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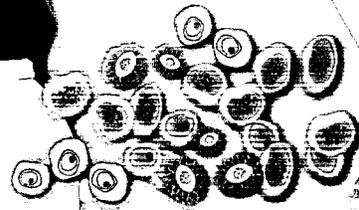
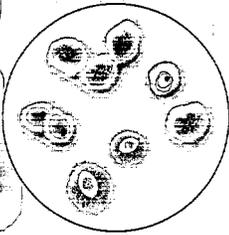
Annual Report 2003

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Aastrom
BIOSCIENCES INC



The Cell Therapy Company

MISSION

Aastrom Biosciences, Inc. (NasdaqSC: ASTM) is developing proprietary bone marrow stem cell products for the regenerative repair of human tissues, and dendritic cell products for the treatment of cancer and infectious disease.

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President
The Dominion Group

Gunnar Kvalheim, M.D.
Head Clinical Stem Cell Laboratory
Norwegian Radium Hospital

October 1, 2003

To Our Shareholders,

I am pleased to report that in a year that has been both challenging and exciting for the tissue engineering and cell therapy sector, Aastrom is emerging stronger than ever. I believe our success in reaching this position is the most important message I can give to you, our shareholders.

The concept of using human cells as therapeutic agents to treat or repair medical problems continues to generate enthusiasm within the healthcare and investment communities. Capturing the therapeutic potential of this technology and converting it into effective products is the key to success in this industry. Aastrom's accomplishments in these two critical areas have been the impetus of our growing momentum. Today, we have a proprietary bone marrow stem cell product that has been proven safe and functional in patients, and we have the capability to produce these cells for standard medical use.

A goal of our operational plan for the past year was to move the most promising of our programs from the technology stage to an active and defined clinical path for major medical market products. What is the evidence of our progress? During the past year Aastrom received independent third-party validation of our plans and programs in these areas that serves to illustrate our progress to date, as well as suggest some of the directions that may hold significant potential for our future.

I'd like to take this opportunity to review with you some of these important events.

- ⊙ We established new strategic relationships with other companies including our manufacturing relationship with Astro Instrumentation, L.L.C., our bone graft trial collaboration with Mathys Medical, and our most important new alliance with the Musculoskeletal Transplant Foundation (MTF), the market leader in orthopedic allograft matrices.
- ⊙ We formed clinical collaborations such as our European bone graft clinical study with Bergmannsheil University, and our dendritic cell clinical trial with Dr. Ronald Levy and Stanford University here in the United States.
- ⊙ We announced the publication of gratifying clinical results in a compassionate-use case that demonstrated the ability of our Tissue Repair Cells (TRCs) to generate healthy skeletal bone in an infant who had an otherwise fatal genetic bone disease, hypophosphatasia.
- ⊙ We received funding for our development programs through the award of four consecutive grants in two quarters from the National Institutes of Health (NIH) and a fifth grant from the Defense Advanced Research Projects Agency (DARPA).

Strategic Focus

In recent years, Aastrom has been active in two therapeutic areas that are attracting a great deal of attention from the general public and the medical community: stem cells for tissue regeneration and dendritic cell vaccines for cancer. These programs have been the foundation of our Prescription Cell Products business plan, which develops proprietary cell products for patient treatment.

During the past year, we made significant progress with both programs, and have evaluated how to effectively continue the development process, as we determine our main strategic focus. Through this evaluation process, we have concluded that the dendritic cell vaccine field represents enormous potential, but is progressing more slowly than other product areas, and that the time required to demonstrate a clinically active cancer vaccine can be lengthy. Accordingly, we have decided to modify our strategy in a manner that will allow us to be active in the field, but not develop our own vaccines at this time. The new strategy is to pursue a business plan that will embed our cells and manufacturing technology in as many different vaccine approaches as possible, including both company and academic programs.

This plan takes the ability to drive the vaccine development process out of our hands for now, and places it into those of third parties, but it has several distinct benefits. First, we intend to establish customer and other collaborative relationships that will be revenue generating. We began this approach during the past year with some success, as evidenced by our recent reports of revenues from sales. Second, for those approaches that become successful clinically, our technology will be an integral component of each new cell therapy. This new area is called our Cell Production Products business, which generates revenues through sales of single-use kits for the production of cells using the AastromReplicell™ System instrumentation. We are also exploring additional relationships based on other cell types. This is a new business in a new field; therefore, you should look for moderate revenue growth from the Cell Production Products business, until the dendritic cell vaccine field expands.

The Promise of Tissue Repair Cells

A result of this modified strategic plan is the ability to better focus our resources on our Prescription Cell Products business, specifically on our stem cell technology for tissue regeneration. The revenue potential in this sector is considerable, and includes large multi-million dollar markets such as bone grafting, vascular and cardiac tissue regeneration, joint reconstruction and severe osteoporosis. We believe our Prescription Cell Products business, lead by our Tissue Repair Cells (TRCs), has the potential to serve these markets.

For over a decade, Aastrom has been committed to stem cell-based therapies. We continue to discover new and exciting opportunities for our TRCs, which are intended for medical problems that require the generation of normal human tissue. A potentially significant market opportunity for our TRCs has emerged for the generation of bone, with the lead indication being their use in bone grafting procedures. This year we accomplished a number of objectives that have moved us into an active clinical, product-oriented program that targets this promising market.

Our research scientists have made enormous strides, demonstrating the capability of TRCs to effectively develop into bone, and to do so in a more potent fashion than normal bone marrow. As a result, we submitted our first clinical trial plan to the FDA, to use TRCs to repair a very severe form of leg fracture called "tibial non-union". The Investigational New Drug (IND) application was approved by the FDA on September 2nd of this year, and we are currently preparing to begin this multi-center Phase I/II bone grafting clinical trial.

The data supplied by our scientists, combined with the publication in a major medical journal of clinical results supporting the use of TRCs to safely generate bone growth, also led to the completion of a collaboration agreement with Mathys Medical and Bergmannsheil University to begin a similar bone graft trial in Germany. This European trial should also begin in this fiscal year.

The bone graft market is large and diverse. We believe that our TRCs may offer a very attractive alternative to traditional "autograft" bone grafting techniques that involve the use of the patient's own bone chips and cells to build new bone tissue. Autograft requires chiseling material from the hip, a painful surgical procedure with negative side effects and a high cost of recovery. Our TRCs should provide a much larger number of bone-forming cells than can be harvested through the autograft procedure. This may facilitate a more effective treatment while eliminating the invasive collection process and undesirable after-effects.

The most significant business advancement for our bone program is the completion of our major strategic alliance with MTF (Musculoskeletal Transplant Foundation), the leading provider of allograft matrices to the orthopedic market. This joint development alliance combines Aastrom's TRCs with the preferred matrix for bone graft applications in the U.S., provides funding support for the preclinical and clinical development pathway, and supplies access to MTF's extensive orthopedic network and marketing expertise. We view this strategic relationship as an important validation of our bone program, and a highly promising development that should improve our ability to bring our bone graft products to the orthopedic markets.

The use of bone marrow stem cell therapies, and by extension our TRC program, received an unexpected, but very exciting boost this year. Data from a clinical research center was published suggesting that large volumes of bone marrow stem cells, when injected into the surrounding tissue area, could regenerate vascular tissue in diabetic patients. This discovery, if proven reproducible, will dramatically impact the treatment of many thousands of diabetic patients suffering from very poor circulation, a condition that causes limb ischemia. Currently, this condition is not effectively treatable, and often leads to immobility, serious foot ulcers, and in some cases limb amputation in these patients.

The relevance of this new development to Aastrom is that we have established in clinical trials that our TRCs can produce a similar level of tissue regeneration as that produced using a large volume (about 1 liter) of bone marrow. With this potential new use of large volume bone marrow gaining increasing attention as a potential therapeutic approach, Aastrom is formulating research and clinical programs to evaluate the effectiveness of our TRCs in generating vascular tissue. We expect to tell you more about our progress in this area in the coming year.

The Coming Year

Aastrom's employees and management have greeted the new fiscal year with enormous excitement, and it's easy to see why. We are moving our technology back into the clinic to help patients with serious medical problems. We are entering into important strategic relationships. We are developing products for multi-million dollar markets that are of great therapeutic significance. We have established two lines of business that provide for immediate revenues and a pathway to even greater revenues in the future. Most importantly, we are generating momentum, a positive identity and enthusiastic interest from the medical and financial fields.

We recognize the many hurdles ahead of us, but I believe we are in an excellent position to continue our progress. The coming year should bring the clinical results that will more clearly define our path and timeline for delivering our new products to the medical market. We invite you to continue with us as we move into the next phase of bringing our cell therapies to patients, and we thank you for your patience, loyalty and support.



R. Douglas Armstrong, Ph.D.
Chairman, Board of Directors
Chief Executive Officer and President

This letter contains forward-looking statements, including, without limitation, our expectations relating to the implementation of our strategic plan, product development activities, anticipated levels and growth of sales, the timing and results of clinical trials and market sizes, all of which involve risks and uncertainties. Our actual results may differ significantly from the expectations discussed in the forward-looking statements. Among the factors that may result in differences are the results of clinical trial and product development activities, competitive developments and the availability of resources. These and other factors are discussed in greater detail in our report on Form 10-K, which is included later in this report.

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, 2003

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 90 days. Yes No

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

Indicate by check mark whether the registrant is 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, 2002 was approximately \$24 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, 2003, 71,244,315 shares of Common Stock, no par value, were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

<u>Document</u>	<u>Form 10-K Reference</u>
Proxy Statement for the Annual Meeting of Shareholders scheduled for November 12, 2003	Items 10, 11, 12, 13 and 15 of Part III

AASTROM BIOSCIENCES, INC.
ANNUAL REPORT ON FORM 10-K
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Except for the historical information presented, the matters discussed in this Report, including our product development and commercialization goals and expectations, 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 that has strategically moved from a business model that was originally based on the Bone Marrow Transplantation market to a company focused on other human cell-based therapies. We have identified multiple paths to revenue based on our proprietary *ex vivo* (outside the body) cell production technology, including the near-term Cell Production Products operations, and an active Prescription Cell Product pipeline for stem cell tissue repair and regeneration, and cancer and infectious disease treatments.

Our core technology is based on our proprietary AastromReplicell™ System, an integrated system of instrumentation and single-use consumable kits that implements our patented single-pass perfusion process in a fully automated closed-loop culturing system to optimize cell growth and viability. This system provides nutrients to cells by mimicking the natural cell-growth environment, and enabling cells to grow effectively while retaining high biological function, without various cloning approaches. Our programs currently use bone marrow, cord blood and blood cells as starting sources of cells. As such, federal support or other factors relating to embryonal stem cell research have no direct impact on our current product programs. In addition, this system provides Good Manufacturing Practices, GMP-compliant manufacturing and automated process control for the commercial-scale production of human cells. We do not believe that any other comparable system currently exists.

Our Cell Production Products operation has created a path to near-term revenue. 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 are being sold to academic researchers and companies that are developing cancer vaccines. The recent commercialization of our automated cell production instruments and cell-specific production kits is expected to generate revenues although we are not yet able to project the market size and growth for these products.

In addition, we are leveraging our *ex vivo* cell production technology for a growing Prescription Cell Product pipeline focused on two areas: Tissue Repair Cells (TRCs) for stem cell-derived tissue repair and regeneration, and Therapeutic Cells (TCs) for immune system-directed attacks on certain cancers and other infectious diseases.

Using the AastromReplicell™ System with its patented single-pass perfusion, TRCs are grown from a small sample of a patient's bone marrow and, once administered back to the patient, are intended to generate normal tissue. The primary TRC product being evaluated is our OCG-I cells for bone grafting (fusions, fractures or dental defects). We are currently preparing for OCG-I clinical trials in both the United States and Europe. We also have in development OC-I cells for osteoporosis, and SC-I cells for autologous bone marrow transplants in lymphoma patients. The SC-I product has been CE-Marked in Europe and is currently being evaluated by a limited number of centers in Europe. In the United States, the SC-I therapy reached Phase III trials, although we halted these trials due to a shift in medical practice that reduced patient need and availability. We also believe that the stem cell components of our TRCs may be useful for other medical indications, including the regeneration of cardiac and vascular tissues. Our CB-I clinical trials have been

closed out. We have no plans to continue this product development of our CB-I kits at this time, unless entirely funded by grants, due to the limited size of the potential market.

We are developing TC products using human cells to cause the patient's immune system to attack certain cancers and other infectious diseases. Blood-derived dendritic cells, which are the body's crucial mobilizers of the immune T-cells response, are cultured in the AastromReplicell™ System to produce our proprietary Dendricell™. After being exposed to a particular biological signal, or antigen, the Dendricell™ may act to trigger a cell-mediated immune response in a patient against the cancer cells or viral pathogens. The first Dendricell™ clinical trials are planned at Stanford University for a multiple myeloma cancer vaccine and at Duke University for a colorectal cancer vaccine. In addition, we are in the pre-clinical stage for a T-cell therapeutic targeting the Epstein-Barr Virus.

In addition to our consumable DC-I, DCV-I and DCV-II cell product kits, we have begun marketing our automated cell production instruments in Europe and the United States for research use. Through Zellera AG, our wholly owned subsidiary located in Berlin, Germany, we are actively coordinating country-specific sub-distributorships and service networks in Europe.

We are led by a seasoned management team, which is advised by a Technology Review Board comprised of well-respected senior medical, financial and marketing executives with extensive knowledge of our technology and industry. Management is leading a transition from our genesis as a medical device manufacturer to a contributor and developer in the broader and more potentially lucrative therapeutic sector.

Cell Therapy

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, and more recently has expanded to include specialized procedures including hematopoietic stem cell transplants obtained from the marrow or from the blood stream after stem cell mobilization. Recent pre-clinical and clinical observations appear to extend the potential use of bone marrow-derived stem cells to regenerate multiple tissues including heart, lung, liver, bone, cartilage, nerve and blood vessels.

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. Most recently, researchers are developing emerging cell therapies utilizing bone marrow-derived stem cells that may restore various tissues of the body including bone, cartilage, spinal cord, heart muscle, liver, blood vessels and beta-cells of the pancreas. While these forms of cell therapy are emerging as potential new treatment options for several diseases, 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. The AastromReplicell™ System is being developed to fill this need.

Tissue Repair Cells

Bone marrow stem and stromal cells (sometimes also referred to as mesenchymal stromal cells) contribute to the repair of various solid tissues including bone marrow, connective tissues such as bone and cartilage, and other tissues including the heart. These cells are present in Aastrom's TRCs. Diseases that could be treated with bone marrow-derived stem cells include bone fractures, osteoporosis, congestive heart failure, myocardial infarct, liver damage, diabetes, peripheral vascular insufficiency and spinal cord damage. Thus, cell based therapy could provide therapeutic intervention for millions of patients annually.

Currently, there are unmet medical needs in the areas of bone grafting, osteoarthritis and osteoporosis that could be addressed by a cell therapy approach. In bone grafting, there is an unmet need for an effective bone substitute that does not require the invasive and highly morbid autograft procedure for harvesting the patient's own bone. Aastrom's TRCs could meet this need by providing a large number of bone forming cells

to produce a response that is similar to autograft but without the invasive and morbid collection procedure. In osteoarthritis, the Aastrom cell therapy approach has the potential to be a means of repairing cartilage and delaying the need for joint replacement. In the osteoporosis market, there is a need for more regenerative/disease modifying therapies that is partially being met by emerging anabolic treatments. However, the requirements for daily oral medicines or needle injection for administration makes these emerging treatments highly inconvenient. For patients with severe osteoporosis, an Aastrom approach using a systemic infusion of expanded cells may have the potential to help rebuild bone while requiring fewer courses of therapy.

Aastrom is in the late stages of initiating clinical trials with our bone marrow-derived stem cells (TRCs) to regenerate bone for the treatment of serious fractures. The Aastrom approach of expanding a small amount of marrow collected by needle aspiration could eliminate the requirement to collect large amounts of bone from patients, a procedure known as iliac crest bone harvest. Although highly effective, bone harvesting involves invasive surgical collection of tissues from the patient's hip, often causing long term pain. Additionally, some patients, especially elderly patients, are unable to donate adequate amounts of harvested bone. The Aastrom approach would eliminate bone harvest morbidity and facilitate a more rapid patient recovery. If successful in the treatment of bone fractures, the use of bone marrow stem cells could be extended to the treatment of other orthopedic conditions such as spinal disk surgery requiring bone fusion.

Recently, bone marrow-derived cells have been demonstrated to be able to form other unrelated tissues of the body such as muscle, nerve, brain, heart and liver. When studied in small animal models, marrow cells injected directly into the heart or mobilized into the blood stream have shown significant improvement in heart function after a myocardial infarct allowing more mice to survive. In these studies, marrow cells differentiated into cells of the damaged heart such as muscle and blood vessel. The potential implications of these observations are enormous, raising the possibility of organ regeneration from adult-derived stem cells avoiding the many issues of embryonal stem cells. Such observations will require demonstration in large animal models and eventually, in human trials. In human clinical trials, bone marrow cells have regenerated blood vessels to treat patients with peripheral vascular insufficiency. This indication occurs in up to 15% of adults and development of an effective treatment could improve the quality of life for patients by allowing ambulation without the pain of vascular insufficiency known as claudication, and by avoiding the extreme need for amputation in end-stage patients.

The expansion of Aastrom's Tissue Repair Cell program, as mentioned above, is based on the progress of Aastrom's lead SC-I bone marrow stem cell product. Aastrom's *ex vivo*-produced SC-I bone marrow stem cell product has demonstrated clinical success for hematopoietic and bone engraftment in humans. Aastrom's SC-I cells have also been able to regenerate bone when given intravenously and will be studied to treat fractures by installation directly into the fracture site. The SC-I cell mixture is comprised of expanded bone marrow, including both hematopoietic, endothelial and mesenchymal stem cells, and is intended for the restoration of normal blood and immune system function in patients that have undergone aggressive chemotherapy or radiation treatment. The SC-I cell mixture is intended to provide either an alternative method of obtaining cells used in stem cell transplantation, or to augment cells obtained through a peripheral blood stem cell ("PBSC") collection in situations where it is difficult to obtain the desired quantity of PBSCs.

Once collected, the stem cell mixture is infused intravenously and the stem and stromal accessory cells migrate into the bone cavity where they engraft to form new marrow tissue. The hematopoietic progenitor cell components of the cell mixture provide early restoration of circulating white blood cells and platelets. The replenished bone marrow will normally provide long-term hematopoietic function, but complete restoration of bone marrow may, in some cases, take months following myeloablative cancer therapy. When the patient's hematopoietic system contains malignant cells, such as in the case of leukemia, stem cells from a suitable donor are generally required in order to avoid reintroducing the disease during cell infusion if stem cells for the transplant had been collected from the patient. Such donor-derived transplants are termed "allogeneic" transplants. Procedures using cells derived from the patient are termed "autologous" transplants.

In July 2002, Aastrom's SC-I autologous bone marrow stem cells produced using the AastromReplicell™ System, were granted orphan product status by the U.S. Food and Drug Administration. Aastrom's therapeutic *ex vivo*-produced bone marrow stem cells received the orphan product designation for use in

cancer patients requiring a stem cell transplant following high-dose chemotherapy, but who are unable to provide sufficient numbers of blood stem cells for adequate treatment using current transplant methods. This orphan product classification is awarded to select approaches that offer potential therapeutic value in the treatment of rare disease and conditions.

Therapeutic Cells for Immunotherapy

Therapeutic Cells for Immunotherapy involves using cells of the immune system to eradicate a disease target. A number of research institutions and other companies are investigating T-lymphocytes (T-cells) and dendritic cells for this purpose. We anticipate that many of these procedures will require *ex vivo* cell production and manipulation, and present a significant market opportunity for our products and technologies.

Dendritic cells are blood system-derived cells that play an important role in the function of the immune system by presenting antigen to the immune system to trigger an immune response. Dendritic cells, when exposed to cancer cells or other pathogens, can serve as “educator” cells to activate other cells of the immune system. Researchers believe that cultured dendritic cells could augment the natural ability of a patient to present tumor antigens or antigens from infectious agents to the immune system and aid in the generation of a cytotoxic T-cell response to the offending agent.

Clinical trials are currently underway at leading cancer centers to demonstrate the effectiveness of this new therapeutic approach in multiple cancer types. Common to these new therapeutic approaches is the requirement to culture and activate the dendritic cells outside of the patient (*ex vivo*). In these initial trials, production of the dendritic cells is performed using manual research laboratory equipment, open culture processes and specialized personnel. In order for these procedures to receive regulatory approval to be used in standard medical practice, we believe that they must be standardized and implemented through user-friendly, sterilely-closed, automated and process-controlled products. The AastromReplicell™ System is designed to address this key need by enabling automated therapeutic dendritic cell production through a standardized product format.

T-lymphocytes, a class of white blood cells, play an important role in the human immune system and are responsible as the effector cell of the immune response in a broad spectrum of cancers and infectious diseases. Therapeutic procedures using cytotoxic T-lymphocytes (CTLs) involve collecting T-lymphocytes from a patient and culturing them in an environment resulting in significantly increased numbers of T-cells including those with specificity for a particular disease target. Another approach is to generate only antigen-specific CTLs *ex vivo* by stimulating their growth with antigen-specific dendritic cells or other antigen-specific presenting cells. Clinical trials have demonstrated that both kinds of T-cell therapy can be very effective to treat cancer and viral infections. Other companies and institutions have initiated clinical trials to demonstrate CTL effectiveness. The *ex vivo* production of these cells under conditions for use in medical treatment represents a critical step in the advancement of this therapy and the AastromReplicell™ System in being developed to support this application.

We have developed our Dendricell™ products to provide a base dendritic cell for certain of these emerging immunotherapies. Following CE Mark approval, we are selling the Dendricell™ products in Europe. In the U.S., we intend to sell the Dendricell™ products for clinical research use, and we are evaluating plans to develop our own proprietary cancer vaccines, subject to additional funding or strategic partnerships

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 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 therapy 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. 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 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 other cell types. The AastromReplicell™ System is comprised of several components, including single-use therapy kits such as the OCG-I, SC-I, OC-I, DC-I, DCV-I and DCV-II Therapy kits, and microprocessor-controlled instruments. The single-use therapy kits include an AastromReplicell™ System Cell Cassette cartridge which contains our proprietary cell culture chamber, supply and waste reservoirs and harvest bag and 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 medical or laboratory technician and can implement clinical-scale cell production at the patient care site. The endpoint of the AastromReplicell™ System process is a blood-bag containing cell product. The control and documentation features of the AastromReplicell™ System have been designed to meet GMP requirements for the therapeutic production of cells. The product configuration of the AastromReplicell™ System consists of an instrumentation platform that can be integrated within the hospital or other centralized facility operating a variety of single-use therapy kits that are specific to the desired medical application. The System can be scaled-up producing simultaneously multiple independent cell batches and is suitable for installation in a regional or decentralized 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 product design of the AastromReplicell™ System will allow us to develop additional cell therapy kits to provide a commercialization pathway for a number of emerging cell therapies being developed by other researchers.

Potential Advantages of AastromReplicell™ System

The AastromReplicell™ System is designed to enable a cost-efficient and minimally invasive alternative, or supplement, to existing procedures, which could offer numerous advantages for both patients and medical staff:

The AastromReplicell™ System can generate larger quantities of cells from a small starting sample. Alternative procedures to obtain the large quantity of stem cells necessary for transplantation require a patient to endure up to multiple hours of procedure time or up to approximately 100 invasive needle sticks to obtain the necessary quantity of stem cells required for the transplant. The AastromReplicell™ System offers an alternative that requires less than two hours of procedure time and significantly fewer needle sticks.

Pre-clinical tests have demonstrated tumor cell purging of certain cancer cells in the AastromReplicell™ System expansion process. Cancer patients with tumor metastases, in which the cancer has spread to the blood and bone marrow, have not traditionally been candidates for autologous stem cell transplants because such transplants might reintroduce cancer cells into the patient. Moreover, patients may have undetected tumor cells present in their marrow or PBSC transplant, which could re-establish cancer in the patient following transplant. Our initial pre-clinical results, as well as studies conducted by third-party investigators, have shown that some primary human tumor cells die or do not grow during hematopoietic cell culture. The smaller volume of starting cells used for the AastromReplicell™ System compared with bone marrow harvest or PBSC transplants may provide approximately 10 to 70 fold less tumor cells in a transplant. Further, in an evaluation of 14 tumor-contaminated bone marrow samples that were expanded with the AastromReplicell™ System process, the presence of breast cancer cells in each sample was either substantially reduced or was no longer detectable. Tumor cells that were detectable after expansion in the AastromReplicell™ System showed a significant reduction in clonogenicity (the ability to replicate). We believe that this combination of passive depletion during culture with the lower starting volume of tumor cells may result in a tumor-free or tumor-reduced cell product for transplant. The clinical benefit of such tumor depletion, if any, will vary depending upon the type of cancer and state of disease.

Supplemental therapy with AastromReplicell™ System produced cells. Collection of cells for transplant is a variable procedure requiring longer collection procedures for some patients compared to others. The AastromReplicell™ System offers a means to augment current collection techniques, thereby reducing variability and the overall collection burden for the patient and care provider. For some patients, these standard collection techniques are unable to collect enough cells for a therapeutic dose and the AastromReplicell™ System offers a means to obtain the required cell volumes to permit continuation of treatment.

The AastromReplicell™ System automates the process of growing human cells and is designed to be used directly in a hospital setting. Growing human cells has largely been a research laboratory process, requiring substantial time and technical expertise. The AastromReplicell™ System is designed to provide sterilely-

closed, automated cell production capabilities directly at the patient care site in compliance with regulatory standards, providing process reliability and reducing the need for highly skilled operators.

Product Development

The AastromReplicell™ System is an automated clinical system designed to produce therapeutic cells for the treatment of a broad range of diseases, including cancer, infectious diseases and the restoration of solid tissues.

The AastromReplicell™ System is designed as a family of products consisting of an instrumentation platform that operates single-use, patient-specific therapy kits. Each therapy kit, which is specific to the desired cell or tissue type, is operated by the AastromReplicell™ System instrument platform, which automates the otherwise complex cell production processes. This instrument platform allows for on-site cell manufacturing that is compliant with GMPs. The process instructions contained within each therapy kit, and where applicable, the reagents, growth medium and cytokines, are specific for the production of each cell type. This product design feature provides for a variety of therapy kits to be integrated into the AastromReplicell™ System product line.

Prescription Cell Products

Our initial development efforts had been 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 in this market has led to the discontinuance of further product development in this area. Our current product development efforts are focused on the development of bone marrow stem cells for use in orthopedic indications (OCG-I product for bone grafting and OC-I product for osteoporosis) and the development of bone marrow stem cells for use in vascular system regeneration (VC-I product). 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 in current development for OCG-I to demonstrate bone formation in patients with large bone fractures. Opportunities for the utility of bone marrow stem cells in cardiac repair are being evaluated. 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.

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 cells, keratinocytes and neuronal cells. For example, Aastrom recently 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) in certain cases, 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. These business opportunities are dependent upon successful development and regulatory approval of these novel cell therapies. These novel therapies may not be successfully developed by other companies or approved by applicable regulatory authorities, and our processes or product candidates may not be able to be successfully applied in such therapies. In addition, we may be required to obtain license rights to such technologies in order to develop or

modify existing or future products for use in such therapies. We may not be able to obtain such licenses and such licenses, if available, may not be obtained on commercially reasonable terms. See "Clinical Development" and "Business Risks."

Research and development expenses for the fiscal years ended June 30, 2001, 2002 and 2003 were \$4,983,000, \$5,428,000 and \$5,647,000, respectively.

Clinical Development

The clinical trial direction of our studies has been influenced by observations limiting the scope of hematopoietic stem cell transplantation and by observations that our bone marrow cell products may be suitable as an adjunct to substantial market opportunities in bone and blood vessel regeneration.

Planned Activities

In reviewing the pre-clinical and clinical data for our bone marrow cell products in various Aastrom supported trials, we have noted a substantial increase in the mesenchymal stromal cell content. Mesenchymal stromal cells are integral for bone marrow to generate non-hematopoietic tissues such as bone and cartilage. Our bone marrow cell product had been given to one patient, on a compassionate basis, with a congenital genetic defect (hypophosphatasia) which results in a lethal condition of abnormal bone and cartilage formation. This compassionate use treatment, now published in the *Journal of Bone and Mineral Research*, resulted in sustained bone formation in the child that has continued after expanded cell infusion. Subsequently, we have demonstrated in the laboratory that our expanded bone marrow cell product is capable of forming bone. Based on these pre-clinical and clinical observations, we are now preparing to initiate clinical trials for bone regeneration in patients with severe fractures who require the addition of bone forming cells to their fracture site. The results of the fracture studies may allow our bone marrow cell product (termed "OCG-I") to also be used as an adjunct to spinal fusion surgery after appropriate clinical trials and review by the FDA. The market value of these two orthopedic procedures is substantially greater in comparison to the static and rather limited hematopoietic stem cell market. We are also planning to evaluate OCG-I cells to augment dental bone engraftment treatment as a method to improve the well-being of patients.

Our bone marrow cell product has also been demonstrated in the laboratory to contain a substantial number of cells capable of both forming and stimulating blood vessel growth. We are considering concepts of studying expanded bone marrow cells for the treatment of peripheral vascular disease based on clinical observations of efficacy using large volumes of unexpanded bone marrow cells.

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 this system have been evaluated in multi-site clinical trials in the U.S. under Investigational Device Exemption (IDE) and Investigational New Drug (IND) from the FDA. The initial goals of our clinical trial program were to obtain a Pre-Market Approval (PMA) in the U.S., necessary to market the AastromReplicell™ System for autologous hematopoietic stem cell support after high-dose cytotoxic therapy for the treatment of patients with carcinoma of the breast or lymphoma, and to support European marketing activities. Recent discussions with the FDA have indicated that the cell products will now require a Biologics License Application (BLA) for product registration, which was not originally expected or planned.

We have conducted clinical trials in the U.S. evaluating bone marrow cells produced in the AastromReplicell™ System from a small starting amount of the patient's own bone marrow. Results from initial studies demonstrated the ability of the AastromReplicell™ System to safely and reliably produce stem

and progenitor 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.

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. This procedure appears to improve the certainty of hematopoietic engraftment by providing a more reliable means of cell collection and blood count recovery.

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:

- 1) 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.
- 2) 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.
- 3) 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.
- 4) 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.

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 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. During the formation of this alliance, MTF purchased, for cash consideration of \$750,000, 1,759,112 shares of our common stock pursuant to a private placement. During the formation of this alliance, MTF purchased, for cash consideration of \$750,000, 1,759,112 shares of our common stock pursuant to a private placement which required subsequent registration. We have no information as to if, or when, MTF would sell its shares.

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 matrices and our Tissue Repair Cells (TRCs). The companies will share in the development and clinical trial expense of these treatment approaches and products, and will adopt a coordinated promotion and marketing strategy for future products. In addition to the initial focus of allograft-based bone graft treatments employing combination products, the companies will explore new approaches for the regeneration of joint cartilage, as well as effective combinations of TRCs with MTF's new ceramic technology.

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. The agreement provided for Immunex to receive up-front and renewal fees totaling \$5,500,000. The amended agreement, allowed us to extend the term for successive two-year terms upon written notice and was subject to certain minimum purchase requirements. We have provided a notice extending the agreement through March 2003, and 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.

In December 1996, we entered into a Collaborative Supply Agreement with Anchor Advanced Products, Inc., Mid-State Plastics Division (MSP), now a division company of Moll Industries. Under this agreement, MSP conducted both pre-production manufacturing development and now performs commercial manufacturing and assembly of the Cell Cassette component of the AastromReplicell™ System for us. Throughout the term of this agreement, we have agreed to treat MSP as our preferred supplier of Cell Cassettes, using MSP as our supplier of at least 60% of our requirements for Cell Cassettes. The term of the manufacturing agreement is seven years, expiring in December 2003. Moll, which had filed for bankruptcy in September 2002, has announced that effective June 5, 2003 its plan of reorganization was confirmed by the courts and that it officially emerged from bankruptcy with a plan that became effective June 24, 2003. We are currently negotiating a new agreement with Moll. We retain all proprietary rights to our intellectual property that is utilized by MSP 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 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 2006. 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 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 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 potentially subject to regulation as medical products under the Federal Food, Drug and Cosmetic Act, and 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 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 medical devices and 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.

Some of our products may be classified as Class III medical devices. The FDA categorizes devices into three regulatory classifications subject to varying degrees of regulatory control. In general, Class I devices require compliance with labeling and record keeping regulations, Quality System Regulation (QSR), 510(k) pre-market notification, and are subject to other general controls. Class II devices may be subject to additional regulatory controls, including performance standards and other special controls, such as post-market surveillance. Class III devices, which are either invasive or life-sustaining products, or new products never before marketed (for example, non-“substantially equivalent” devices), require clinical testing to demonstrate safety and effectiveness and FDA approval of a PMA prior to marketing and distribution. The FDA also has the authority to require clinical testing of Class I and Class II devices.

We, and any contract manufacturer, may be required to be registered as a medical device manufacturer with the FDA. These manufacturers will be inspected on a routine basis by the FDA for compliance with the FDA’s QSR regulations. These regulations would require that we, and any contract manufacturer, design, manufacture and service products and maintain documents in a prescribed manner with respect to manufacturing, testing, distribution, storage, design control and service activities. The Medical Device Reporting regulation requires that we provide information to the FDA on deaths or serious injuries alleged to be associated with the use of our devices, as well as product malfunctions that are likely to cause or contribute to death or serious injury if the malfunction were to recur. In addition, the FDA prohibits a company from promoting an approved device for unapproved applications and reviews company labeling for accuracy.

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 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. The BLA describes 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™ 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 European Union (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.

The MDD vest 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™ 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 European Union. 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.

Competition

The biotechnology and medical device industries are characterized by rapidly evolving technology and intense competition. Our competitors include major pharmaceutical, medical device, medical products, chemical and specialized biotechnology companies, many of which have financial, technical and marketing resources significantly greater than ours. In addition, many biotechnology companies have formed collaborations with large, established companies to support research, development and commercialization of products that may be competitive with ours. Academic institutions, governmental agencies and other public and private research organizations are also conducting research activities and seeking patent protection and may commercialize products on their own or through joint ventures. We are aware of certain other products manufactured or under development by competitors that are used for the prevention or treatment of certain diseases and health conditions that we have targeted for product development. There can be no assurance that developments by others will not render our product candidates or technologies obsolete or noncompetitive, that we will be able to keep pace with new technological developments or that our product candidates will be able to supplant established products and methodologies in the therapeutic areas that are targeted by us. The

foregoing factors could have a material adverse affect on our business, financial condition and results of operations.

Our products under development are expected to address a broad range of existing and new markets. We believe that our stem cell therapy products will, in large part, face competition by existing procedures rather than novel new products. Further, in instances that do not require our patented processes for growing cells, we will face competition for our products from existing manual cell culture techniques, which techniques may be viewed by potential customers as more cost effective than our process. Our competition will be determined in part by the potential indications for which our products are developed and ultimately approved by regulatory authorities. In addition, the first product to reach the market in a therapeutic or preventive area is often at a significant competitive advantage relative to later entrants to the market. Accordingly, the relative speed with which we, or our potential corporate partners, can develop products, complete the clinical trials and approval processes and supply commercial quantities of the products to the market are expected to be important competitive factors. Our competitive position will also depend on our ability to attract and retain qualified scientific and other personnel, develop effective proprietary products, develop and implement production and marketing plans, obtain and maintain patent protection and secure adequate capital resources. We expect our products, if approved for sale, to compete primarily on the basis of product efficacy, safety, patient convenience, reliability, value and patent position.

Aastrom competes in several key business segments. Within each business segment, we believe there are multiple competitors including the following competitors: (i) Tissue Repair Cell: Genzyme Corporation, Osiris Therapeutics, Inc., Isolagen, Isotis and Johnson & Johnson are active in the market, (ii) Dendritic Cells: Dendreon Corporation, Genzyme Corporation, Immuno-Designed Molecules (vaccine market only), and (iii) Cell Production Products: Baxter Oncology, Miltenyi Biotec, Inc., and Nalge Nunc International.

Employees

As of August 13, 2003, we employed approximately 44 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 13, 2003, are as follows:

<u>Name</u>	<u>Age</u>	<u>Position</u>
R. Douglas Armstrong, Ph.D. . .	50	President, Chief Executive Officer and Chairman of the Board of Directors
Robert J. Bard, J.D., R.A.C. . . .	52	Vice President Regulatory Affairs and Quality Systems
Brian S. Hampson	46	Vice President Product Development
Steven N. Wolff, M.D.	54	Vice President Medical Research
Alan M. Wright	58	Senior Vice President Administrative and Financial Operations and Chief Financial Officer

R. Douglas Armstrong, Ph.D. joined Aastrom in June 1991 as a Director, and as its President and Chief Executive Officer. In 1999, Dr. Armstrong was elected as Chairman of Aastrom's Board of Directors. From 1987 to 1991, Dr. Armstrong served in different capacities, including Executive Vice President and Trustee of the La Jolla Cancer Research Foundation (LJCRF), now named the Burnham Institute, a 250-employee scientific research institute located in San Diego, California. Dr. Armstrong received a Bachelor of Arts degree in Chemistry from the University of Richmond, and a Doctorate in Pharmacology and Toxicology from the Medical College of Virginia. Dr. Armstrong has held various faculty and staff positions at Yale University, University of California, San Francisco, LJCRF and University of Michigan. In addition, he was a participant in the formation of Telios Pharmaceuticals, Inc., has served on the boards of both biotechnology companies and a venture capital fund, and currently serves as Chairman of the Board for the Center for Cell Therapy.

Robert J. Bard, J.D., R.A.C. joined Aastrom in October 2002 as Vice President Regulatory Affairs & Quality Systems with over 29 years of extensive domestic and international regulatory experience in the pharmaceutical, medical device and biotechnology sector. Prior to joining Aastrom, Mr. Bard served in several senior management capacities for a number of other companies in the medical industry, including: Gliatech, Inc., McKinley Medical, LLLP, I-Flow Corp., IVAC Corp. and Ultra Medical Devices, Inc., where he was responsible for regulatory compliance, quality assurance and manufacturing operations for biotech pharmaceuticals and medical devices. Mr. Bard earned a law degree from the American College of Law, and has a B.S. in Microbiology, with a minor in Biological Chemistry, from the University of California-Los Angeles. In addition, he has studied Pharmaceutical Sciences at Idaho State University and Mechanical Engineering at California State University — Long Beach. Mr. Bard is a member of the California Bar. He completed his ISO 9001 Lead Assessor Training in 1995, is a certified member of the Regulatory Affairs Professional Society, and is an ASQ-certified Quality Engineer. Mr. Bard is also the author of numerous professional and scientific papers and articles.

Brian S. Hampson joined Aastrom 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™ 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 a Bachelor of Science and Master of Engineering degrees in Electrical Engineering from Cornell University.

Steven N. Wolff, M.D. joined Aastrom in April 2001 as Vice President Medical Research. Prior to joining Aastrom, Dr. Wolff held various distinguished positions at the Vanderbilt University School of Medicine, most recently as Professor of Medicine in the Division of Hematology/Oncology, and as Director of the Bone Marrow Transplant Program. In addition, Dr. Wolff has served on the National Marrow Donor Program Council from 1995 to 1997, as the Council's President in 1997, and as the Chairman of the Finance Committee. Currently, Dr. Wolff participates as a Board Member for the Lance Armstrong Foundation, having served as Board President in 1998. Dr. Wolff holds an M.D. from the University of Illinois, with postgraduate training at Vanderbilt University School of Medicine and Washington University School of Medicine, and holds an undergraduate degree from Queens College. Dr. Wolff's role with Aastrom changed effective August 31, 2003. At that time, Dr. Wolff relinquished his executive officer status as Vice President, and moved to a consulting role with the Company. In this capacity, Dr. Wolff will continue to provide Aastrom with leadership in the clinical trial and research areas. The new role will allow Dr. Wolff to resume his activity in academic medicine.

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. 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.

ITEM 2. PROPERTIES

We lease approximately 23,000 square feet of office and research and development space in Ann Arbor, Michigan under a lease agreement expiring in December 2004. We believe that our facilities are adequate for our current needs. Additional facilities may be required to support expansion for research and development abilities or to assume manufacturing operations that are currently fulfilled through contract manufacturing relationships.

ITEM 3. LEGAL PROCEEDINGS

We are 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 applicable Nasdaq Market:

Price Range of Common Stock

	<u>High</u>	<u>Low</u>
Year ended June 30, 2002:		
1st Quarter	\$2.40	\$.93
2nd Quarter	1.21	.94
3rd Quarter	1.05	.72
4th Quarter71	.36
Year ended June 30, 2003:		
1st Quarter46	.27
2nd Quarter66	.23
3rd Quarter53	.25
4th Quarter	1.45	.30

As of August 31, 2003, there were approximately 542 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.

In May 2003, we issued in two separate transactions a total of 1,759,112 share of our common stock to Musculoskeletal Transplant Foundation (MTF) for an aggregate of \$750,000. These shares were sold in a private placement under the exemption from registration provided by Section 4(2) of the Securities Act.

In September 2002 and February 2003, we agreed to issue warrants for public and investor relations 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. In addition, we have 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. 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.

The following table sets forth information as of June 30, 2003 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)	4,345,759	\$1.24	888,545
Equity compensation plans not approved by security holders (financings or services related)	<u>797,595</u>	\$0.74	<u>—</u>
Balance, June 30, 2003	<u>5,143,354</u>		<u>888,545 (1)</u>

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

ITEM 6. SELECTED FINANCIAL DATA

The statement of operations data for the years ended June 30, 2001, 2002 and 2003 and for the period from March 24, 1989 (Inception) to June 30, 2003 and the balance sheet data at June 30, 2002 and 2003, 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, 1999 and 2000, and the balance sheet data at June 30, 1999, 2000 and 2001, 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, 2003
	1999	2000	2001	2002	2003	
Statement of Operations Data:						
Revenues:						
Product sales and rentals ..	\$ 34,000	\$ 169,000	\$ 85,000	\$ 80,000	\$ 314,000	\$ 682,000
Research and development agreements	—	—	—	—	10,000	2,030,000
Grants	847,000	981,000	814,000	797,000	520,000	6,348,000
Total revenues	881,000	1,150,000	899,000	877,000	844,000	9,060,000
Costs and expenses:						
Cost of product sales and rentals(1)	6,000	1,251,000	13,000	202,000	893,000	2,365,000
Research and development	10,871,000	6,289,000	4,983,000	5,428,000	5,647,000	87,148,000
Selling, general and administrative	2,836,000	3,364,000	2,482,000	3,528,000	4,017,000	28,127,000
Total costs and expenses	13,713,000	10,904,000	7,478,000	9,158,000	10,557,000	117,640,000
Loss from operations	(12,832,000)	(9,754,000)	(6,579,000)	(8,281,000)	(9,713,000)	(108,580,000)
Other income (expense):						
Other income	1,237,000	—	—	—	—	1,237,000
Interest income	571,000	364,000	653,000	342,000	134,000	5,202,000
Interest expense	(4,000)	—	—	—	—	(267,000)
Net loss	<u>\$(11,028,000)</u>	<u>\$(9,390,000)</u>	<u>\$(5,926,000)</u>	<u>\$(7,939,000)</u>	<u>\$(9,579,000)</u>	<u>\$(102,408,000)</u>
Net loss applicable to common shares	<u>\$(11,507,000)</u>	<u>\$(9,598,000)</u>	<u>\$(5,926,000)</u>	<u>\$(7,939,000)</u>	<u>\$(9,579,000)</u>	
Net loss per common share (basic and diluted)	<u>\$ (.75)</u>	<u>\$ (.41)</u>	<u>\$ (.17)</u>	<u>\$ (.19)</u>	<u>\$ (.19)</u>	
Weighted average number of common shares outstanding	<u>15,342,000</u>	<u>23,344,000</u>	<u>34,030,000</u>	<u>42,121,000</u>	<u>50,984,000</u>	

	June 30,				
	1999	2000	2001	2002	2003
Balance Sheet Data:					
Cash, cash equivalents and short-term investments	\$ 7,528,000	\$ 12,745,000	\$ 10,659,000	\$ 9,605,000	\$ 10,512,000
Working capital	8,009,000	12,143,000	10,715,000	10,597,000	11,273,000
Total assets	9,540,000	13,437,000	11,905,000	11,553,000	12,155,000
Deficit accumulated during the development stage	(70,334,000)	(79,932,000)	(85,858,000)	(93,797,000)	(103,376,000)
Total shareholders' equity	8,511,000	12,435,000	10,894,000	10,803,000	11,575,000

(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 and June 30, 2003 includes a charge of \$202,000 and \$748,000 for obsolete and excess inventory, respectively.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Overview

Aastrom Biosciences, Inc. (Aastrom) was incorporated in March 1989 (Inception), began employee-based operations in 1991, and is in late-stage development. 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.

We are a late-stage development company that has strategically moved from a business model that was originally based on the Bone Marrow Transplantation market to a company focused on human cell-based therapies. We have identified multiple paths to revenue based on our proprietary *ex vivo* cell production technology, including the near-term Cell Production Products operation, and an active Prescription Cell Product pipeline for stem cell tissue repair and regeneration, and cancer and infectious disease treatments.

Our core technology is based on the Company's proprietary AastromReplicell™ System, an integrated system of instrumentation and single-use consumable kits that implements our patented Single-Pass Perfusion process in a fully automated closed-loop culturing system to optimize cell growth and viability. This system provides nutrients to cells by mimicking the natural cell-growth environment, and enabling cells to grow effectively while retaining high biological function, without various cloning approaches. Our programs currently use bone marrow, cord blood and blood cells as starting sources of cells. As such, federal support or other factors relating to embryonal stem cell research have no direct impact on our current product programs. In addition, this system provides GMP-compliant manufacturing and automated process control for the commercial-scale production of human cells. We do not believe that any other comparable system currently exists.

Our Cell Production Products operation has created a path to near-term revenue. The Aastrom-Replicell™ 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 are being sold to academic researchers and companies that are developing cancer vaccines. The recent commercialization of our automated cell production instruments and cell-specific production kits is expected to generate revenues although we are not yet able to project the market size and growth for these products.

In addition, we are leveraging our *ex vivo* cell production technology for a growing Prescription Cell Product pipeline focused on two areas: Tissue Repair Cells (TRCs) for stem cell-derived tissue repair and regeneration, and Therapeutic Cells (TCs) for immune system-directed attacks on certain cancers and other infectious diseases.

Using the AastromReplicell™ System with its patented single-pass perfusion, TRCs are grown from a small sample of a patient's bone marrow and, once administered back to the patient, are intended to generate normal tissue. The primary TRC application being evaluated is our OCG-I cells for bone grafting (fusions, fractures or dental defects). We are currently planning and preparing for OCG-I clinical trials in both the United States and Europe. We also have in development OC-I cells for osteoporosis, and SC-I cells for autologous bone marrow transplants in lymphoma patients. The SC-I product has been CE-Marked in Europe and is currently being evaluated by a limited number of centers in Europe. In the United States, the SC-I therapy reached Phase III trials, although these trials have halted due to a shift in medical practice that reduced patient need and availability. We also believe that the stem cell components of our TRCs may be useful for other medical indications, including the regeneration of cardiac and vascular tissues. Our CB-I clinical trials have been closed out. We have no plans to continue product development of the CB-I kit at this time, unless entirely funded by grants, due to the limited size of the potential market.

We are developing TC products using human cells to cause the patient's immune system to attack certain cancers and other infectious diseases. Blood-derived dendritic cells, which are the body's crucial mobilizers of the immune T-Cells response, are cultured in the AastromReplicell™ System to produce our proprietary Dendricell™. After being exposed to a particular biological signal, or antigen, the Dendricell™ may act to trigger a cell-mediated immune response in a patient against the cancer cells or viri. The first Dendricell™ clinical trials are planned at Stanford University for a multiple myeloma cancer vaccine and at Duke University for a colorectal cancer vaccine. In addition, we are in the pre-clinical stage for a T-cell therapeutic targeting the Epstein-Barr Virus.

In addition to our consumable DC-I and DCV-I cell product kits, we have begun marketing our automated cell production instruments in Europe and the United States for research use. Through Zellera AG, Aastrom's wholly owned subsidiary located in Berlin, Germany, we are actively coordinating country-specific sub-distributorships and service networks in Europe.

Since our inception, we have been in the development stage and engaged in research and product development, conducted principally on our own behalf, but also in connection with various collaborative research and development agreements with others. We commenced our initial pilot-scale product launch in Europe of the AastromReplicell™ System 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've initiated marketing activities in Europe 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 two to three 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, milestone payments 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. 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. Through June 30, 2003, we have accumulated losses of approximately \$102 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, 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.

Inventory. We value our inventory that consists primarily of finished components of our lead product, the AastromReplicell™ Cell Production System, at the lower of cost (specific identification using first in, first out) or market. Furthermore, 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, 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 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.

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. Revenue from product sales is recognized when title to the product transfers and there are no remaining obligations that will affect the customer's final acceptance of the sale, generally after installation and training. If there are remaining obligations, including training or installation (which we believe to be significant) revenue is recognized upon completion of these obligations. Revenue from licensing fees under licensing agreements is recognized as revenue when there are no future performance obligations remaining with respect to such fees. Payments received before all obligations are fulfilled are classified as deferred revenue.

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.

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 \$844,000 in 2003, \$877,000 in 2002, and \$899,000 in 2001. Revenues include product sales and rentals of \$314,000 in 2003, \$80,000 in 2002 and \$85,000 in 2001, reflecting increased marketing efforts in Europe of our lead product, the AastromReplicell™ System, following resumption in fiscal year 2001 of our initial product launch that had been suspended in fiscal year 2001 pending receipt of additional funding. Grant revenues decreased to \$520,000 in 2003 from \$797,000 in 2002 and from \$814,000 in 2001, reflecting the award of research grants and related research activities, to the extent that such associated costs are reimbursed under the grants. Grant revenues accounted for 62% of total revenues for the year ended June 30, 2003 and 91% for the years ended June 30, 2002 and 2001 and are recorded on a cost-reimbursement basis. Revenues for the year ended June 30, 2003 also include \$10,000 in research and development agreements resulting from the sublicense agreement with Corning, Inc.

Total costs and expenses were \$10,557,000 in 2003, \$9,158,000 in 2002 and \$7,478,000 in 2001. The increase in costs and expenses from 2002 to 2003 is primarily the result of increased cost of product sales and rentals to \$893,000 in 2003 from \$202,000 in 2002 and \$13,000 in 2001. These increases relate to the non-cash provision for obsolete and excess AastromReplicell™ System inventory that increased to \$748,000 in 2003 from \$202,000 in 2002 and \$0 in 2001. Research and development expenses increased to \$5,647,000 in 2003 from \$5,428,000 in 2002 and \$4,983,000 in 2001, reflecting increased research and product development activities in the areas of dendritic cell-based vaccines, tissue regeneration and preparation of our pending bone grafting clinical trials. Selling, general and administrative expenses increased to \$4,017,000 in 2003 from \$3,528,000 in 2002 and \$2,482,000 in 2001, reflecting the continued expansion of marketing activities in

Europe 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, 2003 also includes a non-cash charge of \$335,000 relating to certain warrants issued in August 2002 for investment banking services and in June 2003 for public and investor relations services.

Interest income was \$134,000 in 2003, \$342,000 in 2002 and \$653,000 in 2001. The fluctuations in interest income are due primarily to corresponding changes in the levels of cash, cash equivalents and short-term investments during the periods and decreases from yields from our investments.

Our net loss was \$9,579,000, or \$.19 per common share in 2003, \$7,939,000, or \$.19 per common share in 2002, and \$5,926,000, or \$.17 per common share in 2001. These increases in net loss are primarily the result of increased costs and expenses as the result of expanded research and market 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 profits to date 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, the utilization of net operating loss and tax credit carryforwards is significantly limited due to the multiple ownership changes, which have occurred under taxation rules. At June 30, 2003, we estimate the maximum Federal tax net operating loss and tax credit carryforwards, which could be utilized were \$50,000,000 and \$320,000 respectively, which will expire from 2005 to 2023, 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 \$115 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 \$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.

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, or distribution and marketing, agreements with suitable corporate collaborators, grants 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 2004. These estimates are forward-looking statements 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 and economic conditions affecting the public markets generally or some portion or all of the technology sector. 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 Company has contractual obligations for operating leases as disclosed in Footnote 6 — Commitments in “Notes to Consolidated Financial Statements”.

New Accounting Standards

In December 2002, the FASB issued SFAS No. 148, “Accounting for Stock-Based Compensation — Transition Disclosure — an amendment of SFAS No. 123” (SFAS No. 148). This Statement amends SFAS No. 123, “Accounting for Stock-Based Compensation,” to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, this Statement amends the disclosure requirements of SFAS No. 123 to require prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reported results. The provisions of SFAS No. 148 are effective for financial statements for fiscal years ending after December 15, 2002, and disclosure requirements shall be effective for interim periods beginning after December 15, 2002. The Company will continue to account for stock-based compensation to its employees and directors using the intrinsic value method prescribed by APB Opinion No. 25, and related interpretations. The Company adopted the provisions of SFAS No. 148 and has made certain disclosures required by SFAS No. 148 in the consolidated financial statements presented in this report. The adoption of SFAS No. 148 did not impact Aastrom’s financial position or results of operations.

In November 2002, the FASB issued Interpretation No. 45, “Guarantor’s Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others.” This interpretation elaborates on the disclosures required in financial statements concerning obligations under certain guarantees. It also clarifies the requirements related to the recognition of liabilities by a guarantor at the inception of certain guarantees. The disclosure requirements of this interpretation were effective for Aastrom on December 31, 2002 but did not require any additional disclosures. The recognition provisions of the interpretation are effective for Aastrom in 2004 and are applicable only to guarantees issued or modified after December 31, 2002. The adoption of Interpretation No. 45 did not have a material impact on the financial position or results of operations of Aastrom.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As of June 30, 2003, 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 or 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, 2003, we have incurred net losses totaling approximately \$102 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.

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. While we have commenced initial marketing on a limited basis of the AastromReplicell™ System in Europe, we believe that the United States will be the largest market for our products. 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 2004 fiscal year (ending June 30, 2004). 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 rates, 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. Pursuant to previously approved shareholder resolutions, the Board of Directors has the authority to increase the maximum number of authorized shares from 100 million to 150 million.

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 \$0.23 and \$1.45 during the fiscal year ended June 30, 2003. 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.

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

To be able to market cell products in the United States, we must demonstrate, through extensive pre-clinical 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.

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.

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 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 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. Patients receiving cells produced with our technologies and product candidates may not demonstrate long-term engraftment in a manner comparable to cells obtained from current hematopoietic stem cell therapy procedures. 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, other regulatory agencies, and governments in other countries continue to review and inspect marketed products, manufacturers and manufacturing facilities. 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, governmental regulatory agencies may establish additional regulations which could prevent or delay regulatory approval of our products.

Even if we obtain regulatory approvals to sell our products, lack of commercial acceptance would 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 Aastrom Replicell™ 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.

Failure of third parties to manufacture component parts or provide limited source supplies 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.

Furthermore, some of the compounds used by us 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. Our inability to develop or obtain alternative compounds would harm our product development and commercialization efforts.

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.

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.

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 initial marketing on a limited basis of the AastromReplicell™ System and SC-I, DC-I and DCV-I cell production kits in Europe and domestically for research 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.

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. The AastromReplicell™ System may be regulated 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 Class III 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 BLA. Other countries are adopting new strict policies and requirements for cell products. These new requirements may delay, restrict or prevent the sale or use of our products.

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 individual products. For each of our potential products, we believe that there are potentially many competitive approaches being pursued, including some by private companies for which information is difficult to obtain.

Many of our competitors have significantly greater resources, more product candidates and have developed product 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 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, researchers and practitioners may 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, the Chairman, Chief Executive Officer and President 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.

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.

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.

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.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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REPORT OF INDEPENDENT AUDITORS

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 at June 30, 2002 and 2003, and the results of their operations and their cash flows for each of the three years in the period ended June 30, 2003, and for the period from March 24, 1989 (Inception) to June 30, 2003 in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedules 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 schedules are the responsibility of the Company's management; our responsibility is to express an opinion on these financial statements and financial statement schedules based on our audits. We conducted our audits of these statements in accordance with auditing standards generally accepted in the United States of America, which 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 8, 2003

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

	June 30,	
	2002	2003
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 8,605,000	\$ 10,512,000
Short-term investments	1,000,000	—
Receivables, net	120,000	350,000
Inventory, net	1,397,000	806,000
Other current assets	<u>225,000</u>	<u>185,000</u>
Total current assets	11,347,000	11,853,000
PROPERTY, NET	<u>206,000</u>	<u>302,000</u>
Total assets	<u>\$ 11,553,000</u>	<u>\$ 12,155,000</u>
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	\$ 589,000	\$ 406,000
Accrued employee expenses	<u>161,000</u>	<u>174,000</u>
Total current liabilities	<u>750,000</u>	<u>580,000</u>
COMMITMENTS (Note 6)		
SHAREHOLDERS' EQUITY:		
Common Stock, no par value; shares authorized — 100,000,000; shares issued and outstanding — 43,726,557 and 64,812,422, respectively	104,600,000	114,951,000
Deficit accumulated during the development stage	<u>(93,797,000)</u>	<u>(103,376,000)</u>
Total shareholders' equity	<u>10,803,000</u>	<u>11,575,000</u>
Total liabilities and shareholders' equity	<u>\$ 11,553,000</u>	<u>\$ 12,155,000</u>

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

AASTROM BIOSCIENCES, INC.
(a development stage company)

CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended June 30,			March 24, 1989 (Inception) to June 30, 2003
	2001	2002	2003	
REVENUES:				
Product sales and rentals	\$ 85,000	\$ 80,000	\$ 314,000	\$ 682,000
Research and development agreements ...	—	—	10,000	2,030,000
Grants	814,000	797,000	520,000	6,348,000
Total revenues	899,000	877,000	844,000	9,060,000
COSTS AND EXPENSES:				
Cost of product sales and rentals	13,000	—	145,000	388,000
Cost of product sales and rentals — provision for obsolete and excess inventory	—	202,000	748,000	1,977,000
Research and development	4,983,000	5,428,000	5,647,000	87,148,000
Selling, general and administrative	2,482,000	3,528,000	4,017,000	28,127,000
Total costs and expenses	7,478,000	9,158,000	10,557,000	117,640,000
LOSS FROM OPERATIONS	(6,579,000)	(8,281,000)	(9,713,000)	(108,580,000)
OTHER INCOME (EXPENSE):				
Other income	—	—	—	1,237,000
Interest income	653,000	342,000	134,000	5,202,000
Interest expense	—	—	—	(267,000)
Total other income	653,000	342,000	134,000	6,172,000
NET LOSS	<u>\$(5,926,000)</u>	<u>\$(7,939,000)</u>	<u>\$(9,579,000)</u>	<u>\$(102,408,000)</u>
NET LOSS PER SHARE (Basic and Diluted)	<u>\$ (.17)</u>	<u>\$ (.19)</u>	<u>\$ (.19)</u>	
Weighted average number of common shares outstanding	<u>34,030,000</u>	<u>42,121,000</u>	<u>50,984,000</u>	

The accompanying notes are an integral part of these 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					(78,964,000)	(78,964,000)
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			1,937,204	639,000		639,000
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				534,000		534,000
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 \$200,000			5,264,827	12,900,000		12,900,000
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, 2000	—	—	33,607,659	92,367,000	(79,932,000)	12,435,000
Net loss and comprehensive loss					(5,926,000)	(5,926,000)
Exercise of stock options and issuance of stock under Employee Stock Purchase Plan			244,600	246,000		246,000
Exercise of stock purchase warrant			765,381	8,000		8,000
Compensation expense related to stock options granted			—	120,000		120,000
Issuance of common stock, net of issuance costs of \$39,000			3,063,595	4,011,000		4,011,000
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

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

AASTROM BIOSCIENCES, INC.
(a development stage company)

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended June 30,			March 24, 1989
	2001	2002	2003	(Inception) to June 30, 2003
OPERATING ACTIVITIES:				
Net loss	\$(5,926,000)	\$(7,939,000)	\$(9,579,000)	\$(102,408,000)
Adjustments to reconcile net loss to net cash used for operating activities:				
Depreciation and amortization	171,000	126,000	119,000	3,446,000
Loss on property held for resale	—	—	—	110,000
Amortization of discounts and premiums on investments	(69,000)	—	—	(543,000)
Stock compensation expense	120,000	—	335,000	999,000
Inventory write downs and reserves	—	202,000	748,000	1,977,000
Stock issued pursuant to license agreement	—	—	—	3,300,000
Changes in assets and liabilities:				
Receivables	113,000	9,000	(230,000)	(374,000)
Inventory	(725,000)	(874,000)	(253,000)	(2,879,000)
Other current assets	(55,000)	(12,000)	40,000	(185,000)
Accounts payable and accrued expenses	19,000	(267,000)	(183,000)	406,000
Accrued employee expenses	(10,000)	6,000	13,000	174,000
Net cash used for operating activities	(6,362,000)	(8,749,000)	(8,990,000)	(95,977,000)
INVESTING ACTIVITIES:				
Organizational costs	—	—	—	(73,000)
Purchase of short-term investments	(1,500,000)	(5,500,000)	—	(62,124,000)
Maturities of short-term investments	12,250,000	4,500,000	1,000,000	62,667,000
Capital purchases	(58,000)	(153,000)	(119,000)	(2,915,000)
Proceeds from sale of property held for resale	—	—	—	400,000
Net cash provided by (used for) investing activities	10,692,000	(1,153,000)	881,000	(2,045,000)
FINANCING ACTIVITIES:				
Issuance of preferred stock	—	—	—	51,647,000
Issuance of common stock	4,265,000	7,848,000	10,016,000	54,579,000
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	4,265,000	7,848,000	10,016,000	108,534,000
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	8,595,000	(2,054,000)	1,907,000	10,512,000
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	2,064,000	10,659,000	8,605,000	—
CASH AND CASH EQUIVALENTS AT END OF PERIOD	\$10,659,000	\$ 8,605,000	\$10,512,000	\$ 10,512,000
SUPPLEMENTAL CASH FLOW INFORMATION:				
Interest paid	\$ —	\$ —	\$ —	\$ 267,000
Additions to capital lease obligations	\$ —	\$ —	\$ —	\$ 1,174,000

The accompanying notes are an integral part of these 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. (Aastrom) 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 2004, 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 company accounted for 22% of total revenues for the period from Inception to June 30, 2003. However, for the fiscal year ended June 30, 2003, there was no revenue recognized from this source. Grant revenues consist of grants sponsored by federal and state programs.

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, 2003, 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 remaining 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, 2003 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 maintain safety and liquidity. 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 of its lead product, the AastromReplicell™ Cell Production System, at the lower of cost (specific identification using first in, first out) or market. Furthermore, the Company regularly reviews inventory quantities on hand and records 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, the Company utilizes a systematic approach to determine its reserve for obsolete and excess inventory. Under this systematic approach, 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. The Company feels this approach is appropriate given its limited product sales history and the risk associated with its ability to recover the inventory as it is still in the process of establishing its 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 the Company's inventory and its reported operating results. The Company charged \$202,000 and \$748,000, for the years ended June 30, 2002 and 2003, respectively to cost of product sales and rentals — provision for obsolete and excess inventory.

Property — Property 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.

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, generally installation and training (which the Company generally believes to be significant). 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 \$1,645,000 for the period from Inception to June 30, 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). 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 as prescribed by SFAS No. 123, the following operating results would have occurred using the Black-Scholes option-pricing model to determine the fair value of the options:

	June 30,	
	2002	2003
Reported net loss	\$(7,939,000)	\$ (9,579,000)
Add: Stock-based employee compensation expense included in reported net income, net of related tax effects	—	—
Deduct: Stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	(1,243,000)	(827,000)
Pro forma net loss	\$(9,182,000)	\$(10,406,000)
Earnings per share:		
As reported	\$ (.19)	\$ (.19)
Pro forma	\$ (.22)	\$ (.20)

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,		
	2001	2002	2003
Dividend rate	None	None	None
Expected stock price volatility	100%	100%	120%
Risk-free interest rate	4.8% - 5.9%	4.0% - 4.8%	2.5% - 3.3%
Expected life of options	5 years	5 years	5 years

The weighted average fair value of options granted during the years ended June 30, 2001, 2002 and 2003 was \$1.93, \$.80 and \$.28 per share, respectively.

Income Taxes — The Company recognizes deferred tax assets and liabilities for the differences between the carrying amounts and the tax basis of assets and liabilities, as well as net operating loss and tax credit carryforwards. Additionally, the Company establishes a valuation allowance to reflect the likelihood of realization of deferred tax assets.

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 affect 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, 2001, 2002 and 2003 is approximately 4,662,000, 6,143,000 and 5,144,000, respectively.

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

Financial Instruments — The Company evaluates the fair value of those assets and liabilities identified as financial instruments and estimates that the fair value of such financial instruments approximates the carrying

AASTROM BIOSCIENCES, INC.
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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

value in the accompanying financial statements. Fair values have been determined through information obtained from market sources and management estimates.

Long-Lived Assets — The Company evaluates the impairment of long-lived assets whenever events or changes in circumstances indicate that the carrying amount of those assets may not be recoverable. If such an event or change in circumstance occurs and potential impairment is indicated because the carrying value exceed the future undiscounted cash flow, the Company would measure the impairment loss as the amount by which the carrying value exceeds the fair value of the asset. 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 2002, the FASB issued SFAS No. 148, “Accounting for Stock-Based Compensation — Transition Disclosure — an amendment of SFAS No. 123” (SFAS No. 148). This Statement amends SFAS No. 123, “Accounting for Stock-Based Compensation,” to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, this Statement amends the disclosure requirements of SFAS No. 123 to require prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reported results. The provisions of SFAS No. 148 are effective for financial statements for fiscal years ending after December 15, 2002, and disclosure requirements shall be effective for interim periods beginning after December 15, 2002. The Company will continue to account for stock-based compensation to its employees and directors using the intrinsic value method prescribed by APB Opinion No. 25, and related interpretations. The Company adopted the provisions of SFAS No. 148 and has made certain disclosures required by SFAS No. 148 in the consolidated financial statements presented in this report. The adoption of SFAS No. 148 did not impact Aastrom’s financial position or results of operations.

In November 2002, the FASB issued Interpretation No. 45, “Guarantor’s Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others.” This interpretation elaborates on the disclosures required in financial statements concerning obligations under certain guarantees. It also clarifies the requirements related to the recognition of liabilities by a guarantor at the inception of certain guarantees. The disclosure requirements of this interpretation were effective for Aastrom on December 31, 2002 but did not require any additional disclosures. The recognition provisions of the interpretation are effective for Aastrom in 2004 and are applicable only to guarantees issued or modified after December 31, 2002. The adoption of Interpretation No. 45 did not have a material impact on the financial position or results of operations of Aastrom.

2. Selected Balance Sheet Information

Short-Term Investments — All short-term investments are available-for-sale and have maturities of one year or less and are summarized as follows:

The Company did not have any short-term investments at June 30, 2003.

	<u>Amortized Cost</u>	<u>Gross Unrealized Gains</u>	<u>Gross Unrealized Losses</u>	<u>Market Value</u>
June 30, 2002				
Commercial Paper	<u>\$1,000,000</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$1,000,000</u>

Receivables — Receivables are presented, net of allowance for doubtful accounts of \$34,000 and \$31,000 at June 30, 2002 and 2003, respectively.

AASTROM BIOSCIENCES, INC.
(a development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Inventory — Inventory is presented, net of reserve for obsolescence and excess inventory of \$202,000 and \$950,000 at June 30, 2002 and 2003, respectively.

Property — Property consists of the following:

	June 30,	
	2002	2003
Machinery and equipment	\$ 1,440,000	\$ 1,538,000
Office equipment	956,000	965,000
Leasehold improvements	622,000	622,000
Equipment under lease	120,000	217,000
	3,138,000	3,342,000
Less accumulated depreciation and amortization	(2,932,000)	(3,040,000)
	\$ 206,000	\$ 302,000

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

	June 30,	
	2002	2003
Accounts payable	\$351,000	\$251,000
Accrued expenses:		
Clinical studies	135,000	13,000
Professional services	10,000	71,000
Manufacturing and engineering	53,000	5,000
Deferred revenue	—	9,000
Other	40,000	57,000
	\$589,000	\$406,000

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 9,144,615 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.

AASTROM BIOSCIENCES, INC.

(a development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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:

	<u>Options Outstanding</u>	<u>Options Available for Grant Under Option Plans</u>	<u>Weighted Average Exercise Price Per Share</u>	<u>Options Exercisable At Period End</u>
March 24, 1989 (Inception)				
Options authorized	—	4,399,927		
Options canceled	(2,087,068)	1,987,068	\$4.28	
Options granted	4,892,701	(4,792,701)	\$2.29	
Options exercised	<u>(1,617,577)</u>	—	\$.36	
Balance, June 30, 2000	1,188,056	1,594,294	\$1.30	1,000,224
Options authorized	—	1,550,000		
Options canceled	(44,852)	44,852	\$2.57	
Options granted	1,134,700	(1,134,700)	\$2.50	
Options exercised	<u>(230,042)</u>	—	\$.99	
Balance, June 30, 2001	2,047,862	2,054,446	\$2.03	880,171
Options authorized	—	2,100,000		
Options abandoned with approval of 2001 Plan	—	(808,206)		
Options canceled	(412,324)	412,324	\$1.41	
Options granted	<u>1,893,564</u>	<u>(1,893,564)</u>	\$1.05	
Balance, June 30, 2002	3,529,102	1,865,000	\$1.58	1,331,815
Options authorized	—	—		
Options abandoned 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	<u>(4,163)</u>	—	\$1.15	
Balance, June 30, 2003	<u>4,345,759</u>	<u>790,100</u>	\$1.24	1,925,884

The following table summarizes information about stock-based compensation plans as of June 30, 2003:

<u>Range of Exercise Prices</u>	<u>Number of Options Outstanding</u>	<u>Remaining Contractual Life-years</u>	<u>Weighted Average Exercise Price</u>	<u>Number Exercisable</u>	<u>Weighted Average Exercise Price of Exercisable Options</u>
\$.31 - \$.99	1,864,050	8.7	\$.54	558,684	\$.81
\$1.05 - \$1.91	1,638,109	8.0	\$1.13	731,650	\$1.16
\$2.44 - \$2.94	676,400	7.2	\$2.91	473,275	\$2.91
\$3.20 - \$4.75	<u>167,200</u>	5.9	\$3.32	<u>162,275</u>	\$3.32
	<u>4,345,759</u>		\$1.24	<u>1,925,884</u>	\$1.67

AASTROM BIOSCIENCES, INC.
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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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 the year ended June 30, 2001, a charge of \$120,000 was recorded with respect to stock options that were exercised and was included in research and development expense. During fiscal year 2002 and 2003, there was no charge to expense because the Company's stock price did not exceed \$2.41. At June 30, 2003, options to purchase 317,000 shares remain outstanding.

Employee Stock Purchase Plan — The Company has an employee stock purchase plan under which eligible employees can purchase common stock, at a discount to the market price, through payroll deductions up to 10% of the employees 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 is 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, 2001, 2002 and 2003, 14,558 shares, 42,075 shares and 34,560 shares, respectively, of common stock were purchased under this plan. From inception to June 30, 2003, 151,555 shares were purchased under this plan.

Stock Purchase Warrants Issued for Services — During 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. 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 relations' 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.

In addition, the Company has 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. The fair value of all warrants was estimated 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%. 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.

Common Shares Reserved — As of June 30, 2003, the Company has reserved shares of common stock for future issuance as follows:

Issuance under stock option and stock purchase plans	7,982,418
Issuance under stock purchase warrants	<u>797,595</u>
	<u>8,780,013</u>

No cash dividends have ever been declared or paid.

AASTROM BIOSCIENCES, INC.
(a development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

4. Income Taxes

Deferred tax assets consist of the following:

	June 30,	
	2002	2003
Net operating loss carryforwards	\$ 15,540,000	\$ 18,500,000
Tax credits and other	145,000	320,000
Gross deferred tax assets	15,685,000	18,820,000
Valuation allowance	(15,685,000)	(18,820,000)
	\$ —	\$ —

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

The Company has issued shares of common stock in prior years, which resulted in multiple ownership changes under Section 382 of the Internal Revenue Code. Consequently, the utilization of net operating loss and tax credit carryforwards is significantly limited due to the multiple ownership changes, which have occurred. At June 30, 2003 the Company estimates the maximum Federal tax net operating loss and tax credit carryforwards, which could be utilized were \$50,000,000 and \$320,000, respectively, which will expire from 2005 through 2023, 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

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.

Corning Incorporated — In December 2002, the Company entered into an agreement with Corning Incorporated that granted them an exclusive sublicense relating to our 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 an up-front fee of \$10,000 and future royalty payments on net sales of licensed products sold under the sublicense.

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.

AASTROM BIOSCIENCES, INC.
(a development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

6. Commitments

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

Year Ending June 30,	Operating Leases
2004	\$617,000
2005	316,000
	\$933,000

Rent expense for the years ended June 30, 2001, 2002 and 2003, was \$495,000, \$547,000 and \$602,000, respectively, and \$4,463,000 for the period from Inception to June 30, 2003.

7. Employee Savings Plan

The Company has a 401(k) 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 contributions. The Company has made contributions of \$146,000 and \$109,000 for the years ended June 30, 2002 and 2003, respectively. There were no contributions made by the Company during the year ended June 30, 2001.

8. Quarterly Financial Data (Unaudited)

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)
Year Ended June 30, 2002	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Fiscal Year
Revenues	\$ 151,000	\$ 267,000	\$ 232,000	\$ 227,000	\$ 877,000
Loss from operations	(2,015,000)	(2,126,000)	(2,133,000)	(2,007,000)	(8,281,000)
Net loss	(1,893,000)	(2,020,000)	(2,072,000)	(1,954,000)	(7,939,000)
Net loss per common share	(.05)	(.05)	(.05)	(.04)	(.19)

9. Subsequent Events

During July 2003, the Company has issued 6,405,840 shares of its common stock through multiple transactions, for net cash proceeds of approximately \$5,200,000. As part of one of these transactions, the Company will also issue warrants to the private placement investors, exercisable for 4 years to purchase up to 1.26 million shares of common stock at a price of \$1.23, as well as warrants to purchase up to approximately one million shares of common stock at \$1.50 per share prior to October 31, 2003. In addition, warrants to purchase 0.3 million shares of common stock were issued to the private placement agent, exercisable for 4 years at a price of \$1.23.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

There are none to report.

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 2003 Annual Meeting of Shareholders to be held on November 12, 2003.

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. CONTROLS AND PROCEDURES

Under the supervision and with the participation of our management, including our President and Chief Executive Officer, and our Senior Vice President, 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 President and Chief Executive Officer, and our Senior Vice President, Chief Financial Officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this annual report.

ITEM 15. 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 Public Accountants".

PART IV

ITEM 16. EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K

(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.

(b) Reports on Form 8-K:

The following reports on Form 8-K were filed submitted the fourth quarter:

1. May 12, 2003 (Earnings release)
2. May 30, 2003 (Press releases relating to Stanford collaboration and Nasdaq notification)
3. June 10, 2003 (Press release relating to MTF collaboration)

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: September 8, 2003

AASTROM BIOSCIENCES, INC.

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

R. Douglas Armstrong, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below on September 8, 2003 by the following persons in the capacities indicated.

<u>Signature</u>	<u>Title</u>
<u>/s/ R. DOUGLAS ARMSTRONG, PH.D.</u> R. Douglas Armstrong, Ph.D.	President, Chief Executive Officer (Principal Executive Officer)
<u>/s/ ALAN M. WRIGHT</u> Alan M. Wright	Senior Vice President, Administrative and Financial (Principal Financial and Accounting Officer)
<u>/s/ MARY L. CAMPBELL</u> Mary L. Campbell	Director
<u>/s/ ARTHUR F. STAUBITZ</u> Arthur F. Staubitz	Director
<u>/s/ JOSEPH A. TAYLOR</u> Joseph A. Taylor	Director
<u>/s/ SUSAN L. WYANT</u> Susan L. Wyant	Director

EXHIBIT INDEX

<u>Number</u>	<u>Notes</u>	<u>Description of Document</u>
3.1	K	Restated Articles of Incorporation of Aastrom.
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.
10.16	A	Collaborative Supply Agreement, dated December 16, 1996, between Aastrom and Anchor Advanced Products, Inc. Mid-State Plastics Division.
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.
10.41†	C	Manufacturing Supply Agreement, dated as of August 14, 1998, by and between Aastrom and SeaMED Corporation.
10.42#	D	Employment Agreement, dated August 10, 1998, by and between Aastrom and Bruce Husel.
10.46#	E	Executive Retention and Severance Agreement, dated February 2, 1999, between Aastrom and R. Douglas Armstrong.
10.49#	F	Supplemental Agreement by and between Aastrom and Bruce W. Husel dated October 5, 1999.
10.55#	G	Pay to Stay Severance Agreement between R. Douglas Armstrong, Ph.D. and Aastrom dated October 15, 1999.
10.63#	I	Agreement Regarding Pay-to-Stay, by and between Aastrom and R. Douglas Armstrong, Ph.D. dated April 28, 2000.
10.65#	I	Agreement Regarding Pay-to-Stay, by and between Aastrom and Brian S. Hampson dated April 28, 2000.
10.66#	I	Form of Retention Bonus Agreement, by and between Aastrom and each of Brian S. Hampson and Bruce W. Husel.
10.67#	I	Form of Relocation Bonus Agreement, by and between Aastrom and each of Brian S. Hampson and Bruce W. Husel.
10.69#	J	Employment Agreement, dated February 1, 2001, by and between Aastrom and Steven Wolff.
10.70	K	Seventh Amendment to Office Lease.
10.72#	K	Aastrom Biosciences 2001 Stock Option Plan.
10.73#		Employment Agreement with Alan Wright
10.74#		Retention Bonus Agreement with Alan Wright
10.75#		Employment Agreement, dated October 21, 2002, with Robert J. Bard

<u>Number</u>	<u>Notes</u>	<u>Description of Document</u>
10.76		Master Supply Agreement with Astro Instrumentation, LLC
21		Subsidiaries of Registrant.
23.1		Consent of Independent Accountants.
31		Rules 13a-14(a) and 14d-14(a) Certifications.
32		Section 1350 Certifications.
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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, 1998, as filed on September 29, 1998.
D		Incorporated by reference to Aastrom's Amendment to Registration Statement on Form S-1 (No. 333-37439), as filed on November 21, 1997.
E		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.
F		Incorporated by reference to Aastrom's Quarterly Report on Form 10-Q for the quarter ended September 30, 1999, as filed on November 12, 1999.
G		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.
I		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.
J		Incorporated by reference to Aastrom's Annual Report on Form 10-K for the year ended June 30, 2001, as filed on September 14, 2001.
K		Incorporated by reference to Aastrom's Annual Report on Form 10-K for the year ended June 20, 2002, as filed on September 30, 2002.
†		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**

<u>Allowance for Doubtful Accounts:</u>	<u>Years Ended June 30,</u>		
	<u>2001</u>	<u>2002</u>	<u>2003</u>
Balance at beginning of year	\$ 94,000	\$34,000	\$34,000
Additions charged to income	—	—	—
Write-offs, net of recoveries	<u>(60,000)</u>	<u>—</u>	<u>(3,000)</u>
Balance at end of year	<u>\$ 34,000</u>	<u>\$34,000</u>	<u>\$31,000</u>

<u>Reserve for Obsolescence and Excess Inventory:</u>	<u>Years Ended June 30,</u>		
	<u>2001</u>	<u>2002</u>	<u>2003</u>
Balance at beginning of year	\$ —	\$ —	\$202,000
Additions charged to income	—	202,000	748,000
Reductions	<u>—</u>	<u>—</u>	<u>—</u>
Balance at end of year	<u>\$ —</u>	<u>\$202,000</u>	<u>\$950,000</u>

Shareholder Information

Executive Offices

Aastrom Biosciences, Inc.
Domino's Farms, Lobby L
24 Frank Lloyd Wright Drive
Ann Arbor, MI 48105
Phone: (734) 930-5555

Auditors

PricewaterhouseCoopers LLP
650 Third Avenue South, Suite 1300
Minneapolis, MN 55402
Phone: (612) 596-6000

Market for Registrant's Common Stock

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

Registrar and Transfer Agent

Continental Stock Transfer & Trust Company
17 Battery Place, 8th Floor
New York, NY 10004
Phone: (212) 509-4000

General Counsel

Gray Cary Ware & Freidenrich
4365 Executive Drive, Suite 1100
San Diego, CA 92121
Phone: (858) 677-1400

Annual Shareholders' Meeting

November 12, 2003
Holiday Inn North Campus
3600 Plymouth Road
Ann Arbor, MI 48105
8:30 am

Company Information

For information regarding Aastrom Biosciences, Inc., please visit our website at www.aastrom.com. Additional information is available at www.nasdaq.com.

Investor Relations

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

Investor Relations Department
Aastrom Biosciences, Inc.
P.O. Box 376
Ann Arbor, MI 48106
Phone: (734) 930-5777
Fax: (734) 665-0485



*Aastrom Biosciences, Inc.
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