
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, 2002

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.

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 September 19, 2002 was approximately \$15 million. 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 September 19, 2002, 45,934,129 shares of Common Stock, no par value, were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Document	Form 10-K Reference
Proxy Statement for the Annual Meeting of Shareholders scheduled for November 14, 2002	Items 10, 11, 12 and 13 of Part III

TABLE OF CONTENTS

PART I

[Item 1. Business](#)

[Item 2. Properties](#)

[Item 3. Legal Proceedings](#)

[Item 4. Submission of Matters to a Vote of Security Holders](#)

PART II

[Item 5. Market for Registrant's Common Equity and Related Shareholder Matters](#)

[Item 6. Selected Financial Data](#)

[Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations](#)

[Item 7A. Quantitative and Qualitative Disclosures About Market Risk](#)

[Item 8. Financial Statements and Supplementary Data](#)

[Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure](#)

PART III

[Item 10. Directors and Executive Officers of the Registrant](#)

[Item 11. Executive Compensation](#)

[Item 12. Security Ownership of Certain Beneficial Owners and Management](#)

[Item 13. Certain Relationships and Related Transactions](#)

PART IV

[Item 14. Exhibits, Financial Statement Schedules and Reports on Form 8-K](#)

SIGNATURES

EXHIBIT INDEX

[EXHIBIT 3.1](#)

[EXHIBIT 10.70](#)

[EXHIBIT 10.71](#)

[EXHIBIT 10.72](#)

[EXHIBIT 23.1](#)

[EXHIBIT 99.1](#)

[EXHIBIT 99.2](#)

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

	Page No.
PART I	
Item 1. BUSINESS	3
Item 2. PROPERTIES	18
Item 3. LEGAL PROCEEDINGS	18
Item 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS	18
PART II	
Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED SHAREHOLDER MATTERS	19
Item 6. SELECTED FINANCIAL DATA	20
Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS	21
Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK	25
Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA	33
Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE	48
PART III	
Item 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT	48
Item 11. EXECUTIVE COMPENSATION	48
Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT	48
Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS	48
PART IV	
Item 14. EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K	48
SIGNATURES	49
CERTIFICATIONS	50

[Table of Contents](#)

Except for the historical information presented, the matters discussed in this Report, including our product development and commercialization goals and expectations, potential market opportunities, our plans and anticipated results of our 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

Aastrom Biosciences, Inc. is a leader in the development of human cell therapy products intended for a broad range of medical applications based on its patented process and device capabilities. The Company has three product areas in various stages of development, which are: Tissue Repair Cells; Therapeutic Cells for Immunotherapy; and, Devices for cell production. The Tissue Repair Cell products under development include the SC-I and CB-I cells for use in stem cell therapy and the OC cell products for the restoration of bone tissue, which have all reached the clinical trial stage in the US. Our lead Device products under development include the AastromReplicell™ System and the DC-I and DCV-I kits for the clinical-scale production of dendritic cells intended for the emerging cancer vaccine market. All of these products, except for the OC-I kit, have received the CE mark, making them available for sale and use in Europe.

Our business model builds on two complementary components: (i) proprietary procedures and devices to enable certain types of stem cells and other types of human cells to be produced with excellent biological capabilities as compared with standard cell culture approaches, and (ii) the AastromReplicell™ System clinical platform that is designed to standardize and enable an effective commercialization pathway for bringing cell production to medical practice. The AastromReplicell™ System consists of an instrumentation platform, to be integrated within the hospital or other centralized facility, that can operate a variety of single-use therapy kits that are specific to the desired medical application. Through this product configuration, we intend to either directly provide cells for therapeutic use, or 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 similar to a pharmaceutical 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.

The AastromReplicell™ System is both a key technology and product platform. It is used by the Company to produce its proprietary Tissue Repair and Therapeutic Cell products, and has also been developed to be sold as an independent product. Dendritic cells, a type of blood cell that have the ability to stimulate an immune response against specific targets, are being investigated as a potential new treatment for cancer and viral diseases. We intend to sell the AastromReplicell™ System and the DC-I and DCV-I kits to clinical researchers and centers that are developing dendritic cell-based vaccines designed to treat cancer and other disorders. During the year ended June 30, 2002, we initiated our external site testing of the AastromReplicell™ System and the DC-I and DCV-I with leading research centers. The Company was successful in obtaining CE Mark approvals for both kits, which is necessary for European marketing. We also plan to market these dendritic cell production device products to U.S. clinical and research groups that are developing dendritic cell-based cancer vaccines. With this capability to produce human dendritic cells, the Company is investigating plans for our own proprietary vaccines, pending additional funding or strategic partnerships. The SC-I stem cell therapy product has also received CE Mark approval, allowing us to begin commercialization activities in Europe. The SC-I cells have been in Phase III-Type clinical studies in the U.S. Additionally, the Company has recently initiated a development program for the production of bone-forming cells in the

[Table of Contents](#)

AstromReplicell™ System. Our OC-I cell product is being developed for the treatment of patients with degenerative bone diseases such as osteoporosis and is currently in a Phase I/II-Pilot clinical study in the U.S. The Company's OCG-I cell product for bone grafting applications, is in active pre-clinical development.

Although we may not market the AstromReplicell™ System or our Tissue Repair Cell and Therapeutic Cell Products in the United States for stem cell therapy unless and until approval is obtained from the U.S. Food and Drug Administration (FDA), we have completed production-level versions of the AstromReplicell™ System. The System and disposables may be sold to U.S. investigators with IND approval for clinical studies. We have begun European commercialization activities for the AstromReplicell™ System instrumentation and the kits to produce the SC-I cells (led through the Company's German-based subsidiary Zellera AG). The Company has also initiated commercialization of the DC-I and DCV-I products in Europe, and we are developing our marketing plan to establish relationships with leading sites to build a customer foundation for these products in the U.S.

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 bone marrow, or stem cell transplants. In this procedure, 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. Most recently, researchers are developing emerging cell therapies utilizing T-cells and dendritic cells to stimulate an immune response in patients with various forms of cancers and infectious diseases, such as viral infections. 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 AstromReplicell™ System is being developed to fill this need.

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.

In a study published in March 2000, researchers at leading German medical centers reported positive results of a new dendritic cell-based therapy. In this study, renal cell carcinoma patients were treated with dendritic cells that had been produced outside of the body, and then fused with tumor cells collected from the patient. The modified dendritic cells, once injected into the patient, triggered an immune response against the cancer in some patients. The results indicated a major new treatment modality against renal cell cancer. Further, additional 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 AstromReplicell™ System is

[Table of Contents](#)

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 for 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. 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 to in Europe. In the U.S., we intend to sell the Dendricell™ for clinical research use, and we are evaluating plans to develop our own proprietary cancer vaccines, subject to additional funding or strategic partnerships

Tissue Repair Cells

Bone marrow stromal cells (sometimes also referred to as mesenchymal cells) may also contribute to the repair of various solid tissues including bone marrow, connective tissues such as bone and cartilage, and other tissues. Industry sources estimate that over 10 million Americans suffer from osteoporosis, a disease characterized by low bone mass and structural deterioration of bone tissue, leading to bone fragility and an increased susceptibility to fractures, especially of the hip, spine and wrist. We have initiated a Phase I/II clinical study of our OC-I cell mixture to treat severe osteoporosis. The trial will evaluate the production of bone progenitor cells in the AastromReplicell™ System from a small amount of the patient's own stem cells. The new expanded cells will then be infused intravenously with the intention of helping to restore the degenerated bone tissue. Trial results will focus on establishing safety and measuring bone formation, blood alkaline phosphatase and osteocalcin levels and bone catabolism.

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. An Aastrom solution could meet this need by making use of a small bone marrow aspirate, that can be collected in a simple outpatient procedure, and then expanding the sample in the Company's cell production system, making the aspirate more viable as an alternative to autograft. 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 ingestion or 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.

A new form of cell therapy involves the production of chondrocytes for the restoration of cartilage. Chondrocyte therapy involves the surgical removal of a small amount of tissue from the patient's knee and a production of therapeutic quantity of chondrocytes from this surgical biopsy. The cells are then re-implanted back into the knee. Published reports indicate that such cells then reestablish mature articular cartilage. Currently, this cell production process is completed in highly specialized laboratory facilities using trained scientists and manual laboratory procedures. We believe that the AastromReplicell™ System may have the potential to reduce costs associated with the cell production procedure and, if successfully developed by us for this application, may eventually facilitate the transfer of the cell production capability away from highly specialized facilities to regional clinical care sites. It is also conceivable that marrow cells, due to their multi-potential capability, could generate cartilage forming-cells replacing the need to collect chondrocytes.

[Table of Contents](#)

Recently, 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.

The expansion of Aastrom's Tissue Repair Cell program, as mentioned above, is derived from 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 engraftment in humans. The SC-I cell mixture is comprised of expanded bone marrow, including both hematopoietic 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.

We currently have a clinical trial evaluating the SC-I cell mixture in breast cancer patients and lymphoma patients. In this study, the SC-I cell mixture is being used to augment low-doses of PBSCs that were collected from the patient. 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.

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 similar to a pharmaceutical 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. 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. The same perfusion approach that enables stem cells to grow and improves the biological features of other types of human cells, when compared with cells grown using standard cell culture techniques. 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 tissues 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 SC-I, CB-I, OC-I, DC-I, and DCV-I Therapy kits, and microprocessor-controlled instruments. The single use therapy kits contain 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 is user interface software that simultaneously tracks and monitors the cell production process in multiple incubators and records relevant process variables and operator actions.

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 good manufacturing practices (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

[Table of Contents](#)

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 de-centralized cell production facility. This is intended to provide a product pathway for each cell therapy that is similar to a pharmaceutical 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.

The AastromReplicell™ System enables the production of certain cells, such as umbilical cord blood (CB) cells, for which there might otherwise be insufficient quantities available for many transplants. Having access to a sufficient number of cells is essential to successful clinical outcomes. This is particularly the case with umbilical cord blood transplants. This source of stem cells is increasingly being used as an alternative to traditional stem cell transplant procedures. However, the limited quantities of available cells and difficulties in expanding the starting volumes to therapeutic quantities have restricted the widespread practice of CB transplants. The AastromReplicell™ System is designed to solve this dilemma by providing the capability to easily and cost-effectively expand CB cells to higher quantities for therapeutic treatments.

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 transplant 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 collection techniques are unable to collect enough cells for a therapeutic dose and the AastromReplicell™ System offers a means to continue with 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-

[Table of Contents](#)

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 be used by medical personnel at hospitals and patient care centers 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 directly at the hospital 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.

Our development efforts have been focused on the development of the SC-I kit for the production of bone marrow stem cells, the CB-I Therapy kit for the production of cord blood cells, and the OC kits for the production of bone forming cells. All of these products use Aastrom's proprietary process and device technologies. We believe that additional therapy kits may be developed for application to a variety of other emerging cell therapies. 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 and DCV-I kits for dendritic cell production. In current development is a clinical trial to demonstrate bone formation in patients with large bone fractures. Other than a limited application of chondrocyte therapy, novel cell therapies are still in early stages of development by third parties, and no assurance can be given that such other cell therapies will 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. There can be no assurance that we will be able to successfully modify or develop existing or future products to enable such additional cell production processes. Our business opportunity is dependent upon successful development and regulatory approval of these novel cell therapies. No assurance can be given that such novel therapies will be successfully developed by other companies or approved by applicable regulatory authorities, or that our processes or product candidates will find successful application 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. No assurance can be given that we will be able to obtain such licenses or that such licenses, if available, could be obtained on commercially reasonable terms. See "Clinical Development" and "Business Risks."

Clinical Development

The AastromReplicell™ System is being evaluated in multi-site clinical trials in the U.S. under Investigational Device Exemptions (IDEs) and Investigational New Drug (IND) from the FDA. The initial goals of our clinical trial program are to obtain a Pre-Market Approval (PMA) in the U.S., necessary to market the AastromReplicell™ System for autologous stem cell therapy, and to support European marketing activities.

[Table of Contents](#)

We have conducted clinical trials in the U.S. evaluating stem cells produced in the AastromReplicell™ System from a small starting amount of 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 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 has indicated a way to offer patients a transplant with a lower risk of receiving back tumor cells.

We are now conducting a randomized U.S. clinical trial evaluating the AastromReplicell™ System to compliment traditional therapies by augmenting stem cells collected from a single PBSC apheresis procedure. The objectives of this study are to demonstrate that an optimal targeted recovery can be achieved using the AastromReplicell™ System-produced 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.

We have also conducted clinical feasibility trials to evaluate 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 and enable adult-sized patients to undergo a transplant when they may not otherwise be CB transplant candidates due to low cell dose. We have extended these trials into a comparative trial with concurrent controls. Several CB banking institutions are now being established by other organizations. This banking infrastructure, together with the expansion capabilities of the AastromReplicell™ System, may lead to CB as a promising new source of cells for therapeutic use.

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, there can be no assurance that our pre-pivotal or pivotal trials will be successful, or that biologic license application (BLA) registration or required foreign regulatory approvals for the AastromReplicell™ System will be obtained in a timely fashion, or at all. See “Business Risks.”

Aastrom Product Candidates for Ex Vivo Gene Therapy

The Company has different technologies for the production of cells with genetic modifications. However, the Company is not currently actively developing products based on this technology.

Manufacturing

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

In April 1998, we entered into a manufacturing agreement with SeaMED, now a wholly owned division of Plexus Corporation, for the commercial manufacturing of the instrument components of the AastromReplicell™ System. The initial term of the manufacturing agreement was until April 2001, after which the agreement is automatically renewed until terminated upon a 24-month notice from Plexus or a 6-month notice from us. We retain all proprietary rights to our intellectual property that is utilized by Plexus pursuant to this agreement. Plexus has delivered notice of their intent to terminate the manufacturing agreement, in accordance with the terms of the agreement, on or before February 6, 2004. As a result, we are in advanced negotiations with another supplier which we expect to result in continued supply on commercially reasonable terms. However, there can be no assurance that the new agreement will be completed or that the new agreement will be on terms as favorable to us as the existing contract.

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, as amended, allows for us to extend the term for successive two-year terms upon written notice and is subject

[Table of Contents](#)

to certain minimum purchase requirements. We have provided a notice extending the agreement through March 2003. The agreement provided for Immunex to receive up-front and renewal fees totaling \$5,500,000. Pursuant to agreements between Immunex and Aastrom, the annual fees due in March 1998, 1999 and 2000 were each paid by us through the issuance of \$1,100,000 in our common stock. In August 1997, Aastrom and Immunex amended the agreement to expand our territorial rights to use and sell such materials on a worldwide basis. The supply agreement may be terminated by either party effective immediately upon written notice of termination to the other party in the event that such party materially breaches the agreement and such breach continues unremedied after notice and expiration of a specified cure period or in the event that a bankruptcy proceeding is commenced against a party and is not dismissed or stayed within a 45-day period. In addition, Immunex has the right to cease the supply to us of cytokines and ancillary materials if we fail to purchase a minimum amount of our forecasted annual needs from Immunex after notice to us, and expiration of a specified cure period. In the event that Immunex elects to cease to supply to us cytokines and ancillary materials or is prevented from supplying such materials to us by reason of force majeure, limited manufacturing rights will be transferred to us under certain circumstances. There is, however, 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. We retain all proprietary rights to our intellectual property that is utilized by MSP pursuant to this agreement.

On September 10, 2002 a major creditor of Moll filed an involuntary petition for Bankruptcy against Moll. On September 19, 2002 Moll announced that it had converted the case to a voluntary Chapter 11 reorganization case and had received preliminary approval for a \$50 million debtor-in-possession financing. Although there is a risk that these factors may affect our supply of components, we believe that Moll will continue to meet our supply needs.

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 20 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.

[Table of Contents](#)

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

[Table of Contents](#)

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.

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

To our knowledge, we are the first to develop a GMP-compliant cell culture system for *ex vivo* human cell production to be sold for therapeutic applications. Therefore, to a certain degree, the manner in which the FDA will regulate our products is uncertain.

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 AastromReplicellTM 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 AastromReplicellTM System in this manner.

The FDA is still in the process of developing its requirements with respect to somatic cell therapy and gene cell therapy products and has issued draft documents concerning the regulation of cellular and tissue-based products. If the FDA adopts the regulatory approach set forth in the draft document, 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

[Table of Contents](#)

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 regulatory standards is 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 for the AastromReplicellTM 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

[Table of Contents](#)

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) preclinical 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.

Preclinical 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 preclinical 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 Directives (MDD) being 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

[Table of Contents](#)

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 regulations 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 member states of 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 and DCV-I 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.

[Table of Contents](#)

Aastrom competes in several key business segments. Within each business segment, we can identify the following competitors: (i) Tissue Repair Cell: Genzyme, Osiris and Johnson & Johnson are active in the market, and (ii) Dendritic Cells: Dendreon (vaccine market only).

Employees

As of August 31, 2002, 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 31, 2002, are as follows:

<u>Name</u>	<u>Age</u>	<u>Position</u>
R. Douglas Armstrong, Ph.D.	49	President, Chief Executive Officer and Chairman of the Board of Directors
Michael S. Durski	52	Vice President Finance & Administration, Chief Financial Officer, Secretary and Treasurer
Brian S. Hampson	45	Vice President Product Development
Bruce W. Husel	44	Vice President Quality Systems and Regulatory Affairs
Steven N. Wolff, M.D.	53	Vice President Medical Research
Alan M. Wright	57	Senior Vice President Administrative and Financial Operations

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. In addition, he has held faculty and staff positions at Yale University, University of California, San Francisco, LJCRF and University of Michigan.

Michael S. Durski joined Aastrom in February 2002 as Vice President Finance and Administration and Chief Financial Officer. Mr. Durski also serves as Aastrom's Secretary and Treasurer. Prior to joining Aastrom, Mr. Durski held the positions of Chairman, CEO and CFO of ZeptoMetrix Corporation, a biotechnology manufacturer of kits and reagents engaged in the study, diagnosis and treatment of cancer and infectious diseases, which he co-founded. Prior to that time Mr. Durski held various executive financial positions at Cellular Products, Inc., Treibacher Schleifmittel, Recra Environmental and Comptek Research, Inc. Mr. Durski received a Bachelor of Science degree in Mathematics from the State University College at Buffalo, and a Master of Business Administration degree in Finance from Canisius College.

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 AastromReplicellTM 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.

[Table of Contents](#)

Bruce W. Husel joined Aastrom in November 1997 as Vice President Quality Systems and Regulatory Affairs. From May 1994 to September 1997, Mr. Husel served as Director of Quality Assurance for Sanofi Diagnostics Pasteur, where he led efforts to achieve EN 46001 registration and prepared for CE Marking. From June 1992 to May 1994, Mr. Husel was Director of Quality and Regulatory Affairs for Baxter Anesthesia Division (formerly known as Bard MedSystems). Prior to that, he served as Quality Manager of McGaw, Inc. Mr. Husel received a Bachelor of Business degree in Electrical Engineering from Rice University, a Master of Science degree in Engineering Management from Southern Methodist University and a Master of Business Administration degree in Accounting from the University of Texas at Dallas.

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.

Alan M. Wright joined Aastrom in September 2000 as a member of the Board of Directors. In August 2002, Mr. Wright resigned from Aastrom's Board of Directors and 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.

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	
	High	Low
Year ended June 30, 2001:		
1st Quarter	\$4.31	\$1.53
2nd Quarter	2.78	.81
3rd Quarter	1.59	.78
4th Quarter	2.34	.75
Year ended June 30, 2002:		
1st Quarter	2.40	.93
2nd Quarter	1.21	.94
3rd Quarter	1.05	.72
4th Quarter	.71	.36

As of August 30, 2002, there were approximately 440 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.

[Table of Contents](#)

Item 6. Selected Financial Data

The statement of operations data for the years ended June 30, 2000, 2001 and 2002 and for the period from March 24, 1989 (Inception) to June 30, 2002 and the balance sheet data at June 30, 2001 and 2002, 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, 1998 and 1999, and the balance sheet data at June 30, 1998, 1999 and 2000, 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, 2002
	1998	1999	2000	2001	2002	
Statement of Operations Data:						
Revenues:						
Product sales and rentals	\$ —	\$ 34,000	\$ 169,000	\$ 85,000	\$ 80,000	\$ 368,000
Research and development agreements	3,000	—	—	—	—	2,020,000
Grants	246,000	847,000	981,000	814,000	797,000	5,828,000
Total revenues	249,000	881,000	1,150,000	899,000	877,000	8,216,000
Costs and expenses:						
Cost of product sales and rentals(1)	—	6,000	1,251,000	13,000	202,000	1,472,000
Research and development	15,498,000	10,871,000	6,289,000	4,983,000	5,428,000	81,501,000
Selling, general and administrative	2,858,000	2,836,000	3,364,000	2,482,000	3,528,000	24,110,000
Total costs and expenses	18,356,000	13,713,000	10,904,000	7,478,000	9,158,000	107,083,000
Loss from operations	(18,107,000)	(12,832,000)	(9,754,000)	(6,579,000)	(8,281,000)	(98,867,000)
Other income (expense):						
Other income	—	1,237,000	—	—	—	1,237,000
Interest income	886,000	571,000	364,000	653,000	342,000	5,068,000
Interest expense	(12,000)	(4,000)	—	—	—	(267,000)
Net loss	\$(17,233,000)	\$(11,028,000)	\$ (9,390,000)	\$ (5,926,000)	\$ (7,939,000)	\$(92,829,000)
Net loss applicable to common shares	\$(21,023,000)	\$(11,507,000)	\$ (9,598,000)	\$ (5,926,000)	\$ (7,939,000)	
Net loss per common share (basic and diluted)	\$ (1.57)	\$ (.75)	\$ (.41)	\$ (.17)	\$ (.19)	
Weighted average number of common shares outstanding	13,363,000	15,342,000	23,344,000	34,030,000	42,121,000	

	June 30,				
	1998	1999	2000	2001	2002
Balance Sheet Data:					
Cash, cash equivalents and short-term investments	\$ 11,212,000	\$ 7,528,000	\$ 12,745,000	\$ 10,659,000	\$ 9,605,000
Working capital	10,121,000	8,009,000	12,143,000	10,715,000	10,597,000
Total assets	12,374,000	9,540,000	13,437,000	11,905,000	11,553,000
Deficit accumulated during the development stage	(58,897,000)	(70,334,000)	(79,932,000)	(85,858,000)	(93,797,000)
Total shareholders' equity	10,846,000	8,511,000	12,435,000	10,894,000	10,803,000

- (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 year ended June 30, 2002 includes a charge of \$202,000 for obsolete and excess inventory.

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

Overview

We are pioneering the development of human cell therapy technologies intended for a broad range of medical applications based on our patented process and device capabilities for manufacturing proprietary cell mixtures. Our lead cell therapeutic product areas under development include: Tissue Repair Cells (TRCs), Therapeutic Cells (TCs), and Cell Culture Devices. TRCs are cells that lead to the construction of normal tissue such as bone. TCs are cells that can act like drugs, such as a therapeutic vaccine for cancer or viruses. Cell culture devices have been developed by Aastrom to produce our TRCs and TCs, but they can be sold to authorized third parties as stand-alone products.

Our business model builds on two complementary components: (i) proprietary procedures and devices to enable certain types of stem cells and other types of human cells to be produced with excellent biological capabilities as compared with standard cell culture approaches; and (ii) the AastromReplicell™ System clinical platform that is designed to standardize and enable an effective commercialization pathway for bringing therapeutic cell production to medical practice. The AastromReplicell™ System consists of an instrumentation platform, to be either sold to a hospital or other centralized facility, or alternatively, used by Aastrom, that can operate a variety of single-use cell production kits that are specific to the desired medical application. Each cell product is produced using a specific type of kit. The kit and the cell product produced with the kit share a common identifying nomenclature such as DC-I, DCV-I, OC-I, SC-I and CB-I. Through this product configuration, we intend either directly to commercialize 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 instruments and kits. This approach is intended to provide a product pathway for each cell therapy that is similar to a pharmaceutical product including regulatory approval, reimbursement, marketing and pricing. We believe that the 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.

We have different TRC products in active development, including: SC-I bone marrow cells for bone marrow transplantation application; CB-I cells for cord blood stem cell transplantation application; OC-I cells for severe osteoporosis; and OCG-I cells for bone grafting applications. For the TC product areas, we are investigating immune system dendritic cells, a type of blood cell that has the ability to stimulate an immune response against specific targets as a potential new treatment for cancer and viral diseases. We have developed the DC-I and DCV-I device products, and intend to use for our own TC products, as well as to sell to clinical researchers and centers that are developing dendritic cell-based vaccines designed to treat cancer and other disorders. We have obtained approval to affix the CE Mark to the DC-I and DCV-I kits, allowing us to market and sell these products in Europe, through our German subsidiary, Zellera AG. We also plan to market the DC-I and DCV-I device products to U.S. clinical and research groups that are developing dendritic cell-based

[Table of Contents](#)

cancer vaccines. The development of our own proprietary vaccines may be pursued pending additional funding or strategic partnerships.

Our SC-I and CB-I TRC products have received CE Mark approval allowing us to begin commercialization activities in Europe, through our German subsidiary, Zellera AG, and are in Phase III-Type clinical studies in the U.S. However, we do not believe there is a current market for the CB-I product in Europe, and will be several years before any U.S. approvals may be received, or for the markets to develop for this product. Although able to be sold in Europe, the SC-I product will have to undergo various clinical evaluations at initial customer sites in order to generate the data necessary for reimbursement of the product. This year we established relationships at several European centers for these sites to generate this clinical data.

More recently we have initiated a development program for the production of bone-forming TRCs in the AastromReplicellTM System (our "OC" line of TRCs). The OC-I cell product is being developed for the treatment of patients with degenerative bone diseases such as osteoporosis, for which a Phase I/II-Pilot clinical study is in process in the U.S. Our OCG-I cell product is being developed for bone grafting applications, and we are developing a clinical trial plan for this product.

Our therapeutic cell development efforts to date have focused on using our technology to grow larger quantities of the desired therapeutic cells from small starting amounts of cells or a tissue. Our cell production processes are based on using the natural reproductive capabilities of cells outside the body, 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 research has no direct impact on our current product programs.

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 AastromReplicellTM Cell Production 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 reorganization. While the marketing activities were initiated this year for the CE Marked SC-I, DC-I and the DCV-I products, we do not expect to generate positive cash flows from operations for at least the next several years and then only if more significant product sales commence. Until that time, we expect that our revenue sources will be limited to grant revenue and research funding, milestone payments and licensing fees from potential future corporate collaborators. To date, we have financed our operations 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, 2002, we have accumulated losses of approximately \$93 million. There can be no assurance that we will be able to achieve profitability on a sustained basis, if at all, obtain the required funding, or complete a corporate partnering or acquisition transaction.

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 and revenue recognition.

Inventory. We value our inventory that consists primarily of finished components of our lead product, the AastromReplicellTM 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

[Table of Contents](#)

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 and product sales. 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, 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 \$877,000 in 2002, \$899,000 in 2001, and \$1,150,000 in 2000. Revenues include product sales and rentals of \$80,000 in 2002, \$85,000 in 2001 and \$169,000 in 2000, reflecting the pilot-scale marketing of our lead product, the AastromReplicellTM System. We commenced our initial pilot-scale product launch in Europe of the AastromReplicellTM Cell Production System (System) in fiscal year 1999, but subsequently suspended those activities in fiscal year 2000 pending the receipt of additional financing. Marketing activities were resumed during fiscal year 2001. Grant revenues decreased to \$797,000 in 2002 from \$814,000 in 2001, and from \$981,000 in 2000, 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 91% of total revenues for the years ended June 30, 2002 and 2001 and 85% in 2000 and are recorded on a cost-reimbursement basis.

Total costs and expenses were \$9,158,000 in 2002, \$7,478,000 in 2001 and \$10,904,000 in 2000. The increase in costs and expenses from 2001 to 2002 is principally the result of increased selling, general and administrative expenses to \$3,528,000 in 2002 from \$2,482,000 in 2001, reflecting the expansion of marketing activities to further commercialization efforts in Europe. Research and development expenses increased to \$5,428,000 in 2002 from \$4,983,000 in 2001, reflecting increased research and product development activities in the areas of dendritic cell vaccines and tissue regeneration. The increase in cost of product sales and rentals to \$202,000 in 2002 from \$13,000 in 2001, relates to the provision recorded in 2002 for obsolete and excess AastromReplicellTM System inventory. The decrease in costs and expenses from 2000 to 2001 is principally the result of decreased research and development expense to \$4,938,000 in 2001 from \$6,289,000 in 2000, reflecting declining development activities for the AastromReplicellTM System. Cost of product sales and rentals of \$1,251,000 in 2000 consisted principally of AastromReplicellTM System inventory that was written off in connection with the suspension of marketing activities. Research and development expense includes a charge of \$1,100,000 in 2000, representing a payment pursuant to our supply agreement with Immunex. This license agreement was extended through March 2006, without further annual renewal payments. General and

[Table of Contents](#)

administrative expenses decreased to \$2,482,000 in 2001 from \$3,364,000 in 2000, reflecting planned expense reduction measures associated with the suspension of marketing activities.

Interest income was \$342,000 in 2002, \$653,000 in 2001 and \$364,000 in 2000. 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 \$7,939,000, or \$.19 per common share in 2002, \$5,926,000, or \$.17 per common share in 2001, and \$9,390,000, or \$.41 per common share in 2000. The computation of net loss per common share in 2000 includes the impact of dividends and yields on outstanding preferred stock as well as one-time charges related to the sale of preferred stock. The one-time charge of dividends and yields affect only the computation of net loss per common share and is not included in the net loss for the periods. 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. At June 30, 2002, our Federal tax net operating loss and tax credit carryforwards were \$89,900,000 and \$2,450,000, respectively, which will expire from 2004 through 2022, if not utilized. In July 1998, we issued shares of 1998 Series I Convertible Preferred Stock which resulted in a change in ownership and an annual limitation of \$3,136,000, which applies to losses incurred between October 1993 and July 1998. As of June 2002, the portion of our net operating loss that remains subject to this limitation is approximately \$41,000,000. Our ability to utilize our net operating loss and tax credit carryforwards may become subject to further annual limitation in the event of other change 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, 2002, have totaled approximately \$105 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 historically allowed us to maintain adequate levels of cash and other liquid investments.

Our combined cash, cash equivalents and short-term investments totaled \$9,605,000 at June 30, 2002, a decrease of \$1,054,000 from June 30, 2001. During the year ended June 30, 2002, we raised net proceeds of \$7,848,000 through the sale of our equity securities. The primary uses of cash, cash equivalents and short-term investments during the year ended June 30, 2002 included \$8,749,000 to finance our operations and working capital requirements, and \$153,000 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 into the first quarter of fiscal year 2004. We are currently pursuing additional sources of financing. If we cannot obtain additional funding prior to the end of the second quarter of fiscal year 2003, we will make substantial reductions in the scope and size of our operations, and may curtail activities currently planned to be resumed, in order to conserve cash until such funding is obtained. 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.

[Table of Contents](#)

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 June 2001, the Financial Accounting Standards Board (FASB) issued SFAS No. 143, “Accounting for Asset Retirement Obligations.” SFAS No. 143 requires companies to recognize the fair value of a liability for an asset retirement obligation in the period in which it is incurred if a reasonable estimate of fair value can be made. The identified asset retirement costs are capitalized as part of the carrying amount of the asset and depreciated over the remaining useful life. SFAS No. 143 is effective for the Company in fiscal year 2003.

In August 2001, the FASB issued SFAS No. 144, “Accounting for the Impairment or Disposal of Long-Lived Assets.” SFAS No. 144 establishes a single model for the impairment of long-lived assets and broadens the presentation of discontinued operations to include more disposal transactions. SFAS No. 144 is effective for the Company in fiscal year 2003.

The adoption of SFAS No. 143 and No. 144 are being evaluated by management and are not expected to have a significant impact on the Company’s financial position or result of operations.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

As of June 30, 2002, our cash and cash equivalents included money market securities and commercial paper. 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.

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, 2002, we have incurred net losses totaling approximately \$93 million. These losses have resulted principally from costs incurred in the research and development of our cell culture technologies and the AastromReplicellTM 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

[Table of Contents](#)

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 lead product candidate, the AastromReplicellTM Cell Production System, will require additional research and development as well as substantial clinical trials. While we have commenced initial marketing on a limited basis of the AastromReplicellTM System in Europe, we believe that the United States will be the principal market for our products. We may not be able to successfully complete development of the AastromReplicellTM System or our other 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 intended 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 expected interest income will be sufficient to finance currently planned activities through the first quarter of fiscal year 2004. We are currently pursuing additional sources of financing. If we cannot obtain additional funding prior to the end of second quarter of fiscal year 2003, we will make substantial reductions in the scope and size of our operations, and may curtail activities currently planned to be resumed, in order to conserve cash until such funding is obtained. In order to grow and expand our business, and to introduce our product candidates in to 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.

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 and patent prosecutions;
- 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

[Table of Contents](#)

adequate funds are not available, 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, additional equity funding will be necessary 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. At present, pursuant to two separate shareholder approved resolutions, the Board of Directors has the authority to increase the maximum number of authorized shares from 60 million to 150 million.

The warrants have the potential for substantial dilution.

We have outstanding warrants to purchase 2,614,386 shares of common stock at \$1.58 per share and outstanding options to purchase 3,529,102 shares at a weighted average price of \$1.58 per share outstanding. Holders of common stock could therefore experience dilution of their investment upon exercise of these warrants and options.

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 \$0.36 and \$2.40, for fiscal year 2002. 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;
- 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; and
- changes in potential recommendations by securities analysts.

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. For example, within the last year, our stock price has experienced a day where it closed at approximately 26% over the previous day's closing price and another day when it dropped by over 19% from the previous day's closing price.

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

We were required to meet certain financial tests (including, but not limited to, a minimum bid price of our common stock of \$1.00) to maintain the listing of our common stock on the Nasdaq Stock Market. As a result of recent price fluctuations, our common stock price has traded below the \$1.00 minimum level and we were notified that our common stock would be delisted if we did not regain compliance with this listing requirement prior February 24, 2003. If we do not remain listed on Nasdaq, the market price and liquidity of

[Table of Contents](#)

our common stock could be impaired. Further, the National Association of Securities Dealers has recently adopted a change in minimum listing requirements to include a new \$2.5 million of minimum net equity requirement for the SmallCap Market, which we currently meet. This new standard will replace the minimum tangible net worth requirement and becomes effective for us in November 2002. The result of such a change, or further changes, may be that it will be more difficult for us to maintain compliance with the listing standards, the result of which would be that our stock may be delisted.

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

To be able to market products in the United States, we must demonstrate, through extensive preclinical studies and clinical trials, the safety and efficacy of our processes and product candidates, together with the cells produced by such processes in such products, for application in the treatment of humans. We are currently conducting clinical trials to demonstrate the safety and biological activity of patient-derived cells produced in the AastromReplicell™ System. Depending on the availability of resources, we intend to commence at least one additional clinical trial to demonstrate the safety and biological activity of umbilical cord blood cells produced in the AastromReplicell™ System. 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 stem 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 U.S. Food and Drug Administration (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 product candidates may commence in the United States, which we believe will be the principal 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. Many of the patients enrolled in the clinical trials will have previously undergone extensive treatment which will have substantially weakened the patients and may have irreparably damaged the ability of their blood and immune system to recover. Some patients undergoing the transplant recovery process have died, from causes that were, according to the physicians involved, unrelated to the AastromReplicell™ System procedure, and it is possible that other patients may die or suffer severe complications during the course of either the current or future clinical trials. In addition, 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 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.

Our product development efforts are primarily directed toward obtaining regulatory approval to market the AastromReplicellTM System as an alternative to, or as an improvement for, the bone marrow harvest and peripheral blood progenitor cell stem cell collection methods. These stem cell collection methods have been widely practiced for a number of years, and our technologies or product candidates may not be accepted by the marketplace as readily as these or other competing processes and methodologies. Additionally, 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. As a result, 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.

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 to manufacture our product candidates and their component parts. We also rely solely on third party suppliers such as Plexus, Moll, Biowhittaker and Amgen to provide necessary key mechanical components, 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. Plexus has elected to exercise its right to terminate our Manufacturing Supply Agreement effective in February 2004. As a result, we are in advanced negotiations with another supplier that is currently expected to result in an assured supply on commercially reasonable terms. However, there can be no assurance that the new agreement will be completed or that the new agreement will be on terms as favorable to us as the existing contract. 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.

On September 10, 2002 a major creditor of Moll filed an involuntary petition for Bankruptcy against Moll. On September 19, 2002 Moll announced that it had converted the case to a voluntary Chapter 11 reorganization case and had received preliminary approval for a \$50 million debtor-in-possession financing. Although there is a risk that these factors may affect our supply of components, we believe that Moll will continue to meet our supply needs.

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.

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

While we have commenced initial marketing on a limited basis of the AastromReplicellTM System and SC-I, CB-I, DC-I and DCV-I therapy kits in Europe, we have only limited internal sales, marketing and distribution capabilities. We intend to market our products through collaborative relationships with companies with established sales, marketing and distribution capabilities. Our inability to develop and maintain those relationships would limit our ability to market, sell and distribute our products. Our inability to enter into successful, long-term relationships could require us to develop alternate arrangements at a time when we need sales, marketing or distribution capabilities to meet existing demand.

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, a change in the regulatory classification would affect our ability to obtain FDA approval of our products. The AastromReplicell™ System is capable of producing different cell mixtures, and at least some of these cell mixtures will, under current regulations be regulated as biologic 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 stem cell therapy may have limited clinical benefit in the treatment of breast cancer, which was a significant portion of the overall stem cell transplant market. This has 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 has been or is 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, worldwide 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

[Table of Contents](#)

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 in breast cancer that constitute 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; and
- replacement of manufacturing sources.

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 Report on Form 10-K are made as of the date hereof. We assume no obligation to update any such forward-looking statement or reason why actual results might differ.

[Table of Contents](#)

Item 8. Financial Statements and Supplementary Data

	<u>Page</u>
Report of Independent Accountants	34
Consolidated Balance Sheets as of June 30, 2001 and 2002	35
Consolidated Statements of Operations for the years ended June 30, 2000, 2001 and 2002 and for the Period from March 24, 1989 (Inception) to June 30, 2002	36
Consolidated Statements of Shareholders' Equity from March 24, 1989 (Inception) to June 30, 2002	37
Consolidated Statements of Cash Flows for the years ended June 30, 2000, 2001 and 2002 and for the Period from March 24, 1989 (Inception) to June 30, 2002	38
Notes to Consolidated Financial Statements	39

REPORT OF INDEPENDENT ACCOUNTANTS

To the Board of Directors and Shareholders of

Aastrom Biosciences, Inc.

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, of shareholders' equity and of cash flows present fairly, in all material respects, the consolidated financial position of Aastrom Biosciences, Inc. (a development stage company) at June 30, 2001 and 2002, and the results of its operations and its cash flows for each of the three years in the period ended June 30, 2002, and for the period from March 24, 1989 (Inception) to June 30, 2002, in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management; our responsibility is to express an opinion on these financial statements 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, 2002, except for Note 9,
which is as of August 30, 2002

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

	June 30,	
	2001	2002
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 10,659,000	\$ 8,605,000
Short-term investments	—	1,000,000
Receivables, net	129,000	120,000
Inventory, net	725,000	1,397,000
Other current assets	213,000	225,000
	<u>11,726,000</u>	<u>11,347,000</u>
PROPERTY, NET	<u>179,000</u>	<u>206,000</u>
	<u>\$ 11,905,000</u>	<u>\$ 11,553,000</u>
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	\$ 856,000	\$ 589,000
Accrued employee expenses	155,000	161,000
	<u>1,011,000</u>	<u>750,000</u>
COMMITMENTS (Note 6)		
SHAREHOLDERS' EQUITY:		
Common Stock, no par value; shares authorized — 60,000,000; shares issued and outstanding — 37,681,235 and 43,726,557, respectively	96,752,000	104,600,000
Deficit accumulated during the development stage	(85,858,000)	(93,797,000)
	<u>10,894,000</u>	<u>10,803,000</u>
	<u>\$ 11,905,000</u>	<u>\$ 11,553,000</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
	2000	2001	2002	(Inception) to June 30, 2002
REVENUES:				
Product sales and rentals	\$ 169,000	\$ 85,000	\$ 80,000	\$ 368,000
Research and development agreements	—	—	—	2,020,000
Grants	981,000	814,000	797,000	5,828,000
Total revenues	1,150,000	899,000	877,000	8,216,000
COSTS AND EXPENSES:				
Cost of product sales and rentals	1,251,000	13,000	202,000	1,472,000
Research and development	6,289,000	4,983,000	5,428,000	81,501,000
Selling, general and administrative	3,364,000	2,482,000	3,528,000	24,110,000
Total costs and expenses	10,904,000	7,478,000	9,158,000	107,083,000
LOSS FROM OPERATIONS	(9,754,000)	(6,579,000)	(8,281,000)	(98,867,000)
OTHER INCOME (EXPENSE):				
Other income	—	—	—	1,237,000
Interest income	364,000	653,000	342,000	5,068,000
Interest expense	—	—	—	(267,000)
Total other income	364,000	653,000	342,000	6,038,000
NET LOSS	\$ (9,390,000)	\$ (5,926,000)	\$ (7,939,000)	\$ (92,829,000)
COMPUTATION OF NET LOSS APPLICABLE TO COMMON SHARES:				
Net loss	\$ (9,390,000)	\$ (5,926,000)	\$ (7,939,000)	
Dividends and yields on preferred stock	(208,000)	—	—	
Net loss applicable to common shares	\$ (9,598,000)	\$ (5,926,000)	\$ (7,939,000)	
NET LOSS PER COMMON SHARE (Basic and Diluted)	\$ (.41)	\$ (.17)	\$ (.19)	
Weighted average number of common shares Outstanding	23,344,000	34,030,000	42,121,000	

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					(69,574,000)	(69,574,000)
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			1,531,451	230,000		230,000
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	(11,858,648)	(48,578,000)	10,796,791	48,578,000		—
Compensation expense related to stock options granted				529,000		529,000
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
Dividends and yields on preferred stock		258,000	148,568	502,000	(760,000)	—
Repurchase and retirement of Common Shares outstanding			(32,171)	(73,000)		(73,000)
BALANCE, JUNE 30, 1999	7,000	6,588,000	16,980,161	72,257,000	(70,334,000)	8,511,000
Net loss and comprehensive loss					(9,390,000)	(9,390,000)
Dividend and yields on preferred stock		208,000			(208,000)	—
Exercise of stock options and warrants			405,753	409,000		409,000
Conversion of preferred stock	(7,000)	(6,796,000)	10,956,918	6,796,000		—
Compensation expense related to stock options granted				5,000		5,000
Issuance of common stock, net of issuance costs of \$200,000			5,264,827	12,900,000		12,900,000
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

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
	2000	2001	2002	(Inception) to June 30, 2002
OPERATING ACTIVITIES:				
Net loss	\$ (9,390,000)	\$ (5,926,000)	\$ (7,939,000)	\$(92,829,000)
Adjustments to reconcile net loss to net cash used for operating activities:				
Depreciation and amortization	346,000	171,000	126,000	3,327,000
Loss on property held for resale	—	—	—	110,000
Amortization of discounts and premiums on investments	(21,000)	(69,000)	—	(543,000)
Stock compensation expense	5,000	120,000	—	664,000
Inventory write downs and reserves	1,027,000	—	202,000	1,229,000
Stock issued pursuant to license agreement	1,100,000	—	—	3,300,000
Changes in assets and liabilities:				
Receivables	(129,000)	113,000	9,000	(144,000)
Inventory	117,000	(725,000)	(874,000)	(2,626,000)
Other current assets	95,000	(55,000)	(12,000)	(225,000)
Accounts payable and accrued expenses	1,000	19,000	(267,000)	589,000
Accrued employee expenses	(28,000)	(10,000)	6,000	161,000
Net cash used for operating activities	(6,877,000)	(6,362,000)	(8,749,000)	(86,987,000)
INVESTING ACTIVITIES:				
Organizational costs	—	—	—	(73,000)
Purchase of short-term investments	(10,660,000)	(1,500,000)	(5,500,000)	(62,124,000)
Maturities of short-term investments	—	12,250,000	4,500,000	61,667,000
Capital purchases	(136,000)	(58,000)	(153,000)	(2,796,000)
Proceeds from sale of property held for resale	—	—	—	400,000
Net cash provided by (used for) investing activities	(10,796,000)	10,692,000	(1,153,000)	(2,926,000)
FINANCING ACTIVITIES:				
Issuance of preferred stock	—	—	—	51,647,000
Issuance of common stock	12,209,000	4,265,000	7,848,000	44,563,000
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	12,209,000	4,265,000	7,848,000	98,518,000
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(5,464,000)	8,595,000	(2,054,000)	8,605,000
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	7,528,000	2,064,000	10,659,000	—
CASH AND CASH EQUIVALENTS AT END OF PERIOD	\$ 2,064,000	\$ 10,659,000	\$ 8,605,000	\$ 8,605,000
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 and *ex vivo* gene 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 into the first quarter of fiscal year 2004 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 include, 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.

The Company is currently pursuing additional sources of financing. If the Company cannot obtain additional funding prior to the end of the second quarter of fiscal year 2003, it will make substantial reductions in the scope and size of its operations, and may curtail activities currently planned to be resumed, in order to conserve cash until such funding is obtained.

Significant Revenue Relationships — One company accounted for 22% of total revenues for the period from Inception to June 30, 2002. However, for the fiscal year ended June 30, 2002, 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, 2002, 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, 2002 the Company has not experienced unrealized gains or losses on its investments.

AASTROM BIOSCIENCES, INC.
(a development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Diversity of Credit Risk — The Company invests its excess cash in U.S. government securities and 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.

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.

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. 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, 2002.

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.

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 Common 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

AASTROM BIOSCIENCES, INC.
(a development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

common equivalent shares that have been excluded from the computations of net loss per common share for the periods ended June 30, 2000, 2001 and 2002 is approximately 2,390,000, 4,662,000 and 6,143,000, respectively. The computation of net loss per common share for the year ended June 30, 2000 reflects dividends and yields on outstanding preferred stock which affect only the computation of net loss per common share and are not included in the computation of net loss for the period.

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 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 and long-lived assets to be disposed of whenever events or changes in circumstances indicate that the carrying amount of those assets may not be recoverable. No significant impairment losses have been identified by the Company for any of the periods presented in the accompanying financial statements.

New Accounting Standards — In June 2001, the Financial Accounting Standards Board (FASB) issued SFAS No. 143, "Accounting for Asset Retirement Obligations." SFAS No. 143 requires companies to recognize the fair value of a liability for an asset retirement obligation in the period in which it is incurred if a reasonable estimate of fair value can be made. The identified asset retirement costs are capitalized as part of the carrying amount of the asset and depreciated over the remaining useful life. SFAS No. 143 is effective for the Company in fiscal year 2003.

In August 2001, the FASB issued SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets." SFAS No. 144 establishes a single model for the impairment of long-lived assets and broadens the presentation of discontinued operations to include more disposal transactions. SFAS No. 144 is effective for the Company in fiscal year 2003.

The adoption of SFAS No. 143 and No. 144 are being evaluated by management and are not expected to have a significant impact on the Company's financial position or result of operations.

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:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Market Value
June 30, 2002				
Commercial Paper	\$1,000,000	\$ —	\$ —	\$1,000,000
	_____	_____	_____	_____

The Company did not have any short-term investments at June 30, 2001.

Receivables — Receivables are presented, net of allowance for doubtful accounts of \$34,000 at June 30, 2001 and 2002.

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 at June 30, 2002. The Company had no such reserve at June 30, 2001.

Property — Property consists of the following:

	June 30,	
	2001	2002
Machinery and equipment	\$ 1,381,000	\$ 1,440,000
Office equipment	918,000	956,000
Leasehold improvements	622,000	622,000
Equipment under lease	120,000	120,000
	3,041,000	3,138,000
Less accumulated depreciation and amortization	(2,862,000)	(2,932,000)
	\$ 179,000	\$ 206,000

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

	June 30,	
	2001	2002
Accounts payable	\$257,000	\$351,000
Accrued expenses:		
Clinical studies	139,000	135,000
Professional services	49,000	10,000
Manufacturing and engineering	277,000	53,000
Deferred revenue	80,000	—
Other	54,000	40,000
	\$856,000	\$589,000

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 7,920,965 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.

Under the Company's outside directors' stock option plan, non-qualified options to purchase 10,000 shares of common stock are granted 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.

AASTROM BIOSCIENCES, INC.
(a development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

As allowed by SFAS 123, the Company does not recognize compensation expense on stock options granted to employees. If the Company had elected to recognize compensation expense based upon the fair value at the grant dates for stock option awards granted in 2000, 2001 and 2002, in accordance with SFAS No. 123, the pro forma net loss and net loss per common share would be as follows.

	Year Ended June 30,		
	2000	2001	2002
Net loss:			
As reported	\$9,390,000	\$5,926,000	\$7,939,000
Pro forma	9,829,000	6,976,000	9,182,000
Net loss per common share:			
As reported	\$ (.41)	\$ (.17)	\$ (.19)
Pro forma	(.43)	(.21)	(.22)

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,		
	2000	2001	2002
Dividend rate	None	None	None
Expected stock price volatility	80%	100%	100%
Risk-free interest rate	5.8% - 6.3%	4.8% - 5.9%	4.0% - 4.8%
Expected life of options	1 - 4 years	4 years	4 years

The weighted average fair value of options granted during the years ended June 30, 2000, 2001 and 2002 was \$.43, \$1.93 and \$.80 per share, respectively.

AASTROM BIOSCIENCES, INC.
(a development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

The following table summarizes option activity:

	Options Outstanding	Options Available for Grant Under Option Plans	Weighted Average Exercise Price Per Share	Options Exercisable At Period End
March 24, 1989 (Inception)				
Options authorized	—	2,999,927		
Options canceled	(995,456)	995,456	\$3.09	
Options granted	3,834,201	(3,734,201)	\$2.64	
Options exercised	(1,531,451)	—	\$.28	
Balance, June 30, 1999.	1,307,294	261,182	\$3.60	729,786
Options authorized	—	1,400,000		
Options canceled	(1,091,612)	991,612	\$3.64	
Options granted	1,058,500	(1,058,500)	\$1.02	
Options exercised	(86,126)	—	\$1.72	
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	(230,042)	—	\$.99	
Balance, June 30, 2001.	2,047,862	2,054,446	\$2.03	880,171
Options authorized	—	2,100,000		
Options canceled	(412,324)	412,324	\$1.41	
Options granted	1,893,564	(1,893,564)	\$1.05	
Balance, June 30, 2002.	3,529,102	2,673,206	\$1.58	1,331,815

The following table summarizes information about stock-based compensation plans as of June 30, 2002:

Range of Exercise Prices	Number of Options Outstanding	Remaining Contractual Life — Years	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price of Exercisable Options
\$.30 - \$.99	864,513	8.4	\$.82	505,668	\$.84
\$1.05 - \$1.91	1,697,339	9.0	\$1.13	295,462	\$1.20
\$2.44 - \$2.94	788,750	8.2	\$2.92	362,766	\$2.91
\$3.20 - \$3.56	163,500	6.5	\$3.39	152,919	\$3.39
\$4.75 - \$7.00	15,000	5.2	\$5.67	15,000	\$5.67
	3,529,102		\$1.58	1,331,815	\$1.83

Effective July 1, 2000, the Company adopted Financial Accounting Standards Board Interpretation Number 44 to APB 25 (Interpretation No. 44) as it relates to options to purchase 759,000 shares of common stock issued by the Company in December 1999. As a result, 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 is included in research and

AASTROM BIOSCIENCES, INC.
(a development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

development expense. During fiscal year 2002, there was no impact to earnings because the Company's stock price did not exceed \$2.41. At June 30, 2002, options to purchase 373,000 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, 2000, 2001 and 2002, 19,627 shares, 14,558 shares and 42,075 shares, respectively, of common stock were purchased under this plan. From inception to June 30, 2002, 116,995 shares were purchased under this plan.

Stock Purchase Warrants — In connection with the sale of common stock in February 2000, the Company issued a three-year warrant that is exercisable into 2,614,386 shares of common stock at an exercise price of \$1.58. The warrant contains an anti-dilution provision that may be triggered by future financings of the Company at prices below the exercise price. The warrant is subject to early termination if the closing bid price (as defined) of Aastrom's common stock exceeds \$7.39 per share for ten consecutive trading days.

Common Shares Reserved — As of June 30, 2002, the Company has reserved shares of common stock for future issuance as follows:

Issuance under stock option and stock purchase plans	6,335,313
Issuance under stock purchase warrants	2,614,386
	8,949,699

No cash dividends have ever been declared or paid.

4. Income Taxes

Deferred tax assets consist of the following:

	June 30,	
	2001	2002
Net operating loss carryforwards	\$ 28,900,000	\$ 31,480,000
Tax credits and other	2,637,000	2,855,000
	31,537,000	34,335,000
Gross deferred tax assets	31,537,000	34,335,000
Valuation allowance	(31,537,000)	(34,335,000)
	\$ —	\$ —

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 valuation allowance as of June 30, 1999 was \$26,028,000.

At June 30, 2002, the Company's Federal tax net operating loss and tax credit carryforwards were \$89,900,000 and \$2,450,000, respectively, which will expire from 2004 through 2022, if not utilized. In July 1998, the Company issued shares of 1998 Series 1 Convertible Preferred Stock which resulted in a change in ownership and an annual limitation of \$3,136,000, which applies to losses incurred between October 1993 and July 1998. As of June 2002, the portion of the Company's net operating loss that remains subject to this

AASTROM BIOSCIENCES, INC.
(a development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

limitation is approximately \$41 million. 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 other 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.

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 renewal fee due in March 2000 was paid through the issuance of common stock valued at \$1,100,000, which is included in research and development expense. The license agreement has been extended for an additional five-year term, ending March 2006, with no additional annual renewal fees due.

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
2003	\$ 596,000
2004	596,000
2005	298,000
	<u>\$1,490,000</u>

Rent expense for the years ended June 30, 2000, 2001 and 2002, was \$485,000, \$495,000 and \$547,000, respectively, and \$3,861,000 for the period from Inception to June 30, 2002.

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. Through June 30, 2002, the Company has made contributions of \$146,000. There were no contributions made by the Company during the years ended June 30, 2001 and 2000.

AASTROM BIOSCIENCES, INC.
(a development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

8. Quarterly Financial Data (Unaudited)

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)

Year Ended June 30, 2001	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Fiscal Year
Revenues	\$ 167,000	\$ 295,000	\$ 191,000	\$ 246,000	\$ 899,000
Loss from operations	(1,615,000)	(1,094,000)	(1,863,000)	(2,007,000)	(6,579,000)
Net loss	(1,406,000)	(916,000)	(1,715,000)	(1,889,000)	(5,926,000)
Net loss per common share	(.04)	(.03)	(.05)	(.05)	(.17)

9. Subsequent Events

During the period from July 1, 2002 through August 30 2002, the Company has issued 1,554,507 shares of its common stock for cash proceeds of approximately \$675,127.

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 2002 Annual Meeting of Shareholders to be held on November 14, 2002.

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."

PART IV

Item 14. Exhibits, Financial Statement Schedules and Reports on Form 8-K

(a) The following documents are filed as part of this Report:

1. *Financial Statements.*

All schedules are omitted because they are not applicable or not required, or because the required information is included in the Financial Statements or Notes thereto.

3. *Exhibits:*

See Exhibit Index.

(b) *Reports on Form 8-K:*

No reports on Form 8-K were filed during the fourth quarter.

EXHIBIT INDEX

Number	Notes	Description of Document
3.1		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.
10.59	H	Stock Purchase Warrant dated February 29, 2000.
10.62	I	Stock Purchase Warrant dated June 8, 2000.
10.63#	J	Agreement Regarding Pay-to-Stay, by and between Aastrom and R. Douglas Armstrong, Ph.D. dated April 28, 2000.
10.65#	J	Agreement Regarding Pay-to-Stay, by and between Aastrom and Brian S. Hampson dated April 28, 2000.
10.66#	J	Form of Retention Bonus Agreement, by and between Aastrom and each of Brian S. Hampson and Bruce W. Husel.
10.67#	J	Form of Relocation Bonus Agreement, by and between Aastrom and each of Brian S. Hampson and Bruce W. Husel.
10.69#	K	Employment Agreement, dated February 1, 2001, by and between Aastrom and Steven Wolff.
10.70		Seventh Amendment to office lease.
10.71		Employment Agreement between Aastrom and Michael Durski.
10.72		Aastrom Biosciences 2001 Stock Option Plan.
23.1		Consent of Independent Accountants.
99.1		Certification of President and CEO.

[Table of Contents](#)

Number	Notes	Description of Document
99.2		Certification of Vice President, Finance & Administration, Chief Financial Officer, Secretary and Treasurer.
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.
H		Incorporated by reference to Aastrom's Report on Form 8-K filed on March 3, 2000.
I		Incorporated by reference to Aastrom's Registration Statement on Form S-3 (333-39698), as filed on June 20, 2000.
J		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.
K		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.
†		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.

MICHIGAN DEPARTMENT OF CONSUMER & INDUSTRY SERVICES
BUREAU OF COMMERCIAL SERVICES

Date Received (FOR BUREAU USE ONLY)

This document is effective on the date filed, unless a subsequent effective date within 90 days after received date is stated in the document.

Name
Randy M. Awdish

Address
36th Floor, 100 Renaissance Center

City State ZIP Code
Detroit MI 48243

Effective Date:

DOCUMENT WILL BE RETURNED TO THE NAME AND ADDRESS YOU ENTER ABOVE.
IF LEFT BLANK DOCUMENT WILL BE MAILED TO THE REGISTERED OFFICE.

RESTATED ARTICLES OF INCORPORATION
FOR USE BY DOMESTIC PROFIT CORPORATIONS
(Please read information and instructions on the last page)

Pursuant to the provisions of Act 284, Public Acts of 1972, the undersigned corporation executes the following Articles:

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

2. The identification number assigned by the Bureau is:
529-456

3. All former names of the corporation are:
Ann Arbor Stromal, Inc.

4. The date of filing the original Articles of Incorporation was:
March 24, 1989

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

ARTICLE I

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

ARTICLE II

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

ARTICLE III

The total authorized shares:

Common Shares 100,000,000 Preferred shares 5,000,000

A statement of all or any of the relative rights, preferences and limitations of the shares of each class is as follows:

See Rider attached hereto and made a part hereof.

ARTICLE IV

1. The address of the registered office is:

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

(Street Address) (City) (ZIP Code)

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

P.O. Box 376 Ann Arbor, Michigan 48106

(Street Address or P.O. Box) (City) (ZIP Code)

3. The name of the resident agent: Michael Durski

ARTICLE V (OPTIONAL. DELETE IF NOT APPLICABLE)

ARTICLE VI (OPTIONAL. DELETE IF NOT APPLICABLE)

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

See Rider attached hereto and made a part hereof.

5. COMPLETE SECTION (a) IF THE RESTATED ARTICLES WERE ADOPTED BY THE UNANIMOUS CONSENT OF THE INCORPORATOR(S) BEFORE THE FIRST MEETING OF THE BOARD OF DIRECTORS; OTHERWISE, COMPLETE SECTION (b). DO NOT COMPLETE BOTH.

- a. These Restated Articles of Incorporation were duly adopted on the _____ day of _____, _____, in accordance with the provisions of Section 642 of the Act by the unanimous consent of the incorporator(s) before the first meeting of the Board of Directors.

Signed this _____ day of _____, _____.

(Signatures of Incorporators; Type or Print Name Under Each Signature)

- b. These Restated Articles of Incorporation were duly adopted on the 9th day of September, 2002, in accordance with the provisions of Section 642 of the Act and: (check one of the following)
- were duly adopted by the Board of Directors without a vote of the shareholders. These Restated Articles of Incorporation only restate and integrate and do not further amend the provisions of the Articles of Incorporation as heretofore amended and there is no material discrepancy between those provisions and the provisions of these Restated Articles.
- were duly adopted by the shareholders. The necessary number of shares as required by statute were voted in favor of these Restated Articles.
- were duly adopted by the written consent of the shareholders having not less than the minimum number of votes required by statute in accordance with Section 407(1) of the Act. Written notice to shareholders who have not consented in writing has been given. (Note: Written consent by less than all of the shareholders is permitted only if such provision appears in the Articles of Incorporation.)
- were duly adopted by the written consent of all the shareholders entitled to vote in accordance with section 407(2) of the Act.
- by consents given by electronic transmissions in accordance with Section 407(3).

Signed this _____ day of _____, _____

By _____
(Signature of an authorized officer or agent)

(Type or Print Name)

Name of person or organization remitting fees:

Pepper Hamilton LLP

Preparer's name and business telephone number:

Rene M.L. Hansemann

313-393-7452

INFORMATION AND INSTRUCTIONS

- 1. The Restated Articles of Incorporation cannot be filed until this form, or a comparable document, is submitted. This form may be used to draft your Articles of Incorporation. A document required or permitted to be filed under the act cannot be filed unless it contains the minimum information required by the act. The format provided contains only the minimal information required to make the document fileable and may not meet your needs. This is a legal document and agency staff cannot provide legal advice.
2. Submit one original of this document. Upon filing, the document will be added to the records of the Bureau of Commercial Services. The original will be returned to your registered office address, unless you enter a different address in the box on the front of this document.
Since the document will be maintained on electronic format, it is important that the filing be legible. Documents with poor black and white contrast, or otherwise illegible, will be rejected.
3. This document is to be used pursuant to sections 641 through 643 of Act 284, P.A. of 1972, for the purpose of restating the Articles of Incorporation of a domestic profit corporation. Restated articles of incorporation are an integration into a single instrument of the current provisions of the corporation's Articles of Incorporation, along with any desired amendments to those articles.
4. Item 2 - Enter the identification number previously assigned by the Bureau. If this number is unknown, leave it blank.
5. Item 5 - Restated Articles of Incorporation submitted before the first meeting of the Board of Directors may be adopted by all of the incorporators by completing Item 5(a). Restated Articles of Incorporation which do not amend the Articles of Incorporation may be adopted by the Board of Directors without a vote of the shareholders by completing Item 5(b). Restated Articles of Incorporation which amend the Articles of Incorporation require adoption by the shareholders by completing Item 5(b).
6. The duration of the corporation should be stated in the restated Articles of Incorporation only if not perpetual.
7. This document is effective on the date endorsed "filed" by the Bureau. A later effective date, no more than 90 days after the date of delivery, may be stated.
8. This document must be signed by: (COMPLETE Item 5(a) or 5(b), BUT NOT BOTH) Item 5(a): a majority of the incorporators. Item 5(b): an authorized officer or agent.
9. FEES: Make remittance payable to the State of Michigan. Include corporation name on check or money order.

Table with 2 columns: Fee Description and Amount. Rows include NONREFUNDABLE FEE (\$10.00) and TOTAL MINIMUM FEE (\$10.00).

ADDITIONAL FEES DUE FOR INCREASED AUTHORIZED SHARES ARE:

Table with 2 columns: Fee Description and Amount. Rows include fees for additional authorized shares, such as 'each additional 20,000 authorized shares or portion thereof' (\$30.00) and 'maximum fee per filing for authorized shares in excess of 10,000,000 shares' (\$200,000.00).

To submit by mail:

Michigan Department of Consumer & Industry Services
Bureau of Commercial Services - Corporation Division
7150 Harris Drive
P.O. Box 30054
Lansing, MI 48909

To submit in person:

6546 Mercantile Way
Lansing, MI

Telephone: (517) 241-6400

Fees may be paid by VISA or Mastercard when delivered in person to our office.

MICH-ELF (Michigan Electronic Filing System):

First Time Users: Call (517) 241-6420, or visit our website at
<http://www.cis.state.mi.us/bcs/corp/>

Customer with MICH-ELF Filer Account: Send document to (517) 241-9845

The Department of Consumer & Industry Services will not discriminate against any individual or group because of race, sex, religion, age, national origin, color, marital status, disability or political beliefs. If you need help with reading, writing, hearing, etc., under the Americans with Disabilities Act, you may make your needs known to this agency.

RIDER TO ARTICLE III

ARTICLE III

PART A: COMMON STOCK

Section 1. Voting Rights.

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

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

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

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

PART B: PREFERRED STOCK

The Preferred Stock may be issued from time to time in one or more series. The Board of Directors of the Corporation is hereby authorized, within the limitations and restrictions

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

RIDER TO ARTICLE VII

ARTICLE VII

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

(a) any breach of the director's duty of loyalty to the Corporation or its shareholders;

(b) any acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;

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

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

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

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

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

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

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

SEVENTH AMENDMENT TO LEASE

This Amendment to Lease is made effective January 1, 2002 by and between DOMINO'S FARMS OFFICE PARK, LLC, a Michigan Corporation, having offices at 24 Frank Lloyd Wright Drive, Ann Arbor, Michigan 48106 ("Landlord"), and AASTROM BIOSCIENCES, INC., a Michigan Corporation, having offices at 24 Frank Lloyd Wright Drive, Ann Arbor, Michigan 48106 ("Tenant").

WHEREAS, Landlord and Tenant entered into a Lease commencing October 1, 1992 (the "Lease") for office space located at Lobby L in the building commonly known as Domino's Farms Prairie House; and

WHEREAS, several modifications have been made to the Lease, including the First, Second, Third, Fourth, Fifth and Sixth Amendments; and

WHEREAS, Tenant has been in a hold-over (month to month) tenancy since the expiration of the Sixth Amendment to Lease; and

WHEREAS, Tenant desires to renew a lease commitment, and Landlord agrees to such lease renewal;

NOW THEREFORE, in consideration of the mutual covenants contained in this Seventh Amendment to Lease, the parties agree to the following:

1. The Premises shall be defined as:
 - > 19,881 square feet of office space located at Lobby L, Level 2 of the building.
 - > 3,080 square feet of storage rooms.
 - > 580 square feet of caged storage (Cages # 4, 5, 7 and 13.)
2. The rental rates currently in effect are:
 - > \$28.66 per square foot for office space of 16,373 square feet
 - > \$20.87 per square foot for office space of 3,508 square feet
 - > \$13.11 per square foot for storage rooms.
 - > \$ 9.55 per square foot for storage cages.
3. The term of this renewal will be three (3) years, and will expire on December 31, 2004.
4. Rental rates as specified above will be increased in the amount of the Consumers Price Index (CPI) for the previous calendar year on May 1, 2002, and each subsequent May 1st for the term of the lease renewal period.

5. Landlord agrees to paint and install new carpeting in portions of the Premises. Tenant will submit a list of areas proposed to be upgraded, and Landlord will provide a bid for performance of requested improvements. Total Landlord contribution for said painting and carpeting will not exceed \$75,000, and will not include costs for moving furniture, cubicles, personal property and communications. Tenant shall be responsible for any costs which exceed the Landlord contribution, as well as costs for moving furniture, cubicles, personal property and communications.
6. The terms and conditions of the Lease shall remain in full force and effect as specifically modified herein.

IN WITNESS WHEREOF, this Seventh Amendment to Lease is executed on the date set forth above.

DOMINO'S FARMS
OFFICE PARK, LLC ("Landlord")
(a Michigan Corporation)

By: _____

Its: _____

AASTROM BIOSCIENCES, INC. ("Tenant")
(A Michigan Corporation)

By: _____

Its: _____

EMPLOYMENT AGREEMENT

This Employment Agreement (the "Agreement") is entered into as of _____ 20____, by and between Aastron Biosciences, Inc., a Michigan corporation ("Employer") and Michael Durski ("Employee").

NOW, THEREFORE, the parties agree as follows:

1. **EMPLOYMENT** Employer hereby engages Employee, and Employee hereby accepts such engagement, upon the terms and conditions set forth herein.

2. **DUTIES** Employee is engaged as Vice President Finance & Administration, Chief Financial Officer. Employee shall perform faithfully and diligently the duties customarily performed by persons in the position for which employee is engaged, together with such other reasonable and appropriate duties as Employer shall designate from time to time. Employee shall devote Employee's full business time and efforts to the rendition of such services and to the performance of such duties. As a full-time employee of Employer, Employee shall not be entitled to provide consulting services or other business or scientific services to any other party, without the prior written consent of Employer.

3. **COMPENSATION**

3.1 **BASE SALARY** During the term of this Agreement, as compensation for the proper and satisfactory performance of all duties to be performed by Employee hereunder, Employer shall pay Employee at an annual salary rate of One hundred Sixty-Five Thousand Dollars (\$165,000), payable in semi-monthly installments, less required deductions for state and federal withholding tax, Social Security and all other employee taxes and payroll deductions. The base salary shall be subject to review and adjustment on an annual basis.

4. **TERM**

4.1 **COMMENCEMENT** The employment relationship pursuant to this Agreement shall commence on or before Monday, February 4, 2002.

4.2 **TERMINATION AT WILL** Although Employer and Employee anticipate a long and mutually rewarding employment relationship, either party may terminate this Agreement, without cause, upon fourteen (14) days' prior written notice delivered to the other. It is expressly understood and agreed that the employment relationship is "at will", and with no agreement for employment for any specified term, and with no agreement for employment for so long as Employee performs satisfactorily. Provided, however, before Employer exercises this right of termination at will, Employer shall first either (i) discuss with Employee the needs of Employer and why Employee no longer meets those needs, or (ii) discuss with Employee any concerns or dissatisfactions which Employer has with Employee's performance, and give to Employee a reasonable opportunity to remedy those concerns or dissatisfactions, to the reasonable satisfaction of Employer.

4.3 **TERMINATION FOR CAUSE** Either party may terminate this employment relationship immediately upon notice to the other party in the event of any good cause, such as a default, dishonesty, neglect of duties, failure to perform by the other party, or death or disability of Employee.

4.4 **PAYMENT OF COMPENSATION UPON TERMINATION** Upon termination for cause, Employee shall be entitled to the compensation set forth as "base salary" herein, prorated to the effective date of such termination as full compensation for any and all claims of Employee under this Agreement.

5. FRINGE BENEFITS

5.1 CUSTOMARY FRINGE BENEFITS Employee shall be entitled to such fringe benefits as Employer customarily makes available to employees of Employer engaged in the same or similar position as Employee ("Fringe Benefits"). Such Fringe Benefits may include vacation leave, sick leave, and health insurance coverage. Employer reserves the right to change the Fringe Benefits on a prospective basis, at any time, effective upon delivery of written notice to Employee.

5.2 ACCUMULATION Employee shall not earn and accumulate unused vacation in excess of Fifteen (15) days. Employee shall not earn and accumulate sick leave or other Fringe Benefits in excess of an unused amount equal to twice the amount earned for one year. Further, Employee shall not be entitled to receive payments in lieu of said Fringe Benefits, other than for unused vacation leave earned and accumulated at the time the employment relationship terminates.

6. INVENTION, TRADE SECRETS AND CONFIDENTIALITY

6.1 DEFINITIONS

6.1.1 Invention Defined. As used herein "Invention" means inventions, discoveries, concepts, and ideas, whether patentable or copyrightable or not, including but not limited to processes, methods, formulas, techniques, materials, devices, designs, programs (including computer programs), computer graphics, apparatus, products, as well as improvements thereof or know-how related thereto, relating to any present or anticipated business or activities of Employer.

6.1.2 Trade Secret Defined. As used herein "Trade Secret" means, without limitation, any document or information relating to Employer's products, processes or services, including documents and information relating to Inventions, and to the research, development, engineering or manufacture of Inventions, and to Employer's purchasing, customer or supplier lists, which documents or information have been disclosed to Employee or known to Employee as a consequence of or through Employee's employment by Employer (including documents, information or Inventions conceived, originated, discovered or developed by Employee), which is not generally known in the relevant trade or industry.

6.2 INVENTIONS

6.2.1 Disclosure. Employee shall disclose promptly to Employer each Invention, whether or not reduced to practice, which is conceived or learned by Employee (either alone or jointly with others) during the term of his employment with Employer. Employee shall disclose in confidence to Employer all patent applications filed by or on behalf of Employee during the term of his employment and for a period of three (3) years thereafter. Any disclosure of an Invention, or any patent application, made within one (1) year after termination of employment shall be presumed to relate to an Invention made during Employee's term of Employment with Employer, unless Employee clearly proves otherwise.

6.2.2 Employer Property; Assignment. Employee acknowledges and agrees that all Inventions which are discovered, conceived, developed, made, produced or prepared by Employee (alone or in conjunction with others) during the duration of Employee's employment with Employer shall be the sole property of Employer. Said property rights of Employer include without limitation all domestic and foreign patent rights, rights of registration or other protection under the patent and copyright laws, and all other rights pertaining to the Inventions. Employee further agrees that all services, products and Inventions that directly or indirectly result from engagement with Company shall be deemed "works for hire" as that term is defined in Title 17 of the United States Codes, and accordingly all rights associated therewith shall vest in the Company. Notwithstanding the foregoing, Employee hereby assigns to Employer all of Employee's right, title and interest in any such services, products and Inventions, in the event any such services, products and Inventions shall be determined not to constitute "works for hire."

6.2.3 Exclusion Notice. The Assignment by Employee of Inventions under this Agreement does not apply to any Inventions which are owned or controlled by Employee prior to the commencement of employment of Employee by Employer (all of which are set forth on Exhibit "A" hereto). Additionally, Employee is not required to assign an idea or invention where the invention or idea meets all of the following criteria; namely if the invention or idea: (i) was created or conceived without the use of any of Employer's equipment, supplies, facilities, or trade secret information, and (ii) was developed entirely on Employee's own time, and (iii) does not relate to the business of Employer, and (iv) does not relate to Employer's actual or demonstrably anticipated research or development, and (v) does not result from any work performed by Employee for Employer.

6.2.4 Patents and Copyrights; Attorney-in Fact. Both before and after termination of this Agreement (and with reasonable compensation paid by Employer to Employee after termination), Employee agrees to assist the Employer to apply for, obtain and enforce patents on, and to apply for, obtain and enforce copyright protection and registration of, the Inventions described in Section 6.2.2 in any and all countries. To that end, Employee shall (at Employer's request) without limitation, testify in any proceeding, and execute any documents and assignments determined to be necessary or convenient for use in applying for, obtaining, registering and enforcing patent or copyright protection involving any of the Inventions. Employee hereby irrevocably appoints Employer, and its duly authorized officers and agents, as Employee's agent and attorney-in-fact, to act for and in behalf of Employee in filing all patent applications, applications for copyright protection and registration, amendments, renewals, and all other appropriate documents in any way related to the Inventions described in Section 6.2.2.

6.3 TRADE SECRETS

6.3.1 Acknowledgment of Proprietary Interest. Employee recognizes the proprietary interest of Employer in any Trade Secrets of Employer. Employee acknowledges and agrees that any and all Trade Secrets of Employer, whether developed by Employee alone or in conjunction with others or otherwise, shall be and are the property of Employer.

6.3.2 Covenant Not to Divulge Trade Secrets. Employee acknowledges and agrees that Employer is entitled to prevent the disclosure of Trade Secrets of Employer. As a portion of the consideration for the employment of Employee and for the compensation being paid to Employee by Employer, Employee agrees at all times during the term of the employment by Employer and thereafter to hold in strictest confidence, and not to use, disclose or allow to be disclosed to any person, firm, or corporation, Trade Secrets of Employer, including Trade Secrets developed by Employee, other than disclosures to persons engaged by Employer to further the business of Employer, and other than use in the pursuit of the business of Employer.

6.3.3 Confidential Information of Others. Employee represents and warrants that if Employee has any confidential information belonging to others, Employee will not use or disclose to Employer any such information or documents. Employee represents that his employment with Employer will not require him to violate any obligation to or confidence with any other party.

6.4 NO ADVERSE USE Employee will not at any time use Employer's Trade Secrets or Inventions in any manner which may directly or indirectly have an adverse effect upon Employer's business, nor will Employee perform any acts which would tend to reduce Employer's proprietary value in Employer's Trade Secrets or Inventions.

6.5 RETURN OF MATERIALS AT TERMINATION In the event of any termination of Employee's employment, Employee will promptly deliver to Employer all materials, property, documents, data, and other information belonging to Employer or pertaining to Trade Secrets or Inventions. Employee shall not take any materials, property, documents or other information, or any

reproduction or excerpt thereof, belonging to Employer or containing or pertaining to any Trade Secrets or Inventions.

6.6 REMEDIES UPON BREACH In the event of any breach by Employee of the provision in this Section 6, Employer shall be entitled, if it so elects, to institute and prosecute proceedings in any court of competent jurisdiction, either in law or in equity, to enjoin Employee from violating any of the terms of this Section 6, to enforce the specific performance by Employee of any of the terms of this Section 6, and to obtain damages for any of them, but nothing herein contained shall be construed to prevent such remedy or combination of remedies as Employer may elect to invoke. The failure of Employer to promptly institute legal action upon any breach of this Section 6 shall not constitute a waiver of that or any other breach hereof.

7. COVENANT NOT TO COMPETE Employee agrees that, during Employee's employment, Employee will not directly or indirectly compete with Employer in any way, and that Employee will not act as an officer, director, employee, consultant, shareholder, lender or agent of any other entity which is engaged in any business of the same nature as, or in competition with, the business in which Employer is now engaged, or in which Employer becomes engaged during the term of Employee's employment, or which is involved in science or technology which is similar to Employer's science or technology.

8. GENERAL PROVISIONS

8.1 ATTORNEYS' FEES In the event of any dispute or breach arising with respect to this Agreement, the party prevailing in any negotiations or proceedings for the resolution or enforcement thereof shall be entitled to recover from the losing party reasonable expenses, attorneys' fees and costs incurred therein.

8.2 AMENDMENTS No amendment or modification of the terms or conditions of this Agreement shall be valid unless in writing and signed by both parties hereto. There shall be no implied-in-fact contracts modifying the terms of this Agreement.

8.3 ENTIRE AGREEMENT This Agreement constitutes the entire agreement between the parties with respect to the employment of Employee. This Agreement supersedes all prior agreements, understandings, negotiations and representation with respect to the employment relationship.

8.4 SUCCESSORS AND ASSIGNS The Rights and obligations of Employer under this Agreement shall inure to the benefit of and shall be binding upon the successors and assigns of Employer. Employee shall not be entitled to assign any of Employee's rights or obligations under this Agreement.

8.5 WAIVER Either party's failure to enforce any provision of this Agreement shall not in any way be construed as a waiver of any such provision, or prevent that party thereafter from enforcing each and every other provision of this Agreement.

8.6 SEVERABLE PROVISIONS The provisions of this Agreement are severable, and if any or more provisions may be determined to be judicially unenforceable, in whole or in part, the remaining provisions shall nevertheless be binding and enforceable.

8.7 EMPLOYMENT ELIGIBILITY During the term of this Agreement, Employee shall maintain citizenship in the United States or documentation to establish employment eligibility in compliance with the Federal Immigration Reform and Control Act of 1986.

9. EMPLOYEE'S REPRESENTATIONS Employee represents and warrants that Employee (i) is free to enter into this Agreement and to perform each of the terms and covenants contained herein, (ii) is not restricted or prohibited, contractually or otherwise, from entering into and performing this

Agreement, and (iii) will not be in violation or breach of any other agreement by reason of Employee's execution and performance of this Agreement.

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date set forth above.

EMPLOYER:

Aastrom Biosciences, Inc.

By: _____
R. Douglas Armstrong, Ph.D.
President and Chief Executive Officer

EMPLOYEE:

Michael Durski

Address: _____

EXHIBIT A

List of Prior Inventions
(Section 6.2.3)

None, other than the following:

AASTROM BIOSCIENCES, INC.
2001 STOCK OPTION PLAN

1. ESTABLISHMENT, PURPOSE AND TERM OF PLAN.

1.1 ESTABLISHMENT. The Aastrom Biosciences, Inc. 2001 Stock Option Plan (the "PLAN") is hereby established effective as of November 14, 2001 (the "EFFECTIVE DATE").

1.2 PURPOSE. The purpose of the Plan is to advance the interests of the Participating Company Group and its stockholders by providing an incentive to attract and retain persons performing services for the Participating Company Group and by motivating such persons to contribute to the growth and profitability of the Participating Company Group.

1.3 TERM OF PLAN. The Plan shall continue in effect until the earlier of its termination by the Board or the date on which all of the shares of Stock available for issuance under the Plan have been issued and all restrictions on such shares under the terms of the Plan and the agreements evidencing Options granted under the Plan have lapsed. However, all Incentive Stock Options shall be granted, if at all, within ten (10) years from the earlier of the date the Plan is adopted by the Board or the date the Plan is duly approved by the stockholders of the Company.

2. DEFINITIONS AND CONSTRUCTION.

2.1 DEFINITIONS. Whenever used herein, the following terms shall have their respective meanings set forth below:

(a) "BOARD" means the Board of Directors of the Company. If one or more Committees have been appointed by the Board to administer the Plan, "Board" also means such Committee(s).

(b) "CODE" means the Internal Revenue Code of 1986, as amended, and any applicable regulations promulgated thereunder.

(c) "COMMITTEE" means the Compensation Committee or other committee of the Board duly appointed to administer the Plan and having such powers as shall be specified by the Board. Unless the powers of the Committee have been specifically limited, the Committee shall have all of the powers of the Board granted herein, including, without limitation, the power to amend or terminate the Plan at any time, subject to the terms of the Plan and any applicable limitations imposed by law.

(d) "COMPANY" means Aastrom Biosciences, Inc., a Michigan corporation, or any successor corporation thereto.

(e) "CONSULTANT" means a person engaged to provide consulting or advisory services (other than as an Employee or a Director) to a Participating Company.

(f) "DIRECTOR" means a member of the Board or of the board of directors of any other Participating Company.

(g) "DISABILITY" means the permanent and total disability of the Optionee within the meaning of Section 22(e)(3) of the Code.

(h) "EMPLOYEE" means any person treated as an employee (including an Officer or a Director who is also treated as an employee) in the records of a Participating Company and, with respect to any Incentive Stock Option granted to such person, who is an employee for purposes of Section 422 of the Code; provided, however, that neither service as a Director nor payment of a director's fee shall be sufficient to constitute employment for purposes of the Plan. The Company shall determine in good faith and in the exercise of its discretion whether an individual has become or has ceased to be an Employee and the effective date of such individual's employment or termination of employment, as the case may be. For purposes of an individual's rights, if any, under the Plan as of the time of the Company's determination, all such determinations by the Company shall be final, binding and conclusive, notwithstanding that the Company or any court of law or governmental agency subsequently makes a contrary determination.

(i) "EXCHANGE ACT" means the Securities Exchange Act of 1934, as amended.

(j) "FAIR MARKET VALUE" means, as of any date, the value of a share of Stock determined as follows:

(i) If, on such date, the Stock is listed on a national or regional securities exchange or market system, the Fair Market Value of a share of Stock shall be the closing price of a share of Stock (or the mean of the closing bid and asked prices of a share of Stock if the Stock is so quoted instead) as quoted on the Nasdaq National Market, The Nasdaq SmallCap Market or such other national or regional securities exchange or market system constituting the primary market for the Stock, as reported in The Wall Street Journal or such other source as the Company deems reliable. If the relevant date does not fall on a day on which the Stock has traded on such securities exchange or market system, the date on which the Fair Market Value shall be established shall be the last day on which the Stock was so traded prior to the relevant date.

(ii) If, on such date, the Stock is not listed on a national or regional securities exchange or market system, the Fair Market Value of a share of Stock shall be as determined by the Board in good faith without regard to any restriction other than a restriction which, by its terms, will never lapse.

(k) "INCENTIVE STOCK OPTION" means an Option intended to be (as set forth in the Option Agreement) and which qualifies as an incentive stock option within the meaning of Section 422(b) of the Code.

(l) "INSIDER" means an Officer, a Director of the Company or other person whose transactions in Stock are subject to Section 16 of the Exchange Act.

(m) "NONEMPLOYEE DIRECTOR" means a Director of the Company who is not an Employee.

(n) "NONEMPLOYEE DIRECTOR OPTION" means a right to purchase Stock (subject to adjustment as provided in Section 4.2) granted to a Nonemployee Director pursuant to the terms and conditions of Section 7. Nonemployee Director Options shall be Nonstatutory Stock Options.

(o) "NONSTATUTORY STOCK OPTION" means an Option not intended to be (as set forth in the Option Agreement) or which does not qualify as an Incentive Stock Option.

(p) "OFFICER" means any person designated by the Board as an officer of the Company.

(q) "OPTION" means a right to purchase Stock (subject to adjustment as provided in Section 4.2) pursuant to the terms and conditions of the Plan. An option may be either an Incentive Stock Option or a Nonstatutory Stock Option.

(r) "OPTION AGREEMENT" means a written agreement between the Company and an Optionee setting forth the terms, conditions and restriction of the Option granted to the Optionee and any shares acquired upon the exercise thereof. An Option Agreement may consist of a form of "Notice of Grant of Stock Option" and a form of "Stock Option Agreement" incorporated therein by reference, or such other form or forms as the Board may approve from time to time.

(s) "OPTIONEE" means a person who has been granted one or more Options.

(t) "PARENT CORPORATION" means any present or future "parent corporation" of the Company, as defined in Section 424(e) of the Code.

(u) "PARTICIPATING COMPANY" means the Company or any Parent Corporation or Subsidiary Corporation.

(v) "PARTICIPATING COMPANY GROUP" means, at any point in time, all corporations collectively which are then Participating Companies.

(w) "RULE 16b-3" means Rule 16b-3 under the Exchange Act, as amended from time to time, or any successor rule or regulation.

(x) "SECTION 162(m)" means Section 162(m) of the Code.

(y) "SECURITIES ACT" means the Securities Act of 1933, as amended.

(z) "SERVICE" means the Optionee's employment or service with the Participating Company Group, whether in the capacity of an Employee, a Director or a Consultant. The Optionee's Service shall not be deemed to have terminated merely because of a change in the capacity in which the Optionee renders Service to the Participating Company Group or a change in the Participating Company for which the Optionee renders such Service, provided that there is no interruption or termination of the Optionee's Service. Furthermore, the Optionee's Service with the Participating Company Group shall not be deemed to have terminated if the Optionee takes any military leave, sick leave, or other bona fide leave of absence approved by the Company; provided, however, that if any such leave exceeds ninety (90) days, on the ninety-first (91st) day of such leave the Optionee's Service shall be deemed to have terminated unless the Optionee's right to return to Service with the Participating Company Group is guaranteed by statute or contract. Notwithstanding the foregoing, unless otherwise designated by the Company or required by law, a leave of absence shall not be treated as Service for purposes of determining vesting under the Optionee's Option Agreement. The Optionee's Service shall be deemed to have terminated either upon an actual termination of Service or upon the corporation for which the Optionee performs Service ceasing to be a Participating Company. Subject to the foregoing, the Company, in its discretion, shall determine whether the Optionee's Service has terminated and the effective date of such termination.

(aa) "STOCK" means the common stock of the Company, as adjusted from time to time in accordance with Section 4.2.

(bb) "SUBSIDIARY CORPORATION" means any present or future "subsidiary corporation" of the Company, as defined in Section 424(f) of the Code.

(cc) "TEN PERCENT OWNER OPTIONEE" means an Optionee who, at the time an Option is granted to the Optionee, owns stock possessing more than ten percent (10%) of the total combined voting power of all classes of stock of a Participating Company within the meaning of Section 422(b)(6) of the Code.

2.2 CONSTRUCTION. Captions and titles contained herein are for convenience only and shall not affect the meaning or interpretation of any provision of the Plan. Except when otherwise indicated by the context, the singular shall include the plural and the plural shall include the singular. Use of the term "or" is not intended to be exclusive, unless the context clearly requires otherwise.

3. ADMINISTRATION.

3.1 ADMINISTRATION BY THE BOARD. The Plan shall be administered by the Board. All questions of interpretation of the Plan or of any Option shall be determined by the Board, and such determinations shall be final and binding upon all persons having an interest in the Plan or such Option.

3.2 AUTHORITY OF OFFICERS. Any Officer shall have the authority to act on behalf of the Company with respect to any matter, right, obligation, determination or election

which is the responsibility of or which is allocated to the Company herein, provided the Officer has apparent authority with respect to such matter, right, obligation, determination or election.

3.3 POWERS OF THE BOARD. In addition to any other powers set forth in the Plan and subject to the provisions of the Plan, the Board shall have the full and final power and authority, in its discretion:

(a) to determine the persons to whom, and the time or times at which, Options shall be granted and the number of shares of Stock to be subject to each Option;

(b) to designate Options as Incentive Stock Options or Nonstatutory Stock Options;

(c) to determine the Fair Market Value of shares of Stock or other property;

(d) to determine the terms, conditions and restrictions applicable to each Option (which need not be identical) and any shares acquired upon the exercise thereof, including, without limitation, (i) the exercise price of the Option, (ii) the method of payment for shares purchased upon the exercise of the Option, (iii) the method for satisfaction of any tax withholding obligation arising in connection with the Option or such shares, including by the withholding or delivery of shares of stock, (iv) the timing, terms and conditions of the exercisability of the Option or the vesting of any shares acquired upon the exercise thereof, (v) the time of the expiration of the Option, (vi) the effect of the Optionee's termination of Service with the Participating Company Group on any of the foregoing, and (vii) all other terms, conditions and restrictions applicable to the Option or such shares not inconsistent with the terms of the Plan;

(e) to approve one or more forms of Option Agreement;

(f) to amend, modify, extend, cancel or renew any Option or to waive any restrictions or conditions applicable to any Option or any shares acquired upon the exercise thereof;

(g) to accelerate, continue, extend or defer the exercisability of any Option or the vesting of any shares acquired upon the exercise thereof, including with respect to the period following an Optionee's termination of Service with the Participating Company Group;

(h) to prescribe, amend or rescind rules, guidelines and policies relating to the Plan, or to adopt supplements to, or alternative versions of, the Plan, including, without limitation, as the Board deems necessary or desirable to comply with the laws of, or to accommodate the tax policy or custom of, foreign jurisdictions whose citizens may be granted Options; and

(i) to correct any defect, supply any omission or reconcile any inconsistency in the Plan or any Option Agreement and to make all other determinations and take such other actions with respect to the Plan or any Option as the Board may deem advisable to the extent not inconsistent with the provisions of the Plan or applicable law.

3.4 ADMINISTRATION WITH RESPECT TO INSIDERS. With respect to participation by Insiders in the Plan, at any time that any class of equity security of the Company is registered pursuant to Section 12 of the Exchange Act, the Plan shall be administered in compliance with the requirements, if any, of Rule 16b-3.

3.5 COMMITTEE COMPLYING WITH SECTION 162(m). If the Company is a "publicly held corporation" within the meaning of Section 162(m), the Board may establish a Committee of "outside directors" within the meaning of Section 162(m) to approve the grant of any Option which might reasonably be anticipated to result in the payment of employee remuneration that would otherwise exceed the limit on employee remuneration deductible for income tax purposes pursuant to Section 162(m).

3.6 INDEMNIFICATION. In addition to such other rights of indemnification as they may have as members of the Board or officers or employees of the Participating Company Group, members of the Board and any officers or employees of the Participating Company Group to whom authority to act for the Board or the Company is delegated shall be indemnified by the Company against all reasonable expenses, including attorneys' fees, actually and necessarily incurred in connection with the defense of any action, suit or proceeding, or in connection with any appeal therein, to which they or any of them may be a party by reason of any action taken or failure to act under or in connection with the Plan, or any right granted hereunder, and against all amounts paid by them in settlement thereof (provided such settlement is approved by independent legal counsel selected by the Company) or paid by them in satisfaction of a judgment in any such action, suit or proceeding, except in relation to matters as to which it shall be adjudged in such action, suit or proceeding that such person is liable for gross negligence, bad faith or intentional misconduct in duties; provided, however, that within sixty (60) days after the institution of such action, suit or proceeding, such person shall offer to the Company, in writing, the opportunity at its own expense to handle and defend the same.

4. SHARES SUBJECT TO PLAN.

4.1 MAXIMUM NUMBER OF SHARES ISSUABLE. Subject to adjustment as provided in Section 4.2, the maximum aggregate number of shares of Stock that may be issued under the Plan shall be two million one hundred thousand (2,100,000) and shall consist of authorized but unissued or reacquired shares of Stock or any combination thereof. If an outstanding Option for any reason expires or is terminated or canceled or if shares of Stock are acquired upon the exercise of an Option subject to a Company repurchase option and are repurchased by the Company at the Optionee's exercise or purchase price, the shares of Stock allocable to the unexercised portion of such Option or such repurchased shares of Stock shall again be available for issuance under the Plan. However, except as adjusted pursuant to Section 4.2, in no event shall more than two million one hundred thousand (2,100,000) shares of

Stock be available for issuance pursuant to the exercise of Incentive Stock Options (the "ISO SHARE ISSUANCE LIMIT").

4.2 ADJUSTMENTS FOR CHANGES IN CAPITAL STRUCTURE. In the event of any stock dividend, stock split, reverse stock split, recapitalization, combination, reclassification or similar change in the capital structure of the Company, appropriate adjustments shall be made in the number and class of shares subject to the Plan and to any outstanding Options, in the ISO Share Issuance Limit set forth in Section 4.1, in the Section 162(m) Grant Limit set forth in Section 5.4, in the automatic Nonemployee Director Option grant provisions set forth in Section 7.1 and in the exercise price per share of any outstanding Options. If a majority of the shares which are of the same class as the shares that are subject to outstanding Options are exchanged for, converted into, or otherwise become (whether or not pursuant to an Ownership Change Event, as defined in Section 9.1) shares of another corporation (the "NEW SHARES"), the Board may unilaterally amend the outstanding Options to provide that such Options are exercisable for New Shares. In the event of any such amendment, the number of shares subject to, and the exercise price per share of, the outstanding Options shall be adjusted in a fair and equitable manner as determined by the Board, in its discretion. Notwithstanding the foregoing, any fractional share resulting from an adjustment pursuant to this Section 4.2 shall be rounded down to the nearest whole number, and in no event may the exercise price of any Option be decreased to an amount less than the par value, if any, of the stock subject to the Option. The adjustments determined by the Board pursuant to this Section 4.2 shall be final, binding and conclusive.

5. ELIGIBILITY AND OPTION LIMITATIONS.

5.1 PERSONS ELIGIBLE FOR OPTIONS. Options may be granted only to Employees, Consultants, and Directors. For purposes of the foregoing sentence, "Employees," "Consultants" and "Directors" shall include prospective Employees, prospective Consultants and prospective Directors to whom Options are granted in connection with written offers of an employment or other service relationship with the Participating Company Group. Eligible persons may be granted more than one (1) Option. However, eligibility in accordance with this Section shall not entitle any person to be granted an Option, or, having been granted an Option, to be granted an additional Option.

5.2 OPTION GRANT RESTRICTIONS. Any person who is not an Employee on the effective date of the grant of an Option to such person may be granted only a Nonstatutory Stock Option. An Incentive Stock Option granted to a prospective Employee upon the condition that such person become an Employee shall be deemed granted effective on the date such person commences Service with a Participating Company, with an exercise price determined as of such date in accordance with Section 6.1. Nonemployee Director Options shall be granted only to a person who at the time of grant is a Nonemployee Director.

5.3 FAIR MARKET VALUE LIMITATION. To the extent that options designated as Incentive Stock Options (granted under all stock option plans of the Participating Company Group, including the Plan) become exercisable by an Optionee for the first time during any calendar year for stock having a Fair Market Value greater than One Hundred Thousand Dollars (\$100,000), the portions of such options which exceed such amount shall be treated as

Nonstatutory Stock Options. For purposes of this Section 5.3, options designated as Incentive Stock Options shall be taken into account in the order in which they were granted, and the Fair Market Value of stock shall be determined as of the time the option with respect to such stock is granted. If the Code is amended to provide for a lower limitation from that set forth in this Section 5.3, such different limitation shall be deemed incorporated herein effective as of the date and with respect to such Options as required or permitted by such amendment to the Code. If an Option is treated as an Incentive Stock Option in part and as a Nonstatutory Stock Option in part by reason of the limitation set forth in this Section 5.3, the Optionee may designate which portion of such Option the Optionee is exercising. In the absence of such designation, the Optionee shall be deemed to have exercised the Incentive Stock Option portion of the Option first. Separate certificates representing each such portion shall be issued upon the exercise of the Option.

5.4 SECTION 162(m) GRANT LIMIT. Subject to adjustment as provided in Section 4.2, no Employee or prospective Employee shall be granted one or more Options within any fiscal year of the Company which in the aggregate are for the purchase of more than five hundred thousand (500,000) shares (the "SECTION 162(m) GRANT LIMIT"). An Option which is canceled in the same fiscal year of the Company in which it was granted shall continue to be counted against the Section 162(m) Grant Limit for such period.

6. TERMS AND CONDITIONS OF OPTIONS.

Options shall be evidenced by Option Agreements specifying the number of shares of Stock covered thereby, in such form as the Board shall from time to time establish. No Option or purported Option shall be a valid and binding obligation of the Company unless evidenced by a fully executed Option Agreement. Option Agreements may incorporate all or any of the terms of the Plan by reference and, except as otherwise provided in Section 7 with respect to Nonemployee Director Options, shall comply with and be subject to the following terms and conditions:

6.1 EXERCISE PRICE. The exercise price for each Option shall be established in the discretion of the Board; provided, however, that (a) the exercise price per share for an Incentive Stock Option shall be not less than the Fair Market Value of a share of Stock on the effective date of grant of the Option, (b) the exercise price per share for a Nonstatutory Stock Option shall be not less than eighty-five percent (85%) of the Fair Market Value of a share of Stock on the effective date of grant of the Option, and (c) no Incentive Stock Option granted to a Ten Percent Owner Optionee shall have an exercise price per share less than one hundred ten percent (110%) of the Fair Market Value of a share of Stock on the effective date of grant of the Option. Notwithstanding the foregoing, an Option (whether an Incentive Stock Option or a Nonstatutory Stock Option) may be granted with an exercise price lower than the minimum exercise price set forth above if such Option is granted pursuant to an assumption or substitution for another option in a manner qualifying under the provisions of Section 424(a) of the Code.

6.2 EXERCISABILITY AND TERM OF OPTIONS. Options shall be exercisable at such time or times, or upon such event or events, and subject to such terms, conditions, performance criteria and restrictions as shall be determined by the Board and set forth in the

Option Agreement evidencing such Option; provided, however, that (a) no Option shall be exercisable after the expiration of ten (10) years after the effective date of grant of such Option, (b) no Incentive Stock Option granted to a Ten Percent Owner Optionee shall be exercisable after the expiration of five (5) years after the effective date of grant of such Option, and (c) no Option granted to a prospective Employee, prospective Consultant or prospective Director may become exercisable prior to the date on which such person commences Service with a Participating Company. Subject to the foregoing, unless otherwise specified by the Board in the grant of an Option, any Option granted hereunder shall terminate ten (10) years after the effective date of grant of the Option, unless earlier terminated in accordance with its provisions. In addition, unless otherwise specified by the Board, shares subject to any Option granted hereunder shall vest, subject to the Optionee's continued Service, as follows: 1/4 of the shares subject to the Option will vest one (1) year after the vesting commencement date, and thereafter, 1/16 of the shares subject to the Option will vest for each full three (3) months of Service.

6.3 PAYMENT OF EXERCISE PRICE.

(a) FORMS OF CONSIDERATION AUTHORIZED. Except as otherwise provided below, payment of the exercise price for the number of shares of Stock being purchased pursuant to any Option shall be made (i) in cash, by check or cash equivalent, (ii) by tender to the Company, or attestation to the ownership, of shares of Stock owned by the Optionee having a Fair Market Value not less than the exercise price, (iii) by delivery of a properly executed notice together with irrevocable instructions to a broker providing for the assignment to the Company of the proceeds of a sale or loan with respect to some or all of the shares being acquired upon the exercise of the Option (including, without limitation, through an exercise complying with the provisions of Regulation T as promulgated from time to time by the Board of Governors of the Federal Reserve System) (a "CASHLESS EXERCISE"), (iv) by such other consideration as may be approved by the Board from time to time to the extent permitted by applicable law, or (v) by any combination thereof. The Board may at any time or from time to time, by approval of or by amendment to the standard forms of Option Agreement described in Section 8, or by other means, grant Options which do not permit all of the foregoing forms of consideration to be used in payment of the exercise price or which otherwise restrict one or more forms of consideration.

(b) LIMITATIONS ON FORMS OF CONSIDERATION.

(i) TENDER OF STOCK. Notwithstanding the foregoing, an Option may not be exercised by tender to the Company, or attestation to the ownership, of shares of Stock to the extent such tender or attestation would constitute a violation of the provisions of any law, regulation or agreement restricting the redemption of the Company's stock. Unless otherwise provided by the Board, an Option may not be exercised by tender to the Company, or attestation to the ownership, of shares of Stock unless such shares either have been owned by the Optionee for more than six (6) months (and not used for another Option exercise by attestation during such period) or were not acquired, directly or indirectly, from the Company.

(ii) CASHLESS EXERCISE. The Company reserves, at any and all times, the right, in the Company's sole and absolute discretion, to establish, decline to approve or

terminate any program or procedures for the exercise of Options by means of a Cashless Exercise.

6.4 TAX WITHHOLDING. The Company shall have the right, but not the obligation, to deduct from the shares of Stock issuable upon the exercise of an Option, or to accept from the Optionee the tender of, a number of whole shares of Stock having a Fair Market Value, as determined by the Company, equal to all or any part of the federal, state, local and foreign taxes, if any, required by law to be withheld by the Participating Company Group with respect to such Option or the shares acquired upon the exercise thereof. Alternatively or in addition, in its discretion, the Company shall have the right to require the Optionee, through payroll withholding, cash payment or otherwise, including by means of a Cashless Exercise, to make adequate provision for any such tax withholding obligations of the Participating Company Group arising in connection with the Option or the shares acquired upon the exercise thereof. The Fair Market Value of any shares of Stock withheld or tendered to satisfy any such tax withholding obligations shall not exceed the amount determined by the applicable statutory withholding rates. The Company shall have no obligation to deliver shares of Stock or to release shares of Stock from an escrow established pursuant to the Option Agreement until the Participating Company Group's tax withholding obligations have been satisfied by the Optionee.

6.5 EFFECT OF TERMINATION OF SERVICE.

(a) OPTION EXERCISABILITY. Subject to earlier termination of the Option as otherwise provided herein and unless otherwise provided by the Board in the grant of an Option and set forth in the Option Agreement, an Option shall be exercisable after an Optionee's termination of Service only during the applicable time period determined in accordance with this Section 6.5 and thereafter shall terminate:

(i) DISABILITY. If the Optionee's Service terminates because of the Disability of the Optionee, the Option, to the extent unexercised and exercisable on the date on which the Optionee's Service terminated, may be exercised by the Optionee (or the Optionee's guardian or legal representative) at any time prior to the expiration of twelve (12) months (or such longer period of time as determined by the Board, in its discretion) after the date on which the Optionee's Service terminated, but in any event no later than the date of expiration of the Option's term as set forth in the Option Agreement evidencing such Option (the "OPTION EXPIRATION DATE").

(ii) DEATH. If the Optionee's Service terminates because of the death of the Optionee, the Option, to the extent unexercised and exercisable on the date on which the Optionee's Service terminated, may be exercised by the Optionee's legal representative or other person who acquired the right to exercise the Option by reason of the Optionee's death at any time prior to the expiration of twelve (12) months (or such longer period of time as determined by the Board, in its discretion) after the date on which the Optionee's Service terminated, but in any event no later than the Option Expiration Date.

(iii) OTHER TERMINATION OF SERVICE. If the Optionee's Service terminates for any reason, except Disability or death, the Option, to the extent unexercised and

exercisable by the Optionee on the date on which the Optionee's Service terminated, may be exercised by the Optionee at any time prior to the expiration of three (3) months (or such longer period of time as determined by the Board, in its discretion) after the date on which the Optionee's Service terminated, but in any event no later than the Option Expiration Date.

(b) EXTENSION IF EXERCISE PREVENTED BY LAW.

Notwithstanding the foregoing, if the exercise of an Option within the applicable time periods set forth in Section 6.5(a) is prevented by the provisions of Section 12 below, the Option shall remain exercisable until three (3) months (or such longer period of time as determined by the Board, in its discretion) after the date the Optionee is notified by the Company that the Option is exercisable, but in any event no later than the Option Expiration Date.

(c) EXTENSION IF OPTIONEE SUBJECT TO SECTION 16(b).

Notwithstanding the foregoing, if a sale within the applicable time periods set forth in Section 6.5(a) of shares acquired upon the exercise of the Option would subject the Optionee to suit under Section 16(b) of the Exchange Act, the Option shall remain exercisable until the earliest to occur of (i) the tenth (10th) day following the date on which a sale of such shares by the Optionee would no longer be subject to such suit, (ii) the one hundred and ninetieth (190th) day after the Optionee's termination of Service, or (iii) the Option Expiration Date.

7. TERMS AND CONDITIONS OF NONEMPLOYEE DIRECTOR OPTIONS.

Nonemployee Director Options shall be evidenced by Option Agreements specifying the number of shares of Stock covered thereby, in such form as the Board shall from time to time establish. Such Option Agreements may incorporate all or any of the terms of the Plan by reference and shall comply with and be subject to the following terms and conditions:

7.1 AUTOMATIC GRANT. Subject to execution by a Nonemployee Director of an appropriate Option Agreement, Nonemployee Director Options shall be granted automatically and without further action of the Board, as follows:

(a) INITIAL OPTION. Each person who first becomes a Nonemployee Director after the Effective Date shall be granted on the date he or she first becomes a Nonemployee Director a Nonemployee Director Option to purchase ten thousand (10,000) shares of Stock (an "INITIAL OPTION"). Notwithstanding anything herein to the contrary, an Initial Option shall not be granted to a Director who previously did not qualify as a Nonemployee Director but subsequently becomes a Nonemployee Director as a result of the termination of his or her status as an Employee.

(b) ANNUAL OPTION. Each Nonemployee Director (including any Director who previously did not qualify as a Nonemployee Director but who subsequently becomes a Nonemployee Director) shall be granted on the date immediately following each annual meeting of the stockholders of the Company which occurs on or after the Effective Date (an "ANNUAL MEETING") an Option to purchase ten thousand (10,000) shares of Stock (an "ANNUAL OPTION"). Notwithstanding the foregoing, a Nonemployee Director who received an Initial Option on, or within a period of six (6) months prior to, the date of an Annual Meeting

shall not be granted an Annual Option pursuant to this Section with respect to the same Annual Meeting.

(c) RIGHT TO DECLINE NONEMPLOYEE DIRECTOR OPTION.

Notwithstanding the foregoing, any person may elect not to receive a Nonemployee Director Option by delivering written notice of such election to the Board no later than the day prior to the date such Nonemployee Director Option would otherwise be granted. A person so declining a Nonemployee Director Option shall receive no payment or other consideration in lieu of such declined Nonemployee Director Option. A person who has declined a Nonemployee Director Option may revoke such election by delivering written notice of such revocation to the Board no later than the day prior to the date such Nonemployee Director Option would be granted pursuant to Section 7.1(a) or (b), as the case may be.

7.2 EXERCISE PRICE. The exercise price per share of Stock subject to a Nonemployee Director Option shall be the Fair Market Value of a share of Stock on the date of grant of the Nonemployee Director Option.

7.3 EXERCISABILITY AND TERM OF NONEMPLOYEE DIRECTOR OPTIONS.

(a) EXERCISABILITY. Except as otherwise provided in the Plan or in the Option Agreement evidencing such Option, a Nonemployee Director Option shall vest and become exercisable in twelve (12) substantially equal monthly installments following the date of grant, provided that the Optionee's Service has not terminated prior to the relevant date. In addition, any unexercisable or unvested portion of a Nonemployee Director Option will become vested and exercisable in full as of the date ten (10) days prior to the date of a Change in Control which occurs prior to the termination of the Optionee's Service. Any vesting or exercise of the Option that was permitted solely by reason of the preceding sentence shall be conditioned upon the consummation of the Change in Control.

(b) TERM. Each Nonemployee Director Option shall terminate and cease to be exercisable on the date ten (10) years after the date of grant of such Nonemployee Director Option, unless earlier terminated pursuant to the terms of the Plan or the Option Agreement. In the event of the Optionee's termination of Service, the Option, to the extent unexercised and exercisable on the date on which the Optionee's Service terminated, may be exercised by the Optionee (or the Optionee's legal representative, guardian or other person who acquired the right to exercise the Option by reason of the Optionee's death) at any time prior to the expiration of six (6) months after the date on which the Optionee's Service terminated (twelve (12) months if such termination was due to death or Disability), but in any event no later than the Option Expiration Date. In addition, the post-termination exercise periods described in the preceding sentence shall be extended in accordance with Section 6.5(b) and (c), if applicable.

8. STANDARD FORMS OF OPTION AGREEMENT.

8.1 OPTION AGREEMENT. Unless otherwise provided by the Board at the time the Option is granted, an Option shall comply with and be subject to the terms and conditions set forth in the form of Option Agreement approved by the Board concurrently with its adoption of the Plan and as amended from time to time.

8.2 AUTHORITY TO VARY TERMS. The Board shall have the authority from time to time to vary the terms of any standard form of Option Agreement described in this Section either in connection with the grant or amendment of an individual Option or in connection with the authorization of a new standard form or forms; provided, however, that the terms and conditions of any such new, revised or amended standard form or forms of Option Agreement are not inconsistent with the terms of the Plan.

9. CHANGE IN CONTROL.

9.1 DEFINITIONS.

(a) An "OWNERSHIP CHANGE EVENT" shall be deemed to have occurred if any of the following occurs with respect to the Company: (i) the direct or indirect sale or exchange in a single or series of related transactions by the Stockholders of the Company of more than fifty percent (50%) of the voting stock of the Company; (ii) a merger or consolidation in which the Company is a party; (iii) the sale, exchange, or transfer of all or substantially all of the assets of the Company; or (iv) a liquidation or dissolution of the Company.

(b) A "CHANGE IN CONTROL" shall mean an Ownership Change Event or a series of related Ownership Change Events (collectively, a "TRANSACTION") wherein the Stockholders of the Company immediately before the Transaction do not retain immediately after the Transaction, in substantially the same proportions as their ownership of shares of the Company's voting stock immediately before the Transaction, direct or indirect beneficial ownership of more than fifty percent (50%) of the total combined voting power of the outstanding voting securities of the Company or, in the case of a Transaction described in Section 9.1(a)(iii), the corporation or other business entity to which the assets of the Company were transferred (the "TRANSFeree"), as the case may be. For purposes of the preceding sentence, indirect beneficial ownership shall include, without limitation, an interest resulting from ownership of the voting securities of one or more corporations or other business entities which own the Company or the Transferee, as the case may be, either directly or through one or more subsidiary corporations or other business entities. The Board shall have the right to determine whether multiple sales or exchanges of the voting securities of the Company or multiple Ownership Change Events are related, and its determination shall be final, binding and conclusive.

9.2 EFFECT OF CHANGE IN CONTROL ON OPTIONS. In the event of a Change in Control, the surviving, continuing, successor, or purchasing corporation or other business entity or parent thereof, as the case may be (the "ACQUIRING CORPORATION"), may, without the consent of the Optionee, either assume the Company's rights and obligations under outstanding Options

or substitute for outstanding Options substantially equivalent options for the Acquiring Corporation's stock. Except as otherwise provided in an Option Agreement, in the event the Acquiring Corporation elects not to assume the Company's rights or obligations under the Option or substitute for the Option in connection with the Change in Control, and provided that the Optionee's Service has not terminated prior to such date, any unexercised portion of the Option shall be immediately exercisable and vested in full as of ten (10) days prior to the date of the Change in Control. Any vesting or exercise of the Option that was permissible solely by reason of this Section 9.2 shall be conditioned upon the consummation of the Change in Control. Any Options which are neither assumed or substituted for by the Acquiring Corporation in connection with the Change in Control nor exercised as of the date of the Change in Control shall terminate and cease to be outstanding effective as of the date of the Change in Control. Notwithstanding the foregoing, shares acquired upon exercise of an Option prior to the Change in Control and any consideration received pursuant to the Change in Control with respect to such shares shall continue to be subject to all applicable provisions of the Option Agreement evidencing such Option except as otherwise provided in such Option Agreement. Furthermore, notwithstanding the foregoing, if the corporation the stock of which is subject to the outstanding Options immediately prior to an Ownership Change Event described in Section 9.1(a)(i) constituting a Change in Control is the surviving or continuing corporation and immediately after such Ownership Change Event less than fifty percent (50%) of the total combined voting power of its voting stock is held by another corporation or by other corporations that are members of an affiliated group within the meaning of Section 1504(a) of the Code without regard to the provisions of Section 1504(b) of the Code, the outstanding Options shall not terminate unless the Board otherwise provides in its discretion.

10. PROVISION OF INFORMATION.

Each Optionee shall be given access to information concerning the company equivalent to that information generally made available to the Company's common stockholders.

11. TRANSFERABILITY OF OPTIONS.

During the lifetime of the Optionee, an Option shall be exercisable only by the Optionee or the Optionee's guardian or legal representative. No Option shall be assignable or transferable by the Optionee, except by will or by the laws of the descent and distribution. Notwithstanding the foregoing, to the extent permitted by the Board, in its discretion, and set forth in the Option Agreement evidencing such Option, a Nonstatutory Stock Option shall be assignable or transferable subject to the applicable limitations, if any, described in the General Instructions to Form S-8 Registration Statement under the Securities Act.

12. COMPLIANCE WITH SECURITIES LAW.

The grant of Options and the issuance of shares of Stock upon exercise of Options shall be subject to compliance with all applicable requirements of federal, state and foreign law with respect to such securities. Options may not be exercised if the issuance of shares of Stock upon exercise would constitute a violation of any applicable federal, state or foreign securities laws or other law or regulations or the requirements of any stock exchange or market system

upon which the Stock may then be listed. In addition, no Option may be exercised unless (a) a registration statement under the Securities Act shall at the time of exercise of the Option be in effect with respect to the shares issuable upon exercise of the Option or (b) in the opinion of legal counsel to the Company, the shares issuable upon exercise of the Option may be issued in accordance with the terms of an applicable exemption from the registration requirements of the Securities Act. The inability of the Company to obtain from any regulatory body having jurisdiction the authority, if any, deemed by the Company's legal counsel to be necessary to the lawful issuance and sale of any shares hereunder shall relieve the Company of any liability in respect of the failure to issue or sell such shares as to which such requisite authority shall not have been obtained. As a condition to the exercise of any Option, the Company may require the Optionee to satisfy any qualifications that may be necessary or appropriate, to evidence compliance with any applicable law or regulation and to make any representation or warranty with respect thereto as may be requested by the Company.

13. TERMINATION OR AMENDMENT OF PLAN.

The Board may terminate or amend the Plan at any time. However, subject to changes in applicable law, regulations or rules that would permit otherwise, without the approval of the Company's stockholders, there shall be (a) no increase in the maximum aggregate number of shares of Stock that may be issued under the Plan (except by operation of the provisions of Section 4.2), (b) no change in the class of persons eligible to receive Incentive Stock Options, and (c) no other amendment of the Plan that would require approval of the Company's Stockholders under any applicable law, regulation or rule. No termination or amendment of the Plan shall affect any then outstanding Option unless expressly provided by the Board. In any event, no termination or amendment of the Plan may adversely affect any then outstanding Option without the consent of the Optionee, unless such termination or amendment is required to enable an Option designated as an Incentive Stock Option to qualify as an Incentive Stock Option or is necessary to comply with any applicable law, regulation or rule.

PLAN HISTORY

September 12, 2001 Board adopts Plan, with an initial reserve of 2,100,000 shares.

November 14, 2001 Stockholders approve Plan, with an initial reserve of 2,100,000 shares.

CONSENT OF INDEPENDENT ACCOUNTANTS

We hereby consent to the incorporation by reference in each Registration Statement on Form S-8 (Nos. 333-81340, 333-51556, 333-38886 and 333-25021) and Form S-3 (Nos. 333-69400, 333-39698, 333-32914, 333-92675, 333-81399 and 333-60125) of Aastrom Biosciences, Inc. of our report dated August 8, 2002, except for Note 9, which is as of August 30, 2002 relating to the financial statements, which appears in this Form 10-K.

Minneapolis, Minnesota
September 23, 2002

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

I, R. Douglas Armstrong, Chief Executive Officer of Aastrom Biosciences, Inc. (the "Registrant"), do hereby certify in accordance with 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) the Annual Report on Form 10-K of the Registrant, to which this certification is attached as an exhibit (the "Report"), fully complies with the requirements of section 13(a) of the Securities Exchange Act of 1934 (15 U.S.C. 78m); and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

Dated: September 27, 2002

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

R. Douglas Armstrong
President and Chief Executive Officer

CERTIFICATION OF CHIEF FINANCIAL OFFICER

I, Michael S. Durski, Chief Financial Officer of Aastrom Biosciences, Inc. (the "Registrant"), do hereby certify in accordance with 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) the Annual Report on Form 10-K of the Registrant, to which this certification is attached as an exhibit (the "Report"), fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934 (15 U.S.C. 78m); and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

Dated: September 27, 2002

/s/ MICHAEL S. DURSKI

Michael S. Durski
Vice President, Finance & Administration,
Chief Financial Officer, Secretary &
Treasurer