and Moll Industries, Inc., dated December 16, 2003
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, 1997, as filed on September 25, 1997.

C Incorporated by reference to Aastrom's Annual Report on Form 10-K for the year ended June 30, 1999, as filed on September 20, 1999.

D Incorporated by reference to Aastrom's Quarterly Report on Form 10-Q for the quarter ended December 31, 1999, as filed on February 14, 2000.

Table of Contents

- E Incorporated by reference to Aastrom's Annual Report on Form 10-K for the year ended June 30, 2000, as filed on September 22, 2000.
 - F Incorporated by reference to Aastrom's Annual Report on Form 10-K for the year ended June 30, 2002, as filed on September 30, 2002.
 - G Incorporated by reference to Aastrom's Annual Report on Form 10-K for the year ended June 30, 2003, as filed on September 17, 2003.
 - H Incorporated by reference to Aastrom's Quarterly Report on Form 10-Q for the quarter ended September 30, 2003
 - + Confidential treatment has been requested as to a portion of this exhibit.
 - # Management contract or compensatory plan or arrangement covering executive officers or directors of Aastrom.
-

SCHEDULE II

VALUATION AND QUALIFYING ACCOUNTS

	Years Ended June 30,		
	2002	2003	2004
Allowance for Doubtful Accounts:			
Balance at beginning of year	\$34,000	\$34,000	\$ 31,000
Additions charged to income	—	—	4,000
Write-offs, net of recoveries	—	(3,000)	(28,000)
Balance at end of year	\$34,000	\$31,000	\$ 7,000

	Years Ended June 30,		
	2002	2003	2004
Reserve for Obsolescence and Excess Inventory:			
Balance at beginning of year	\$ —	\$202,000	\$ 950,000
Additions charged to income	202,000	748,000	253,000
Reductions	—	—	—
Balance at end of year	\$202,000	\$950,000	\$1,203,000

SUPPLY AGREEMENT
BETWEEN
AASTROM BIOSCIENCES, INC.
AND
MOLL INDUSTRIES, INC.

- (b) "Cell Cassette(s) " Cell Cassette shall mean a single-use, sterile cell culture chamber consisting of plastic injection molded and other parts made, assembled and encased in a plastic injection molded cassette manufactured in accordance with the DMR and as more particularly described in the Specifications and used in the AastromReplicell System or similar products made by or for AASTROM, and all improvements and modifications to Components thereof that are intended to replace the then current Components.
- (c) "Component (s) " Component shall mean any component part of a Cell Cassette (e.g., the individual injection molded pieces, bioreactor assembly or fluid pathway tubing assembly) as more particularly described in the Specifications.
- (d) "Confidential Information" Confidential Information shall mean any and all technical and non-technical information, (including information disclosed by AASTROM under the terms of the Confidentiality Agreement between the Parties dated December 22, 1993 or in furtherance of the Prior Agreement), data, techniques, manufacturing procedures, know-how, discoveries, inventions, trade secrets, improvements or innovations that are maintained as proprietary and confidential by the Party owning or controlling the same; but Confidential Information shall not include information that (i) the Recipient can clearly demonstrate to have been in its possession at the time Confidential Information is disclosed to it, provided that, such information is not known by the Recipient to be subject to another confidentiality agreement with, or under other obligation of secrecy to, the Disclosing Party or another party, or (ii) becomes generally available to the public other than as a result of a disclosure by the Recipient, its agents or employees, or (iii) becomes available to the Recipient on a non-confidential basis from a source other than the Disclosing Party, provided that, the Recipient does not know, or have reason to know, that such source is bound by a confidentiality agreement with, or other obligation of secrecy to the Disclosing Party or another party, or (iv) the Recipient can clearly demonstrate to have developed itself independent of the Confidential Information, or (v) the Disclosing Party consents in writing may be disclosed by the Recipient.
- (e) "Disclosing Party" Disclosing Party shall mean the Party disclosing Confidential Information.
- (f) "DMR" DMR shall mean the Device Master Record for the Cell Cassette consisting of a compilation of records containing the procedures and specifications for a finished device including the complete

manufacturing procedures and specification with the necessary quality assurance requirements and labeling and packaging requirements.

- (g) "Equipment" Equipment shall mean the molds and other equipment listed on Appendix I, annexed hereto, and categorized as being provided either by AASTROM or by MOLL. AASTROM Equipment shall also include any equipment procured by MOLL for manufacture of the Cell Cassettes in accordance with Section 21(b)(1).
- (h) "cGMPs" cGMPs shall mean the then-current Good Manufacturing Practices (QSR) set out in 21 CFR Part 820, et seq. applicable to a Class III medical device that -- --- govern the methods used in, and the facilities and controls used for the design, manufacturing, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use.
- (i) "Initial Term" Initial Term shall have the meaning set forth in Section 17.
- (j) "ISO" ISO (the International Standards Organization) is a worldwide federation of national standards bodies (ISO member bodies).
- (k) "Party or "Parties" Party shall mean either AASTROM or MOLL, and Parties shall mean both AASTROM and MOLL.
- (l) "Prior Agreement" Prior Agreement shall mean that certain Collaborative Supply Agreement dated December 16, 1996 between the Parties.
- (m) "Recipient" Recipient shall mean the Party receiving Confidential Information.
- (n) "Requirements" Requirements shall mean the rolling four-month firm forecast to be provided by AASTROM under Section 3(a), below, of AASTROM's then-current requirements for Cell Cassettes during the Term.
- (o) "Shipment Lot" On a quarterly basis, concurrently with the provision by AASTROM of its rolling twelve-month forecast, the Parties shall mutually review and by mutual written consent will specify the number of Cell Cassettes that constitute a Shipment Lot, for the purchase order to be submitted by AASTROM during such quarter, considering volume requirements and anticipated delivery schedules. The mutually agreed upon quantity constituting the Shipment Lot shall be reflected in each purchase order submitted by AASTROM.
- (p) "Specifications" Specifications shall mean the written specifications for the manufacture of Cell Cassettes and Components (including without limitation the criteria for labeling and packaging, including

graphics, and quality assurance requirements) annexed hereto as Appendix II, as such Specifications may be changed pursuant to Section 6, below.

- (q) "Term" Term shall mean the period of time from the Effective Date until the date upon which this Agreement expires or is earlier terminated pursuant to Section 17, below.
- (r) "UCC" UCC means the Uniform Commercial Code as enacted by the State of New York and in effect during the Term.

SECTION 2. PURCHASE AND SALE.

AASTROM shall purchase from MOLL AASTROM's Requirements of Cell Cassettes, and MOLL shall manufacture, assemble and sell to AASTROM all of AASTROM's purchase orders for Cell Cassettes and Components, subject to the terms and conditions of this Agreement including, without limitation, AASTROM's rights to terminate this Agreement in whole or in part pursuant to Sections 6 or 17, below, and its rights to utilize alternate suppliers of Cell Cassettes and Components pursuant to Sections 3(b), 4(d), 17 or 18 below.

SECTION 3. FORECASTS; DELIVERY; SHIPMENT.

(a) Rolling Forecasts. At the beginning of each calendar quarter during the Term, AASTROM shall provide MOLL with a rolling forecast of the anticipated quantity of each model of Cell Cassettes AASTROM intends to purchase from MOLL during each month of the following twelve-month period. The quantities given for the first four months of each twelve-month rolling forecast shall be firm orders for the immediately succeeding four months (i.e., a forecast given on January 1st would be deemed firm for the period May 1 - August 31) and AASTROM shall issue its purchase order therefor and note on such purchase order the number of units it will require for lot testing in accordance with Section 3(g), the method of shipment and AASTROM destination for delivery, the scheduled delivery date and the required documentation to be included with the Shipment Lot. MOLL shall have no obligation to purchase materials or supplies without a purchase order from AASTROM except as is necessary to meet AASTROM's forecasted requirements. AASTROM shall pay MOLL for labor, materials, supplies and direct costs (as set forth in Appendix III) expended by MOLL to fill purchase orders by AASTROM for Cell Cassettes in the event that they are not used to fulfill such purchase orders. Quantities forecasted beyond the four-month firm-order period are for planning purposes only.

(b) No Limit on Sales. MOLL has no right to limit its sales of Cell Cassettes or Components to AASTROM to a maximum number of units for any period; provided that, the volume of Cell Cassettes and Components ordered is reasonable in the light of forecasted amounts and previous delivery schedules. MOLL shall have adequate capacity to meet AASTROM's then-current total firm-order requirements as forecasted pursuant to Section 3(a), above. MOLL will take all steps to put in place additional adequate capacity, if needed, to meet AASTROM's future requirements as forecasted by AASTROM in accordance with Section 3(a), above; provided that, the Parties shall cooperate to afford a reasonable transition to the availability of such additional capacity. Notwithstanding any other provision of this Agreement (specifically including Sections 2 and

18), if MOLL is unable to meet AASTROM's requirements for Cell Cassettes (including any request for an increase in production by AASTROM at any time during the Term of this Agreement), AASTROM may thereafter utilize one or more third party manufacturers for all or a portion of AASTROM's requirements for Cell Cassettes. Furthermore, even if Moll is unable to produce entire Cell Cassettes, Moll shall be obligated to supply components to AASTROM's Alternate Supplier.

(c) No Liens. MOLL will deliver Cell Cassettes to AASTROM free and clear of all liens, claims and encumbrances.

(d) Delivery. MOLL shall deliver Cell Cassettes, and upon AASTROM's request, any certifications, manufacturing records and test reports as are required for AASTROM to accept or reject Cell Cassettes under this Section 3, pursuant to delivery schedules in AASTROM's purchase orders; provided, that, such schedules are reasonable in light of forecasted amounts and previous delivery schedules. Delivery schedules in AASTROM's purchase orders shall not be less than fifteen (15) days after the date of submission by AASTROM of the purchase order without MOLL's consent. In the event that AASTROM submits a purchase order in excess of its forecasted requirements for said quarter, MOLL agrees to employ good faith efforts to supply such larger quantity of Cell Cassettes within such a reasonable period of time, as the Parties shall mutually agree. MOLL shall not deliver Cell Cassettes more than ten (10) days prior to scheduled delivery dates without AASTROM's prior consent. MOLL shall not be responsible for failure to meet agreed-upon delivery dates if due to reasons of force Majeure as set forth in Section 20, below or if delays are caused by Aastrom-specified material/component suppliers or service providers outside of Moll's control.. In the event of partial failure to deliver, MOLL will have the right to receive payment pro rata for Cell Cassettes in fact delivered and not rejected by AASTROM under Section 3(f), below.

(e) Shipment. MOLL shall make shipment to AASTROM's designated U.S. locations, in accordance with AASTROM's purchase orders, F.O.B. destination. Risk of loss or damage in transit shall remain with MOLL until delivered to the destination specified by AASTROM. AASTROM shall notify MOLL within five (5) business days after receipt if there are any shortages or evidence of damage in transit and will cooperate with MOLL in any claim for loss or damage in transit that MOLL makes against a carrier. The method and route of shipment are at AASTROM's discretion as set forth in its purchase order. MOLL will prepay all costs, insurance premiums, freight and other expenses incurred in shipment until delivered to the destination specified by AASTROM and such shipping costs shall be reimbursed by AASTROM at MOLL's cost without mark-up. If AASTROM defaults in payment for Cell Cassettes, MOLL may suspend further shipments; however, continuation of shipments does not constitute a waiver of such default.

(f) Acceptance Procedures. Delivery of each Cell Cassette unit shall be deemed accepted by AASTROM unless MOLL is notified in writing of AASTROM's rejection of such delivery within ninety (90) days after the delivery date (the "Acceptance Period") due to non-conformance with the Specifications. In such case, AASTROM shall provide MOLL with a written notice of rejection setting forth in detail the reason for rejection and return the rejected Shipment Lot, or portion thereof, to MOLL at MOLL's expense for repair or replacement. Upon receipt of AASTROM's notice of rejection and return of such Shipment Lot of part thereof,

MOLL shall (i) within ten (10) business days thereafter, provide AASTROM with a root-cause analysis and suggested corrective/preventative actions; and (ii) diligently replace the nonconforming Shipment Lot or part thereof by delivery of non-defective conforming units within a reasonable time (not to exceed thirty (30) calendar days after notification) and endeavor to resolve the issues related to the rejection. MOLL shall credit against the purchase price of Cell Cassettes and Components, AASTROM's out of pocket costs of testing, including, without limitation, destructive testing of failed Shipment Lots. AASTROM shall invoice MOLL for such costs, which shall be subject to reasonable audit by MOLL or its representative. MOLL reserves the right, at MOLL's expense, to have one or more representatives present at any inspection conducted by AASTROM and to verify the results of any such inspection and rejection of Shipment Lots. MOLL shall have the right to use conforming units or parts therefrom as replacement units provided that such units or parts therefrom are in conformance with Specifications. In the event MOLL cannot resolve all nonconformities and deliver conforming replacement Cell Cassettes as required herein MOLL shall issue to AASTROM a credit for the price of each unit rejected and AASTROM may pursue its remedies pursuant to this Agreement, including but not limited to Section 17, below. AASTROM shall pay for repair or replacement for defective Cell Cassettes (or shall not receive a credit therefor) only to the extent that rejection is due to a defective component supplied directly by AASTROM. In the event that MOLL's delivery of Cell Cassettes fails to conform to the quantity specified in AASTROM's purchase order, AASTROM may, but shall not be obligated to, accept such partial shipment and MOLL shall deliver any shortfall in delivery quantity within five (5) calendar days. Notwithstanding the foregoing, AASTROM agrees to accept partial shipments from MOLL provided that the quantity delivered is at least ninety percent (90%) of the quantity specified in AASTROM's purchase order, but only if AASTROM may readily use such partial shipment for its intended purposes, and AASTROM also agrees to use commercially reasonable efforts to accept partial shipments of quantities of less than ninety percent (90%) of the quantity specified in AASTROM's purchase order, but only if AASTROM may readily use such partial shipment for its intended purpose(s). Any acceptance of partial shipments by AASTROM shall not be deemed to waive AASTROM's remedies under Section 17(d) and AASTROM shall be entitled to a payment credit reflecting the extent of such unit shortfall under a partial shipment. In the event MOLL fails to deliver any shortfall in quantity within such five (5) day period, AASTROM may pursue its remedies pursuant to this Agreement.

(g) Lot Testing. During the Acceptance Period, AASTROM shall have the right, but not the obligation, to conduct lot testing on a statistically significant number of units from each Shipment Lot. At the time of submission of AASTROM's purchase orders in accordance with Section 3(a), AASTROM shall note on such purchase order the number of units it requires for lot testing. Notwithstanding Section 4(a), MOLL agrees to provide such testing units to AASTROM at MOLL's cost to manufacture such units (without mark-up) provided that the number of units requested does not exceed 10% of the number of units ordered, and provided further that any units provided by MOLL for lot testing shall not be resold by AASTROM. Any lot testing conducted by AASTROM pursuant to this Section shall not be deemed to relieve MOLL of any of its warranties or obligations hereunder.

SECTION 4. PRICES.

(a) Cell Cassette Prices. Prices for Cell Cassettes purchased during the Term shall be determined as shown in Appendix III, hereto. Prices are exclusive of all taxes of any nature imposed by any governmental authority, except taxes imposed on the income or profits of MOLL. All such taxes shall be for AASTROM's account, whether or not collected, advanced or paid by MOLL, and shall be paid by AASTROM, without mark-up, upon MOLL's invoice, unless AASTROM timely provides proper tax exemption documents.

(b) Component Order and Prices. From time to time throughout the Term, AASTROM may submit to MOLL purchase orders for Components and MOLL shall manufacture and sell to AASTROM such Components in accordance with the terms of this Agreement for the manufacture of Cell Cassettes, as they may be applicable, excepting only the provisions of Sections 3(a) with regard to references to AASTROM's obligation to forecast and purchase its specific Requirements from MOLL. Prices for any Components purchased by AASTROM during the Term shall be quoted separately by MOLL at the time of order with such quoted price not to exceed MOLL's actual manufacturing costs to produce such Components, multiplied by the applicable Mark-Up Rates (as set forth in Appendix III) then in effect for the forecasted annual volume of Cell Cassettes to be purchased by AASTROM.

(c) Best Diligent Efforts. At all times during the Term of this Agreement, MOLL shall use its best diligent efforts to manufacture Cell Cassettes, procure components and perform other services as provided in this Agreement at the lowest cost reasonably practicable. Furthermore, subject to Section 21 below, it is the explicit understanding of the parties that MOLL will, on a proactive basis and at no additional cost to AASTROM, seek out additional methods and means that will lead to reduced costs, quality improvements and increased efficiency with regard to the manufacture of Cell Cassettes. AASTROM will reasonably cooperate with MOLL on such cost saving efforts.

(d) Cost Competitive. If AASTROM reasonably believes that MOLL is not remaining cost competitive, AASTROM may obtain a quote from another qualified supplier to manufacture the Cell Cassettes (AASTROM will provide MOLL with the source and supporting information for the price quote for MOLL's review). If such a quote is ten percent (10%) or more lower than MOLL's price under this Agreement, MOLL shall either reduce the price to the quoted price within a reasonable time period (not to exceed sixty (60) days) or AASTROM may thereafter utilize one or more third party manufacturers for all or a portion of AASTROM's Requirements for Cell Cassettes (notwithstanding the provisions of Sections 2 and 18). In order to be considered "qualified", an alternate supplier must be an established, viable medical contract manufacturer with a multi-year track record of good performance with respect to FDA regulations, cGMP's, and ISO certification and must guarantee the new lower price throughout the period covered by this contract. AASTROM will be limited to a maximum of two of these competitive price challenge events during the period covered by this contract and must have placed orders for at least 150 cassettes/month for six consecutive months before initiating the first competitive price challenge.

SECTION 5. PAYMENT AND COLLECTION.

(a) Payment. AASTROM shall pay MOLL the full amount of the purchase price of Cell Cassettes upon the due date set forth on MOLL's invoice; provided, however invoices for Cell Cassettes rightfully rejected by AASTROM shall not be due unless and until repair or replacement units are provided by MOLL. With respect to Cell Cassettes and Components, terms of payment shall be net 30 days from the date of delivery by MOLL pursuant to Section 3, above, and the submission by MOLL of an itemized invoice in the form attached hereto in Appendix IV including the purchase price for such Cell Cassettes calculated in accordance with Appendix III, together with such supporting documents as AASTROM may reasonably request. Accounts unpaid beyond their due date will bear interest at 1% per month on the unpaid balance. If payment by AASTROM is improperly withheld and MOLL retains an agency and/or attorneys to collect amounts overdue, all collection costs, including without limitation, reasonable attorneys' fees, shall be payable by AASTROM.

(b) Deductions from Invoice. AASTROM will promptly notify MOLL of any disputed invoice. It is the intention of the Parties that disputed invoices will be settled by the Parties in good faith negotiations prior to the invoice due date. However, unless MOLL issues a credit memo, or unless AASTROM rightfully rejects Cell Cassettes or notifies MOLL of its acceptance of a partial shipment pursuant to Section 3(f), AASTROM shall make full payment of MOLL invoices for accepted Cell Cassettes without deduction and regardless of any claim, counterclaim or setoff AASTROM may have against MOLL, except as such setoff may otherwise be permitted under Appendix III, Section 3(f) or Section 12(d). Any such claim, counterclaim or setoff shall be resolved exclusively as a separate matter pursuant to Section 24, below.

(c) Relief for Non-Payment. In the event payment for Cell Cassettes becomes past due, MOLL will have the option, in addition to any other rights it may have under the UCC or otherwise, in its sole, absolute discretion, to cancel or delay shipment or orders of AASTROM previously accepted, to declare all sums owing from AASTROM to be immediately due and payable, and to cancel credit previously extended.

SECTION 6. SPECIFICATIONS, DMR AND CHANGES.

(a) Specifications. MOLL shall manufacture and assemble Cell Cassettes to the then-current Specifications and no part of MOLL's responsibility may be subcontracted without the prior written consent of AASTROM.

(b) Establish DMR. As further described in Section 9, MOLL shall prepare and maintain a DMR covering the manufacture of the Cell Cassettes from the Specifications, other requirements and technical information to be provided by AASTROM, and manufacturing and quality processes and procedures established by MOLL. AASTROM shall review and approve the DMR to assure that it accurately reflects the Specifications.

(c) Specification and DMR Changes. Notwithstanding any provision of this Agreement to the contrary, MOLL shall not have the right to change the Specifications without the prior written consent of AASTROM. If AASTROM desires to change the Specifications or any part of the DMR, AASTROM shall submit the proposed change to MOLL, setting forth a detailed

description and drawings thereof. Subject to Section 6(d), the Parties shall work in good faith as expeditiously as is reasonable to reach a determination on the effect that such change will have, if any, on quantities, quality criteria, price and delivery dates.

(d) Implementation of Specifications Changes. If AASTROM proposes a change to the Specifications and if such change is currently able to be manufactured, then MOLL will either (i) implement such change into its manufacture of the Cell Cassettes and/or Components, with an appropriate increase or decrease to the price thereof based upon the effect of such change, or (ii) refuse to implement such change, in which case AASTROM shall have the right, without liability, in accordance with Section 17(b), below, to terminate this Agreement on a prospective basis for all Requirements incorporating the changed Specifications that have not yet been submitted on purchase orders. The Parties will cooperate to implement changes to Specifications in an orderly manner and to afford MOLL a reasonable transition time to the extent necessary to effect such Specification changes.

(e) Other Changes. AASTROM may cancel or change quantities or delivery dates under any purchase order upon terms that make MOLL whole for its costs in respect of materials and work-in-process as set forth in Section 3(a).

(f) Returns. Except as expressly provided in this Agreement including, without limitation, as provided in Sections 3(f) and 12(a), below, in no case may Cell Cassettes be returned to MOLL without first obtaining MOLL's written consent which will not be unreasonably withheld.

SECTION 7. MOLL'S FACILITIES AND MANUFACTURING ENVIRONMENT.

With respect to its manufacturing facilities and assembly obligations applicable to the production of Cell Cassettes, MOLL shall:

(a) be registered with the FDA as a Medical Device Establishment to the extent required by the Act. As such, MOLL will maintain facility registrations and inspection records required by the FDA;

(b) have and maintain a Class 100,000 certified assembly area operating at less than 20,000 particulate-count and arrange for annual certification to be conducted by an independent testing service. A routine monitoring plan, to include at least monthly testing, will also be established and performed by MOLL (the foregoing routine monitoring plan shall be subject to AASTROM's approval, which approval shall not be unreasonably withheld);

(c) maintain adequate personnel and facilities, including but not limited to sufficient engineering support and assembly resources to support the manufacture of Cell Cassettes ordered by AASTROM. MOLL will provide AASTROM annually with a project plan to meet AASTROM's forecast Requirements and AASTROM will provide timely comments thereon;

(d) manufacture and assemble all of the Cell Cassettes in compliance with GMPs as required by the Act; provided that, AASTROM, as the owner of the DMR, shall have the responsibility for approving the DMR and any changes thereto as established by MOLL in accordance with Section 9, below;

(e) shall be certified under an acceptable international quality management system (e.g., ISO 13485 or 13488) and at all times during this Agreement shall maintain their quality management system certification;

(f) together with the Equipment to be provided by AASTROM, provide and maintain adequate manufacturing Equipment to perform its obligations under Section 6 of this Agreement;

(g) have and maintain adequate procedures for procurement, acceptance, supplier quality audits and material control of all component parts to be used or incorporated in Cell Cassettes;

(h) report to AASTROM in writing any known adverse events, circumstances or potential problems relating to MOLL's FDA registration or its EC certifications referred to in Section 7(e), above;

(i) allow AASTROM and its agents, at their own cost and risk, to review and inspect MOLL's facilities, FDA compliance files and correspondence to and from the FDA and notified bodies applicable to this Agreement; and

(j) maintain files of all Cell Cassette-related complaints received by MOLL from AASTROM and conduct failure investigations, including establishing written records with conclusions and corrective measures, for all such Cell Cassettes complaints involving a failure to meet Specifications.

SECTION 8. MOLL MANUFACTURING PROCEDURES.

MOLL's obligation to manufacture Cell Cassettes shall be to deliver Cell Cassettes as described in Section 6(a), above and in accordance with the DMR. Without expanding or diminishing that obligation, and for purposes of illustration only, it is contemplated by the Parties that such obligation shall encompass:

(a) injection molding and processing the main Components of the bioreactor device for the Cell Cassette including any sonic or RF welding and vacuum plasma surface treatment operations;

(b) assembling the aforesaid bioreactor devices utilizing fixtures provided by AASTROM, or alternative fixtures as developed;

(c) injection molding components of the Cell Cassette fluid pathway tubing assembly;

(d) assembly of the fluid pathway tubing assembly;

(e) injection molding non-fluid contact enclosure components for the Cell Cassette using molds supplied by AASTROM;

(f) procuring the waste reservoir and media supply enclosure from an AASTROM-approved source;

(g) assembling the enclosure, the waste reservoir and media supply enclosure, the bioreactor and the fluid pathway tubing assembly described in Sections 8(d), (e), (b), (c), and (f) above, respectively;

(h) performing testing in accordance with the DMR;

(i) validating Cell Cassettes to the applicable sterilization assurance level; and

(j) performing on-going vendor audits and validation procedures, as required by GMPs, and conducting a reasonable incoming inspection of purchased components for compliance with Specifications.

SECTION 9. OTHER RESPONSIBILITIES.

(a) Other Responsibilities of MOLL. In connection with MOLL's manufacturing and assembly obligations under this Agreement, MOLL shall:

(1) prepare and maintain the DMR in accordance with the then-current manufacturing Specifications and the criteria for testing the Cell Cassette, all to be provided by AASTROM. Manufacturing documentation shall be owned by AASTROM and shall consist of: (i) the DMR documentation; (ii) documentation of Specifications and drawings for Cell Cassette parts to be provided by MOLL or acquired by MOLL from approved vendors; (iii) test and acceptance procedures and criteria documentation; (iv) subassembly specifications, drawings and requirements documentation; (v) manufacturing instructions and procedures documentation; and (vi) quality instructions and procedures documentation;

(2) prepare the DMR as set forth in Section 6(b), above, and maintain the DMR in accordance with a documented change management system reasonably acceptable to AASTROM which system shall include the approval of all Cell Cassette manufacturing changes by AASTROM prior to implementation by MOLL. The foregoing change management system documentation shall also include the history of all changes including validation and/or rationale and shall be owned by AASTROM;

(3) shall conduct or subcontract the required processing and laboratory testing as required by AAMI TIR 27:2001 for quarterly dose audits to maintain the approved sterilization validation of the cell cassettes.

(4) to the extent required for submittal by AASTROM to the FDA or other regulatory authorities in connection with the Cell Cassette, prepare a detailed description of MOLL's manufacturing methods, processes, procedures and facility applicable to the manufacture and testing of the Cell Cassette as requested by AASTROM;

(5) provide engineering and other support for validation of the Cell Cassette manufacturing process, for sterility assurance, and for completing changes to the Cell Cassette design or manufacturing processes. AASTROM may request such engineering and other support by submitting a written statement of work executed by a designated AASTROM representative. MOLL shall respond to the request within one week from receipt of the request, and shall prepare a proposal to complete the work. AASTROM shall issue its written authorization to

complete the proposed work. Any changes to be implemented in connection with the work shall be completed in accordance with Section 6. AASTROM has the right to review the implementation of any changes performed by MOLL, and has the right to reject any such implementation of changes that AASTROM deems to be detrimental to the quality of the product;

(6) use reasonable efforts to train AASTROM's technical representatives at MOLL's facilities, at AASTROM's request and expense from time to time during the Term in all applicable procedures for manufacture of the Cell Cassettes. Such representatives shall sign reasonable non-disclosure agreements in accordance with Section 16(b) consistent with the terms of this Agreement to protect MOLL's Confidential Information. AASTROM and such representatives shall also comply with all of MOLL's reasonable regulations with regard to access by visitors during such training sessions and MOLL reserves the right to deny access to its facilities by non-AASTROM employees provided that such access shall not be unreasonably withheld;

(7) develop a quality measurement system acceptable to AASTROM and report in a manner reasonably satisfactory to AASTROM on a monthly basis with regard to MOLL's progress. This system shall include, at a minimum, (i) metrics on the percent of non-conforming Cell Cassettes, including trending data; (ii) the percentage of the top five defects; and (iii) a FRACAS (Failure Report Analysis and Corrective Action System) detailing the root-cause analysis, corrective actions taken, and proof of implementation; and

(8) perform periodic onsite audits of suppliers of components, assemblies, or services to Moll for manufacture of Cell Cassettes where such supplier is deemed to be of substantial importance, such as due to being a sole source supplier, or providing a critical component or service, or providing a complex component or assembly. Each on-site audit will be scheduled as required, but not less than annually. Appendix V specifies the current list of suppliers requiring on-site audit, which can be revised from time to time by mutual agreement between the two parties.

(b) New Products. From time to time during the Term, AASTROM may provide written notification to MOLL of AASTROM's desire to have MOLL manufacture a product other than the Cell Cassette or its Components. Following such notification, the parties shall negotiate in good faith and attempt to reach mutual agreement on the terms and conditions governing the manufacture and supply of such new product, including development obligations, pricing and supply terms.

SECTION 10. EQUIPMENT.

(a) Ownership. The Parties acknowledge that the Equipment is the sole and exclusive property of the Party indicated on Appendix I as such Appendix may be augmented by mutual agreement of the Parties from time to time. Equipment shall be located at the premises of MOLL in SeaGrove, North Carolina or other facilities of MOLL as the Parties may agree. Except for the sole purpose of performing maintenance, MOLL shall relocate none of the Equipment owned by AASTROM without the prior written consent of AASTROM. It is understood that AASTROM shall have the right to remove the Equipment it owns from MOLL's facilities at any time upon

reasonable notice to MOLL, except that if such removal shall impede MOLL's performance under this Agreement, MOLL shall so notify AASTROM and such Equipment shall not be removed until the condition of such impedance shall no longer pertain. Notwithstanding the foregoing, in the event that MOLL suspends MOLL's performance by reason of force Majeure or default, AASTROM shall be entitled to remove its Equipment to enable AASTROM to continue to manufacture Cell Cassettes. Upon removal of its Equipment, AASTROM shall pay MOLL its reasonable costs of disassembly and freight to a location of AASTROM's choice. AASTROM shall return such Equipment to MOLL's facilities upon MOLL's demonstration (to the extent it can reasonably do so without the use of such Equipment) to AASTROM's reasonable satisfaction of MOLL's capability to resume manufacture of the Cell Cassettes. Equipment added to Appendix I shall be owned by the Party that paid for it or in accordance with Section 21(b), as applicable. Upon expiration or earlier termination of this Agreement, and the payment by AASTROM of all outstanding invoices, MOLL shall, within thirty (30) days thereafter, return all of AASTROM's Equipment to AASTROM's facilities (or other location designated by AASTROM in writing) with all reasonable packing, transportation and insurance costs to be paid by AASTROM.

(b) Identification Tags. Identification tags supplied by AASTROM containing information relating to its ownership of Equipment shall be affixed by MOLL and such tags shall not be removed by MOLL without the written approval of AASTROM.

(c) Liens and Insurance. MOLL shall not impair the right, title and interest of AASTROM in and to the Equipment it owns, nor shall MOLL allow any lien or encumbrance to be levied upon such Equipment. During the Term, and until Equipment owned by AASTROM is removed by AASTROM or abandoned, MOLL shall carry and maintain, at its expense, all-risk property insurance covering the Equipment at full replacement cost.

(d) Inspection. AASTROM shall have the right, at reasonable times during normal business hours and upon reasonable notice, to inspect its Equipment from time to time to ensure that it is being maintained in accordance with Section 10(f), below, and utilized in a manner consistent with the provisions of this Agreement.

(e) No Modification. MOLL will not alter or modify AASTROM's Equipment in any material way without the prior consent of AASTROM. If AASTROM gives such consent, any alteration or modification shall become the property of AASTROM.

(f) Maintenance. MOLL will conduct day-to-day preventative and operational maintenance on all of the Equipment. Such day-to-day maintenance will be adequate: (i) to maintain the Equipment in good working order and condition, ordinary wear and tear and casualty excepted; (ii) to meet all expressed conditions required by manufacturers' written warranties, if any, given with the Equipment so that such warranties remain in effect for their stated terms; provided that MOLL has received from AASTROM a copy of such warranty; and (iii) to promote adherence to agreed-upon quality standards as well as the Specifications and to help minimize unscheduled downtime.

(g) Use. Equipment owned by AASTROM shall be used solely for the benefit of AASTROM to produce Cell Cassettes.

SECTION 11. RIGHT OF INSPECTION.

(a) Rights of Inspection. In addition to AASTROM's right to inspect Cell Cassettes upon delivery pursuant to Section 3, AASTROM shall have the following rights of inspection, each such right to be exercised, if at all, at its own cost and expense:

(1) to inspect, sample and test Cell Cassette work-in-progress and review process control reports and manufacturing records at MOLL's facilities upon at least three (3) work days' prior notice to MOLL and shall consult with MOLL if it believes that its inspection shows MOLL is failing to meet its obligations under this Agreement (in such event the parties will work together toward resolution of any such failure); and

(2) to inspect, sample and test Cell Cassettes at MOLL's facilities after notice by MOLL that a Shipment Lot is ready for shipment to a sterilizer location. Such inspection must be conducted, if at all, within ten (10) days after receipt of such notice.

(b) Waiver. AASTROM's right to inspect under this Section 11 and any inspection by AASTROM hereunder, or AASTROM's acceptance of or payment for Cell Cassettes, shall not be deemed to relieve MOLL of any of its obligations under the terms of this Agreement nor a waiver by AASTROM of its rights to inspect upon delivery pursuant to Section 3 or with respect to breach of warranty as set forth in Section 12, below.

(c) Self-Certification. The Parties shall work together toward self-certification pursuant to which MOLL will conduct in-process controls and finished device testing in order to augment, and reduce the need for, exercise by AASTROM of its inspection rights.

(d) Records; Inspection. For at least two years after the expiration or any earlier termination of this Agreement (under Section 17 below), MOLL shall retain accurate and complete records with respect to its work and manufacture of the Cell Cassettes to the extent necessary to reasonably satisfy all applicable FDA and EC requirements and to verify the time worked and material and other costs invoiced to AASTROM. MOLL shall make available to AASTROM, cost information that AASTROM may reasonably request in connection with the establishment of pricing in accordance with Appendix III. Upon reasonable notice to MOLL, AASTROM and/or its designated independent auditor may inspect and conduct a reasonable audit on such records. If MOLL does not agree with the results of the audit, then the dispute shall be resolved pursuant to Section 24, below. Furthermore, if the results of such audit indicate an overcharge by MOLL of ten percent (10%) or more of AASTROM's applicable purchase price from MOLL, MOLL shall reimburse AASTROM for the cost of performing such audit; otherwise the cost of such audit shall be borne by AASTROM. If such audit shows an overcharge by MOLL of AASTROM's applicable purchase price from MOLL, MOLL shall, upon its review of said audit, promptly reimburse AASTROM for such overcharge plus interest at a rate of 1% per month since the date of payment by AASTROM of the applicable invoice(s).

SECTION 12. WARRANTY; RECALLS.

(a) Warranty. MOLL warrants to AASTROM that each Cell Cassette and Component shall comply with the then-current Specifications and shall be free from defects in material (except for such material as is prescribed by AASTROM, and is outside the control of Moll), and

workmanship and shall be manufactured and assembled in compliance with the DMR and all United States federal, state and local laws, rules and regulations and with all applicable EN29002 and EN46002 requirements (and any amendments thereto and replacements thereof), applicable at the time of manufacture. Moll's warranty with respect to Aastrom-specified purchased materials and components is limited to insuring that they meet the incoming inspection criteria mutually agreed upon by Aastrom and Moll. For a period of one (1) year after delivery to AASTROM, AASTROM shall have the right to notify MOLL that a Cell Cassette or Component does not conform to this warranty. Such notice shall set forth in detail the reason for such non-conformance. AASTROM shall prepare for shipment and return to MOLL allegedly defective Cell Cassette or Component in accordance with MOLL's written directions and at MOLL's cost. Upon reasonable verification of noncompliance with this warranty, MOLL shall repair a defective and non-conforming Cell Cassette or Component or, at its option, replace a defective Cell Cassette or Component with non-defective, conforming units within thirty (30) days after receipt of notice from AASTROM of the nonconformance. However, if in MOLL's reasonable judgment such repair or replacement cannot be accomplished within said time, MOLL shall issue to AASTROM a credit for the price of each unit of Cell Cassette or Component verified as defective. MOLL shall pay all shipping and other costs incurred in connection with the repair or replacement of all such nonconforming Cell Cassette or Component units. The foregoing warranty shall not apply to the extent that the non-conformance is due to a defective component supplied by AASTROM or compliance with the Specifications as supplied by AASTROM. Notwithstanding any statutory or other law to the contrary, it is understood that the foregoing one (1) year warranty period begins on delivery of the Cell Cassette or Component to AASTROM regardless as to when a defect in a Cell Cassette or Component may be discovered.

(b) DISCLAIMER. THE WARRANTY SET FORTH IN SECTION 12(a), ABOVE, IS GIVEN TO AASTROM ONLY AND IS IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESSED BY AFFIRMATION, PROMISE, DESCRIPTION, MODEL, SAMPLE OR OTHERWISE. ANY AND ALL OTHER WARRANTIES, INCLUDING, WITHOUT LIMITATION, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR USE OR PURPOSE, ARE HEREBY DISCLAIMED. THE REMEDIES SET FORTH IN THIS AGREEMENT SHALL BE AASTROM'S EXCLUSIVE REMEDIES FOR DEFECTIVE AND NONCONFORMING PRODUCTS.

(c) No Third-Person Warranty. AASTROM will not make any warranty, representation or guaranty to any person, either orally or in writing, in the name of or on behalf of MOLL.

(d) Recalls. From time to time throughout the Term, AASTROM may in its discretion determine that it is necessary or advisable to recall Cell Cassettes manufactured by MOLL. In such event, if AASTROM reasonably determines that the number of reported incidence of defective Cell Cassettes is high in relation to AASTROM's historical incidence rate for defective Cell Cassettes and/or general medical product industry standards and AASTROM recalls one or more Shipment Lots due to a failure of such units to meet Specifications during the Warranty Period, AASTROM shall so notify MOLL of the recall and the Parties shall jointly exchange relevant information and consult on causation of the defective units prior to implementing the recall. In the event it is determined by the Parties that the Cell Cassettes were defective due to a failure of such units to meet Specifications during the Warranty Period, MOLL agrees to reimburse AASTROM for the reasonable direct costs incurred by AASTROM in conjunction with the

recall including the cost of replacing, shipping and testing the units of the Shipment Lot(s) recalled, whether or not all such units are ultimately determined to have been defective, by way of a reduction in MOLL's applicable mark-up rates (as set forth on Appendix III) to 15% until the cost of the recall has been recovered by AASTROM. Any disputes regarding causation of defective units involved in a recall that cannot be resolved by the Parties will be resolved through arbitration in accordance with Section 24(b). Furthermore, in the event this Agreement is terminated for any reason prior to AASTROM recovering the full amount of its recall costs from MOLL, MOLL shall promptly pay to AASTROM the amount of any un-reimbursed costs. For the purpose of clarification, it is agreed that AASTROM shall be solely responsible for determining whether any product recall, correction or withdrawal is required and for complying with all of the medical device reporting requirements pursuant to 21 CFR Part 803.

SECTION 13. LIMITATION OF DAMAGES LIABILITY.

(a) Third Party Claims Not Related to Manufacturing Defect. MOLL shall have no liability for any damages claimed by a third party if the claim does not arise from or relate to a manufacturing defect by MOLL.

(b) Third Party Claims Related to MOLL's Delays. MOLL shall have no liability for any damages claimed by a third party arising from or related to MOLL's delays in manufacturing and delivering Cell Cassettes; provided, however, this limitation of liability shall not apply with respect to any third party which has a contractual relationship with MOLL with respect to claims arising out of such contract.

(c) Third Party Claims for Product Liability. With respect to a third party's claim for products liability in connection with the manufacture of the Cell Cassettes or Components, MOLL's liability shall not exceed \$5,000,000 in the aggregate for the Term of this Agreement.

(d) AASTROM's Claims. MOLL's liability for damages to AASTROM for any breaches of MOLL's obligations, warranties or representations under this Agreement shall not exceed: (i) in the event of a breach which does not result in the termination of this Agreement, an amount equal to the price to be paid by AASTROM for the Cell Cassettes which were specified in the most recent forecast (as specified in Section 3(a) hereof) given by AASTROM to MOLL prior to the breach to be purchased by AASTROM during the period of the breach and which were adversely affected by the breach; or (ii) in the event of a breach which does result in the termination of this Agreement, an amount equal to the price to be paid by AASTROM for the Cell Cassettes which were specified in the most recent forecast (as specified in Section 3(a) hereof) given by AASTROM to MOLL prior to the breach to be purchased by AASTROM during the 12-months following the date of termination of this Agreement.

Notwithstanding the foregoing, the foregoing limitation of liability shall not apply with respect to any breach of MOLL's obligations to maintain and protect AASTROM's Equipment, Intellectual Property and Confidential Information, or MOLL's obligations under Section 23 hereof regarding similar products.

(e) Willful Wrongdoing. Notwithstanding anything to the contrary contained in this Agreement, there shall be no limitation on MOLL's liabilities arising from or related to any criminal activity by MOLL or any willful wrongdoing by MOLL.

(f) Nature of Damages. The damages referenced in this Section 13 include damages of any nature whatsoever including without limitation, direct, indirect, special, incidental and consequential damages. No Party shall have any liability for any punitive damages.

(g) Mitigation. The non-breaching Party, as well as the breaching Party, shall use its best diligent efforts to mitigate the damages caused by the breach.

(h) AASTROM's Liabilities. Except with regard to AASTROM's obligations under Sections 14(a) and (d) and 16, it is agreed that AASTROM's liability to MOLL with regard to any claim for damages that may arise from a breach of any of AASTROM's obligations, warranties and representations under this Agreement shall not exceed the purchase price for the Cell Cassettes or Components with respect to which AASTROM is in breach.

Notwithstanding the foregoing, the foregoing limitation of liability shall not apply with respect to any breach of AASTROM's obligations with regard to the Intellectual Property or Confidential Information of MOLL, nor shall such limitations apply in the event of criminal activity or willful wrongdoing by AASTROM.

SECTION 14. INDEMNITY.

(a) AASTROM's General Indemnity. The Parties acknowledge that AASTROM has designed, developed and established the Specifications for the Cell Cassette and Components. To the extent not covered by MOLL's indemnification obligations under Section 14(b) below, and to the extent MOLL's liabilities to third parties exceed the limitation of damage liabilities specified in Section 13(a), (b) and (c) hereof, AASTROM will indemnify, hold harmless and defend MOLL and its parents and affiliates and its and their officers, directors, agents, employees and contractors and their successors and assigns (individually and collectively, the "MOLL Indemnitees") from and against any and all loss, liability, cost, damage and expense, including, without limitation, reasonable attorneys' fees, in connection with bodily injury, death or otherwise, for claims made by third parties, including, without limitation, a governmental agency or other entity, against any of the MOLL Indemnitees arising out of or in connection with (1) the design, manufacture, sale, use, function or operation of the Cell Cassette and Components or (2) the breach by AASTROM of its covenants, representations or warranties under this Agreement, or (3) the non-compliance by MOLL with GMPs, but only to the extent that such non-compliance is caused by the failure of AASTROM to comply with a covenant under this Agreement, or a Specification or written requirement of AASTROM that is in express direct violation of GMPs. Upon receipt of a claim indemnified hereunder, MOLL shall give AASTROM prompt notice thereof and shall, at no out-of-pocket expense to MOLL, cooperate with AASTROM with respect to the defense of such matter. MOLL shall have the right, without affecting its indemnity hereunder, to participate in the administration, defense or settlement of any such matter at its own expense and with counsel of its own choosing, but AASTROM will control the defense and selection of lead defense counsel. AASTROM's counsel shall give due consideration to suggestions of MOLL's counsel and AASTROM shall not settle any claim

indemnified hereunder unless MOLL is given a full and unconditional release in respect of such matter and any related matter.

(b) MOLL's General Indemnity. MOLL will indemnify, hold harmless and defend AASTROM and its parents and affiliates and its and their officers, directors, agents, employees and contractors and their successors and assigns (individually and collectively, the "AASTROM Indemnitees") from and against any and all loss, liability, cost, damage and expense (collectively, "Losses"), including without limitation, reasonable attorneys' fees, in connection with any claims made by third parties, including without limitation, a governmental agency or other entity, against any of the AASTROM Indemnitees for any product liability claim arising out of or in connection with the breach of any of MOLL's warranties or obligations hereunder; provided, that notwithstanding anything in this Agreement to the contrary, MOLL's total liability under this Section 14(b) shall not exceed Five Million (\$5,000,000) dollars, and AASTROM's indemnity set forth in Section 14(a), above, shall not be affected or limited by Losses that are in excess of MOLL's indemnification obligations under this Section 14(b). Upon the receipt of a claim of indemnification hereunder, AASTROM shall give MOLL prompt notice thereof and shall, at no out-of-pocket expense to AASTROM, cooperate with MOLL with respect to the defense of such matter. AASTROM shall have the right, without affecting its indemnity rights hereunder, to participate in the administration, defense or settlement of any such matter at its own expense and with counsel of its own choosing, but MOLL will control the defense and selection of lead defense counsel. MOLL's counsel shall give due consideration to suggestions of AASTROM's counsel and MOLL shall not settle any claim indemnified hereunder unless AASTROM is given a full and unconditional release in respect of such matter.

(c) Intellectual Property Warranty.

(1) AASTROM represents and warrants that neither the design nor Specifications furnished by AASTROM to MOLL in connection with this Agreement nor the manufacture or sale of Cell Cassettes to such design or Specifications or in conformance with the DMR (but excluding any of MOLL's manufacturing process or methods that may be incorporated into any of the foregoing by MOLL), will infringe any United States or foreign patent, trademark, copyright or other intellectual property right of others.

(2) MOLL represents and warrants to AASTROM that no manufacturing process or method employed by MOLL to manufacture the Cell Cassettes will infringe any United States or foreign patent, trademark, copyright or other intellectual property right of others; provided that, such process or method was developed by, or originated from, MOLL but without regard to whether such process or method is incorporated in the Specifications or DMR.

(3) Without prejudice to the rights of MOLL or AASTROM as set forth in Sections 14(d) and 14(e) below, respectively, if the manufacture or sale of Cell Cassettes to such design Specifications or DMR or the manufacturing process or method, respectively, is held to constitute an infringement of any intellectual property right of any third party or to result in such wrong, and such manufacture and sale is enjoined (by temporary, preliminary or permanent injunction), AASTROM or MOLL, as the case may be, at its own expense, shall use its best diligent efforts to procure for the other party the right to continue to manufacture and sell Cell Cassettes, as applicable.

(d) Intellectual Property Indemnity by AASTROM. AASTROM will indemnify, hold harmless and defend the MOLL Indemnitees from and against any and all liabilities, costs and expenses, including, without limitation, reasonable attorneys' fees, with respect to which a claim is made by a third party against any of the MOLL Indemnitees arising out of or in connection with the breach of AASTROM's warranty and representation set forth in Section 14(c), above. Upon receipt of a claim indemnified hereunder, MOLL shall give AASTROM prompt notice thereof and shall, at no out-of-pocket expense to MOLL, cooperate with AASTROM with respect to the defense of such matter. MOLL shall have the right, without affecting its indemnity hereunder, to participate in the administration, defense or settlement of any such matter at its own expense and with counsel of its own choosing, but AASTROM will control the defense and selection of lead defense counsel. AASTROM's counsel shall give due consideration to suggestions of MOLL's counsel. AASTROM shall not settle any claim indemnified hereunder unless MOLL is given a full and unconditional release in respect of such matter and any related matter.

(e) Intellectual Property Indemnity by MOLL. MOLL will indemnify, hold harmless and defend the AASTROM Indemnitees from and against any and all liabilities, costs and expenses, including, without limitation, reasonable attorneys fees, with respect to which claim is made by a third party against any of the AASTROM Indemnities arising out of or in connection with the breach of MOLL's warranty and representation set forth in Section 14(c), above. Upon receipt of a claim indemnified hereunder, AASTROM shall give MOLL prompt notice thereof and shall, at no out-of-pocket expense to AASTROM, cooperate with MOLL with respect to the defense of such matter. AASTROM shall have the right, without affecting its indemnity hereunder, to participate in the administration, defense or settlement of any such matter at its own expense and with counsel of its own choosing, but MOLL will control the defense and selection of lead defense counsel. MOLL's counsel shall give due consideration to suggestions of AASTROM's counsel. MOLL shall not settle any claim indemnified hereunder unless AASTROM is given a full and unconditional release in respect of such matter and any related matter.

SECTION 15. OWNERSHIP OF INTELLECTUAL PROPERTY.

(a) Ownership of Intellectual Property. Each Party shall retain and own (vis a vis the other Party) all right, title and interest to all copyrightable material, inventions, trademarks, trade secrets, trade dress or other intellectual property (collectively, "Intellectual Property") which it now owns. Notwithstanding the foregoing, AASTROM shall own all Intellectual Property and documentation generated by MOLL in connection with the collaborative development and manufacture of Cell Cassettes, whether or not such Intellectual Property was generated prior to or after the Effective Date, except for Intellectual Property that relates to the molding and fabrication processes performed by MOLL and the know-how in connection therewith. Said documentation to be owned by AASTROM shall include but not be limited to the Specifications for the Cell Cassettes and Components, DMR documentation, material lists, supplier lists and descriptions of manufacturing methods and processes for manufacture of the Cell Cassettes (hereinafter, the "AASTROM Documentation"). Furthermore, notwithstanding anything contained herein, MOLL acknowledges and agrees that the AASTROM Documentation will not embody or constitute the Intellectual Property of MOLL. Nothing in this Agreement shall be deemed to grant a license to either Party under or with respect to the Intellectual Property of the other Party.

(b) Return of Intellectual Property. Upon expiration of the Term or upon any earlier termination of this Agreement, MOLL shall promptly transfer to AASTROM all AASTROM Documentation and Intellectual Property within MOLL's possession or control, and AASTROM shall promptly transfer to MOLL all MOLL Intellectual Property within AASTROM's possession or control. Furthermore, in the event of any expiration or termination of this Agreement by AASTROM "for cause" pursuant to Section 17, or by MOLL, other than in accordance with Section 17, MOLL will provide AASTROM with full cooperation with regard to the transfer of any know-how embodied in AASTROM Documentation that is sufficient to allow AASTROM to manufacture the Cell Cassettes pursuant to this Agreement; provided that, except for copying, MOLL shall bear no expense of any nature in connection therewith.

SECTION 16. CONFIDENTIAL INFORMATION.

(a) Title to Confidential Information and Related Documents. Title to Confidential Information provided by the Disclosing Party to the Recipient shall be and remain the sole and exclusive property of the Disclosing Party. Recipient shall return all such Confidential Information, together with all copies thereof, except for one archive copy, promptly upon the termination of this Agreement.

(b) Non-Disclosure and Non-Use of Confidential Information. The Recipient shall hold all Confidential Information disclosed to it pursuant to this Agreement in confidence and will use Confidential Information only for the purpose of performing its obligations under this Agreement and for no other purpose whatsoever. The Recipient will not disclose Confidential Information to any third person and will disclose Confidential Information only to such of its employees as is necessary or reasonably appropriate to the performance of the Recipient's obligations under this Agreement. Recipient shall ensure that its employees and any permitted subcontractors having access to the Confidential Information of the Disclosing Party have previously agreed, either as condition of employment or to obtain the Confidential Information, to be bound by terms and conditions substantially similar to those found in this Section 16(b) as a condition to such access. In the event that the Recipient is requested or required by court or governmental order to disclose any of the Confidential Information, the Recipient shall provide the Disclosing Party with prompt written notice of such request or requirement so that the Disclosing Party may seek a protective order or other appropriate protection. The Recipient will cooperate with Disclosing Party at the Disclosing Party's expense, to obtain an appropriate protective order or other reliable assurance that confidential treatment will be accorded confidential treatment by such court or governmental entity.

(c) Protection of Confidential Information. The Recipient will observe reasonable precautions and procedures to protect and preserve Confidential Information to the same extent that the Recipient uses with respect to its own like confidential information.

SECTION 17. TERM AND TERMINATION.

(a) Term of Agreement. The initial term of this Agreement shall commence on the Effective Date and shall, unless earlier terminated as provided herein, continue for five (5) years (the "Initial Term"). This Agreement shall, unless earlier terminated as provided herein, thereafter renew automatically for additional one (1) year terms. Either party may terminate this

Agreement as of the end of the Initial Term, or as of the end of any subsequent renewal term, by written notice to the other party at least one (1) year prior to the renewal date.

(b) Termination Upon Default. Except for a failure and the corresponding remedy as expressly specified in Sections 3, 12 and 17(d), if either Party shall commit a material default in any of the material terms or obligations under this Agreement, the non-defaulting Party shall have the right to give the defaulting Party notice specifying with particularity the default and the circumstances surrounding the default. If the defaulting Party shall fail to cure, the noticed default within thirty (30) days after receipt of such notice (fifteen business days with respect to non-payment of amounts owed by AASTROM to MOLL under this Agreement), the non-defaulting Party shall have the right to terminate this Agreement prospectively by giving the defaulting Party further notice of at least twenty (20) days prior to the effective date of termination set forth in such further notice.

(c) Termination Upon Insolvency. Either Party shall have the right to terminate this Agreement prospectively by notice of at least ten (10) days to the other Party if the Party receiving such notice has filed a petition in bankruptcy or insolvency (or if such petition is filed against it and is not vacated, stayed or bonded within one hundred and twenty (120) days after such filing), or files a petition or answer seeking reorganization, readjustment or rearrangement of a substantial part of its business under any law relating to bankruptcy or leading to bankruptcy or is adjudicated by a competent regulatory agency to be bankrupt or insolvent, or a receiver is appointed for all or substantially all of the property of such other Party, or an assignment is made for the benefit of the creditors of such other Party, or any proceeding are instituted for the liquidation or winding up of the business of such other Party.

(d) Termination Upon Inability of MOLL to Perform. If, on any three occasions within a twelve-month period during the Term of this Agreement, one or more of the following events occur, then AASTROM shall have the right to notify MOLL that AASTROM intends to terminate this Agreement prospectively, specifying an effective date of termination not less than thirty (30) days after the date of such notice: (i) more than ten (10%) percent of the Shipment Lots or units of Cell Cassettes delivered to AASTROM are properly rejected by AASTROM under Section 3(f), above; (ii) more than 1 of 1,000 Cell Cassettes accepted by AASTROM fail to meet the warranty set forth in Section 12(a); or (iii) MOLL fails to timely deliver a complete order of Cell Cassettes meeting Specifications. For purposes of this Section 17(d), the term "timely deliver" shall mean delivery not more than ten (10) days prior to, nor more than five (5) days after, scheduled delivery dates. Moll will not be held responsible for performance problems as described above, resulting from inadequacies in (i) approved design specifications or (ii) Aastron-specified materials and components that have passed approved incoming inspection, unless such inadequacies were caused by Moll. The foregoing right of termination shall be in addition to AASTROM's right to seek damages available under law subject to the limitations set forth in Section 13.

(e) Effect of Termination. Termination of this Agreement by either Party shall not affect any purchase order submitted by AASTROM to MOLL pursuant to the terms of this Agreement prior to the effective date of termination and the Parties shall fulfill their obligations under such purchase order or to be undertaken under this Agreement prior to such termination even if the completion of such obligations shall be after the effective date of termination. Notwithstanding

the foregoing, upon any termination of this Agreement by AASTROM pursuant to this Section 17, AASTROM may, in its discretion elect to terminate all in-process manufacturing of Cell Cassettes by MOLL and MOLL shall terminate such manufacturing effective immediately upon notice from AASTROM. Furthermore, upon the expiration of the Term as specified in Section 17(a), or upon the termination of this Agreement other than a termination by AASTROM as permitted by Sections 17(b), (c) or (d), then AASTROM shall purchase, at the price set forth in this Agreement, all Cell Cassette finished goods, work in process and unique materials that have been purchased by MOLL prior to the effective date of this Agreement for the manufacture of Cell Cassettes provided that the quantities of such goods and materials are reasonable in light of AASTROM's forecasted Requirements and provided that such goods and materials are not defective (per the Specifications). Without limiting the generality of the foregoing, to the extent necessary to give effect to the intention of the Parties expressed therein, the obligations of the Parties under Sections 10 ("Equipment"), 11(d) ("Records; Inspection"), 12 ("Warranty; Recalls"), 13 ("Limitation of Damages Liability"), 14 ("Indemnity"), 15 ("Ownership of Intellectual Property"), 16 ("Confidential Information"), 17 ("Term and Termination"), 18 ("Supplier; Alternate Supplier"), 19 ("Representations and Warranties"), 23 ("Similar Products"), 24 ("Governing Law; Dispute Resolution"), 25 ("Notices"), 28 ("Severability"), 29 ("Amendment and Waiver") and 32 ("Entire Agreement") shall survive termination of this Agreement in accordance with their terms.

(f) Liabilities When No Termination. Notwithstanding the foregoing, in the event that MOLL is in material breach of any of its warranties or obligations, and such breach does not allow AASTROM to terminate this Agreement pursuant to Section 17, then MOLL shall be subject to the liabilities and remedies available at law and by this Agreement for such breach, subject to the limitations set forth in Section 13.

(g) Alternative Purchase of Product. If MOLL is in breach of MOLL's obligations to make and sell Cell Cassettes or Components as specified in this Agreement, and such breach does not result in a termination of this Agreement, and if AASTROM has available an alternative manufacturing source for said Cell Cassettes or Components, then AASTROM may cancel all or any part of any pending purchase orders (which purchase orders are within the quantities specified in the 12-month rolling forecast as specified in Section 3(a) hereof) for which MOLL is unable or unwilling to accept and perform; and AASTROM may have said purchase orders performed by the alternative manufacturing source; and any damages suffered by AASTROM as a result of MOLL's breach shall still be recoverable against MOLL (subject to the limitations specified in Section 13 hereof).

SECTION 18. SUPPLIER; ALTERNATE SUPPLIERS.

(a) Supplier. Subject to MOLL fully complying with all the terms and conditions of this Agreement, during the Initial Term, AASTROM will purchase its Requirements of Cell Cassettes from MOLL; provided, however, nothing in this Agreement shall be deemed to preclude AASTROM from manufacturing any of AASTROM's requirements for Cell Cassettes by itself or from utilizing alternate suppliers for such manufacture pursuant to Section 18(b) below.

(b) Alternate Suppliers. AASTROM shall have the right to utilize alternate suppliers to supply AASTROM's requirement of Cell Cassettes or components if (i) MOLL is unable or unwilling to meet AASTROM's requirements for quantity, quality or timing of Cell Cassettes, (ii) MOLL does not remain cost competitive pursuant to Section 4(d), (iii) MOLL breaches any of its obligations under this Agreement (without cure thereof), or (iv) with respect to the supply of Cell Cassettes in a country other than the U.S., on a country-by-country basis, if AASTROM grants rights to a strategic partner to manufacture such Cell Cassettes for sale in such country. In the event that AASTROM elects to utilize an alternative supplier for the Cell Cassettes during the Term due to such an event, MOLL shall provide reasonable cooperation by promptly supplying AASTROM with copies of all AASTROM Documentation at the reasonable expense of AASTROM; provided, however nothing in this Section 18(b) shall be deemed to require MOLL to provide training or consultation services to the alternate supplier with regard to the manufacture of the Cell Cassettes. Furthermore, even if Moll is unable to produce entire Cell Cassettes, Moll shall be obligated to supply components to AASTROM's Alternate Supplier.

SECTION 19. Representations and Warranties.

MOLL and AASTROM each represents and warrants (1) that each has, respectively, the full right and authority to enter into this Agreement, and nothing provided in this Agreement will conflict in any way with any outstanding obligation, contractual or otherwise, of such Party, and (2) that each shall comply with all United States governmental laws, rules, regulations and orders applicable to its obligations under this Agreement.

SECTION 20. FORCE MAJEURE.

(a) Suspension of Performance. In the event that MOLL or AASTROM (other than with respect to its obligations to pay money to MOLL) is rendered unable, wholly or in part, to carry out its obligations under this Agreement by reasons of acts of God, industrial disturbances, outbreak of a state of emergency, war, hostilities, civil commotion, riots, epidemics, fires, earthquakes, floods or any other cause or causes similar or dissimilar to the foregoing beyond the reasonable control of the Party claiming benefit of force Majeure, upon such Party's giving notice and reasonably full particulars of such reason to the other Party within a reasonable time after the occurrence of the cause relied upon, then the obligations of the Party giving such notice, so far as they are affected by such reason, shall be suspended during the continuation of any inability so caused, but no longer, and such cause shall so far as reasonably possible be remedied with all reasonable dispatch without the necessity of expending sums (including, without limitation, for overtime labor) not otherwise required under this Agreement. When the event operating to suspend performance by either Party shall cease, this Agreement shall continue in full force and effect until the expiration or earlier termination as provided in this Agreement.

(b) Cooperation. In the event of a force Majeure, AASTROM and MOLL shall communicate and cooperate in seeking to avoid or minimize potential interruption of supply and to develop mutually acceptable contingency plans in the spirit of this Agreement. In any event, the time for a Party's performance under this Agreement shall be extended to the extent reasonably necessary to perform the suspended obligation.

(c) Allocation of Resources. In the event of a force Majeure resulting in a partial inability of MOLL to supply product to its customers, MOLL may allocate resources that have not specifically been earmarked to this Agreement, to all of its customers (including AASTROM) in an equitable manner as determined solely by MOLL.

SECTION 21. MOLL COMPETITIVENESS; SHARED INVESTMENT RETURN.

(a) MOLL's Competitiveness. The Parties acknowledge that a primary consideration for AASTROM with regard to the selection of MOLL as its supplier was MOLL's expertise and stated intention to be a cost-effective and a capable manufacturer and supplier of Cell Cassettes and Components and that AASTROM's commercialization strategy is dependent in part upon MOLL's stated intention to use best diligent efforts to remain cost effective and capable. Thus, MOLL will use best diligent efforts to search for methods and means that will lead to in-plant cost reductions, savings and maintenance and quality improvement. AASTROM will cooperate with MOLL in these efforts.

(b) Shared Investment Return.

(1) MOLL Capital Investments. If, during the Term, MOLL shall invest in an AASTROM-approved capital project that results in a cost savings in the production of Cell Cassettes, MOLL shall be entitled to retain such cost savings until MOLL has recouped the entire cost of the capital project from Cell Cassettes purchased by AASTROM. Once MOLL recoups such capital expenditure, the cost savings resulting from implementation of the capital expenditure shall be shared by the Parties on a 50%: 50% basis and MOLL shall be deemed to have assigned to AASTROM sole ownership of the capital property purchased by MOLL such that the capital property shall be AASTROM's Equipment. Throughout the Term, MOLL shall use any such capital property purchased by MOLL solely for the manufacture of Cell Cassettes for AASTROM. The method for recoupment of MOLL's capital investments and implementation of cost sharing shall be as set forth in Section 21(b)(2) below.

(2) Recoupment of MOLL Capital Investment; Cost Sharing. Effective on the first day of the quarter immediately following the quarter in which a capital project paid for by MOLL is implemented and cost savings first occur, the Base Cost Assumption (calculated in accordance with Appendix III) shall be recalculated (RBCA) to reflect the cost savings resulting from implementation of the capital project. MOLL shall track the difference between the original Base Cost Assumption (OBCA) and RBCA on future orders of Cell Cassettes and the entire cost savings shall be allocated to MOLL until MOLL has recouped the amount MOLL expended on the capital project. Thereafter, the cost savings resulting from implementation of the capital expenditure shall be allocated to AASTROM and MOLL on a 50%: 50% basis with regard to all Cell Cassette orders submitted by AASTROM.

(3) AASTROM Capital Investments. AASTROM shall enjoy all savings that result from capital projects that are paid for by AASTROM or result from any changes in Specifications made by AASTROM. In the event that any such cost savings are implemented, the Base Cost Assumption utilized to calculate AASTROM's purchase price for Cell Cassettes shall be immediately reduced to reflect the amount of the cost savings. AASTROM shall also retain all

ownership rights with regard to any capital property purchased by AASTROM that may be used by MOLL in the manufacture of Cell Cassettes for AASTROM.

SECTION 22. INSURANCE.

During the Term, each Party shall procure and maintain at its own cost and expense, including the cost of premiums and deductibles, a general liability insurance policy, including product liability (completed operations) insurance, in an amount not less than one million (\$1,000,000) dollars per occurrence, two million (\$2,000,000) dollars aggregate bodily injury, death and property damage liability and commercial umbrella coverage of at least three million (\$3,000,000) dollars each occurrence and annual aggregate. Such insurance shall be written by a reputable insurance company licensed to do business in the United States, shall name the other Party as an additional insured, shall contain a broad form vendor's endorsement. During Term, MOLL shall also carry and maintain in full force and effect all-risk property insurance covering the full replacement value of AASTROM's Equipment and MOLL's building, machinery, equipment and work-in-process, as well as worker's compensation insurance in the statutory limits required by the State of North Carolina (or other applicable jurisdiction). Within ten (10) days after the Effective Date, each Party shall furnish the other Party with a certificate of insurance confirming the existence of such insurance and stipulating that the insurer will give the other Party at least ten (10) days' written notice prior to any cancellation of or material change in such insurance. The availability of the foregoing insurance coverage shall in no event be construed to limit or expand the Parties' agreement to limit liability to one another in accordance with Section 13.

SECTION 23. SIMILAR PRODUCTS.

(a) Continuing Prohibition. At all times both during and after the Term, MOLL shall not make or sell, or enable others to make or sell, the Cell Cassettes or Components, excepting only for making and selling the Cell Cassettes or Components for AASTROM.

(b) Similar Products. During the Term, MOLL shall not (i) manufacture, assemble, produce, ship or in any other way make available for use or distribution, by any party other than AASTROM, any product or system that is functionally the same as the Cell Cassette or Components, or (ii) in any way accept engagement with, or render service to, any individual, firm or corporation, other than AASTROM, as a consultant, instructor, expert, designer, manufacturer or producer, or act in any other capacity, which engagement or rendition of services involves the development or production of any product or system that performs the same function as the Cell Cassette. Furthermore, in the event that this Agreement is terminated by AASTROM "for cause" under Section 17, the foregoing prohibitions shall continue until twelve (12) months after the effective date of such termination. As used herein, a hematopoietic stem cell expansion product or system does not have the same function as a Cell Cassette if it utilizes distinctly different methods and distinctly different disposable components than are used for the Cell Cassette.

SECTION 24. GOVERNING LAW; DISPUTE RESOLUTION.

(a) Governing Law. The construction, interpretation and enforcement of the terms, conditions, rights and liabilities set forth in this Agreement shall be in accordance with the internal laws of the State of New York, excluding its conflict-of-laws principles.

(b) Dispute Resolution.

(1) Any controversy or claim arising out of or relating to this Agreement or the breach thereof, whether common law or statutory, including, without limitation, claims asserting violations of the antitrust laws, will be settled exclusively by arbitration in Dallas, Texas if initiated by AASTROM and in Ann Arbor, Michigan, if initiated by MOLL (unless another location is mutually agreed in writing), using the then-current Commercial Rules of the American Arbitration Association. The arbitration will be heard before three neutral arbitrators, one to be chosen by AASTROM, one to be chosen by MOLL, and the third to be chosen by those two arbitrators.

(2) The arbitrators will apply the internal law of the State of New York as set forth in Section 24(a), except that the arbitrators will not have the power to alter, modify, amend, add to or subtract from any term or provision of this Agreement. To the extent consistent with the terms of this Agreement, the arbitrators shall have the power to grant injunctive relief. In all other respects, the then-current Commercial Rules of the American Arbitration Association will govern the arbitration. Judgment on the award of the arbitrators may be entered by any court having jurisdiction to do so, and the parties to this Agreement hereby irrevocably consent and submit to the personal jurisdiction and venue of the applicable federal courts having jurisdiction in the district and state in which the arbitration is to occur, if at all, in accordance with this Section 24(b) (or in the state court in the county and state in which the arbitration is to occur, if at all, failing jurisdiction of the federal court) in any action or proceeding for that purpose as well as for any and all other permitted purposes, including, without limitation, in respect of a Party seeking injunctive relief, in connection with this Agreement. The Parties hereby irrevocably waive any and all claims and defenses either might otherwise have in any such action or proceeding in any of such courts based upon any alleged lack of personal jurisdiction, improper venue, forum non conveniens or any similar claim or defense.

(3) The failure or refusal of either Party to submit to arbitration as required by Section 24(b) will constitute a material breach of this Agreement. If judicial action is commenced in order to compel arbitration, and if arbitration is in fact compelled, the Party that resisted arbitration will be required to pay to the other parties all costs and expenses, including, without limitation, reasonable attorneys' fees, that they incur in compelling arbitration. The prevailing Party in arbitration shall be entitled to its reasonable attorneys' fees and costs of the arbitration proceeding without regard to the limitations set forth in Section 13. All other fees and charges of the American Arbitration Association will be borne, as the arbitrators will determine in their award.

(c) Notwithstanding the Parties' agreement to submit to arbitration pursuant to this Section 24, either Party may petition any court of competent jurisdiction for injunctive relief in the event of an alleged breach of Section 15(b) or 16.

SECTION 25. NOTICES.

All notices required to be made hereunder shall be sent to the respective Parties set forth below by certified mail, return receipt requested or by facsimile (with confirmation copy by such certified mail):

If to MOLL: Moll Industries
13455 Noel Rd., Suite 1420
Dallas, TX 75240
Attn.: Ron Embree
Facsimile: 973-763-4001

With a copy to: Andrews & Kurth L.L.P.
111 Congress Ave., Suite 1700
Austin, TX 78701
Attn.: Matthew Lyons
Facsimile: 512-542-5226

And

If to AASTROM: AASTROM Biosciences, Inc.
P.O. Box 376
Ann Arbor, Michigan 48106
Attn: Brian Hampson, Vice President
Facsimile: 313-665-0485

With a copy to: Gray Cary Ware & Freidenrich LLP
4365 Executive Drive, Suite 1100
San Diego, CA 92121-2189
Attn.: T. Knox Bell, Esq.
Facsimile: 619-677-1401

AASTROM and MOLL may change their respective addresses and facsimile numbers for notices by a notice given by mail in accordance with this Section 25. Unless otherwise shown by documentary evidence, all notices shall be deemed received upon the earlier of actual receipt or three days after deposit in the U.S. mail, postage prepaid, or if by facsimile, on the business day next following the day sent.

SECTION 26. SUCCESSORS AND ASSIGNS; SURVIVAL.

This Agreement is not intended to benefit any person not a Party hereto or to give any rights to any such non-party. This Agreement shall inure solely to the benefit of and be binding upon the Parties hereto and their successors and permitted assigns. This Agreement shall bind and inure to the benefit of any successor to a Party by merger or purchase of substantially all of the assets of the Party. Except to such a successor, neither AASTROM nor MOLL may assign this Agreement in whole or in part without the prior written consent of the other, which consent

shall not be unreasonably withheld. Any assignment or purported assignment by either party without any such required consent shall be null and void. The representations, warranties and covenants set forth in this Agreement shall survive its expiration or earlier termination as expressly provided or as is necessary to give full effect to the undertakings of the Parties prior to such expiration or termination.

SECTION 27. HEADINGS.

Headings inserted in this Agreement are for the convenience of the parties and shall not govern any conclusion or interpretation of this Agreement or any of its provisions. Nouns and verbs in the singular person or tense shall include the plural person and tense and vice versa.

SECTION 28. SEVERABILITY.

In case any provision or part thereof in this Agreement shall, for any reason, be held invalid, illegal or unenforceable, such invalidity, illegality or unenforceability shall not affect any other provision or part thereof, and this Agreement shall be construed as if such invalid or illegal or unenforceable provision or part thereof had been reformed so that it would be valid, legal and enforceable to the maximum extent permitted. Except as otherwise expressly set forth in this Agreement, neither Party shall have the right to set off all or any part of the damages it incurs as a result of the other Party's breach of its obligations in this Agreement against amounts that are owed to such other Party hereunder.

SECTION 29. AMENDMENT AND WAIVER.

This Agreement may be amended or modified only by a written instrument executed by each Party hereto expressly stating that it is an amendment to the terms of this Agreement. Without limiting the generality of the foregoing, all sales and purchases of Cell Cassettes contemplated by this Agreement shall be made solely pursuant to the terms of this Agreement without consideration of any different or additional terms of any purchase order or sales acknowledgement or other form of either Party and any such additional or different terms are hereby objected to. The failure of a Party at any time or times to require performance of any provision hereof shall in no manner affect the Party's right at a later time to enforce the same. No waiver by any Party of the breach of any term contained in this Agreement, in any one or more instances, shall be deemed to be construed as a further or continuing waiver of any such breach or of the breach of any other term of this Agreement, nor shall any such waiver be deemed to be a custom or practice of the waiving Party. No waiver shall be effective unless in writing, signed by the Party waiving compliance.

SECTION 30. COUNTERPARTS.

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

SECTION 31. INDEPENDENT CONTRACTORS.

The relationship between the Parties is that of independent contractors and neither Party shall have the power to bind or obligate the other in any manner, other than as expressly set forth in this Agreement.

SECTION 32. ENTIRE AGREEMENT.

This Agreement, including, without limitation, its recitals and Appendices, sets forth the entire agreement and understanding of the parties in respect of the subject matter hereof, including, without limitation, the purchase and sale of Cell Cassettes, and supersedes all prior agreements, arrangements, presentations and understandings relative to the subject matter hereof, whether written or oral, express or implied. No oral or written statement, representation, warranty or promise made prior to or contemporaneously with the execution of this Agreement shall be binding upon either party with respect to the subject matter hereof or shall otherwise affect the enforceability of this Agreement in accordance with its terms.

IN WITNESS WHEREOF, the undersigned have executed and delivered this Agreement effective on the Effective Date.

MOLL INDUSTRIES, INC.

By: _____
Ron Embree
President

AASTROM BIOSCIENCES, INC.

By: _____
Alan M. Wright
Senior V.P. Administrative. & Financial
Operations, CFO

APPENDIX I

EQUIPMENT

[TO BE REVIEWED AND UPDATED AS NECESSARY]

I. Cell Cassette-related Manufacturing Equipment to be provided and owned by AASTROM

1. Bioreactor Assembly Fixtures
2. Tissue Culture Treatment Process and Equipment Requiring: 208 Volt 3 Flux 60HZ @ 60 AMPS Clean Earth Ground 2" Exhaust Vent

Nitrogen Carbon Dioxide
Nitrous Oxide Helium
3. Ultrasonic Welder - Dukane 700 Watt Ultracom Assembly System or Equivalent
4. Portable Clean Air Tent (if required)
5. Leak Tester - Industrial Data Systems Sprint LC-P Pressure Decay Leak Tester Equivalent
6. Sealing equipment for Harvest Bag, Waste Reservoir, and finished device packaging (if required)
7. UV curable adhesive application and curing equipment
8. Injection Molds
9. Robotic End Arm Tools
10. EMMA Welder and heat sealing station

II. Manufacturing Equipment To Be Provided and owned by MOLL:

1. Hand Assembly, Pneumatic Tools, and Dimensional Measurement Equipment as required by project
2. AutoCAD and Pro Engineer workstation(s), either on site or readily accessible, to meet program objectives
3. Molding Equipment as Required by Program

(600 ton, 300 ton, and 75 ton molding machines in class 100,000 medical molding facility;

700 ton molding machines in an environment suitable for producing parts to be moved into a clean room)

4. Robotic pickers for molding machine.
5. Class 100,000 Assembly space as required by the Program

APPENDIX II

SPECIFICATIONS

27-369	CELL CASSETTE, PACKAGED
27-328	CONTROLLED ENVIRONMENT SPECIFICATION
15-034	SURFACE TREATMENT, CELL BED
29-036	CELL CULTURE DEVICE ASSEMBLY FOR AUTOMATED SYSTEM
15-036	CONTROLLED ENVIRONMENT INJECTION MOLDING OF COMPONENTS

APPENDIX III

PRICING SCHEDULE

UNIT PRICING SHALL FOLLOW THE BCA METHOD, WHICH SHALL BE UPDATED QUARTERLY AND INCLUDES THE FOLLOWING:

Labor: 30% mark-up on wages/salaries and benefits

Molded Components: 30% mark-up on Moll Standard cost

Purchased Materials and Components: 15% mark-up on actual delivered cost

Freight: 0% mark-up -- passed through at cost

Sterilization: 0% mark-up without certification by Moll; 15% mark-up with certification by Moll

A forecast of monthly volume in excess of 150 cassettes per month for six consecutive months will trigger a joint meeting between Aastrom and Moll to review capacity requirements and cost reduction opportunities. At that time, it may be mutually decided between Aastrom and Moll to adopt a different pricing method than the BCA method for volumes higher than 150 cassettes per month.

APPENDIX IV

Suppliers of components, assemblies, or services to Moll for manufacture of Cell Cassettes where periodic on-site audit is required.

- 1) Ethox Corporation
- 2) Steris Corporation

SUBSIDIARIES OF REGISTRANT

Zellera, AG

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-115505, 333-81340, 333-51556, 333-38886 and 333-25021) and Form S-3 (Nos. 333-109720, 333-108963, 333-101560, 333-108989, 333-108964, 333-107579 333-92675 and 333-81399) of Aastrom Biosciences, Inc. (a development stage company) of our report dated August 6, 2004, relating to the financial statements and financial statement schedule, which appears in this Form 10-K.

PricewaterhouseCoopers LLP
Minneapolis, Minnesota
September 10, 2004

CERTIFICATION

I, R. Douglas Armstrong, 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)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: September 9, 2004

/s/ R. DOUGLAS ARMSTRONG, PH.D.

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

CERTIFICATION

I, Alan M. Wright, 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)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: September 9, 2004

/s/ ALAN M. WRIGHT

Alan M. Wright
Senior 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, 2004, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, R. Douglas Armstrong, Chief Executive Officer and Chairman of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 ("Section 906"), that:

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

Date: September 9, 2004

/s/ R. DOUGLAS ARMSTRONG, PH.D.

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

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, 2004, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Alan M. Wright, Senior Vice President Administrative and Financial Operations and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 ("Section 906"), that:

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

Date: September 9, 2004

/s/ ALAN M. WRIGHT

Alan M. Wright
Senior Vice President Administrative and Financial
Operations and Chief Financial Officer