

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K/A
AMENDMENT NO. 1

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

For the fiscal year ended June 30, 1997

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: (313) 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 National Market) on September 15, 1997 was \$27,338,000. 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 15, 1997, 13,285,511 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 12, 1997 | Items 10, 11, 12 and 13 of Part III |

AASTROM BIOSCIENCES, INC.

ANNUAL REPORT ON FORM 10-K

EXPLANATORY NOTE

This amendment amends the Annual Report on Form 10-K of the registrant, as filed with the Securities and Exchange Commission on September 25, 1997. Items 1, 7, 10 and 14 have been amended, and Items 2, 3, 4, 5, 6, 8, 9, 11, 12 and 13 are restated in their entirety as they appeared in the previously filed Annual Report on Form 10-K.

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Except for the historical information presented, the matters discussed in this Report include forward-looking statements that involve risks and uncertainties. The Company's 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."

PART I

ITEM 1. BUSINESS

OVERVIEW

Astrom Biosciences, Inc. ("Astrom" or the "Company") is developing proprietary process technologies and devices for a range of cell therapy applications, including stem cell therapies and selected emerging therapies such as immunotherapy, solid tissue repair and ex vivo gene therapy. The Company's

lead product under development, the Astrom Cell Production System (the "Astrom CPS"), consists of a clinical cell culture system with single-use cassettes and reagents for use in the rapidly growing cell therapy market. The Company is currently conducting "pre-pivotal" trials at multiple sites in the United States and Europe of the Astrom CPS for use in stem cell therapy in preparation for pivotal trials in the United States and potential marketing in Europe. The Company believes that the Astrom CPS procedure will be a cost-effective, less invasive and less time consuming alternative to currently available stem cell collection methods and may enhance the clinical utility of umbilical cord blood ("UCB") transplants by expanding the number of cells available for transplant. For stem cell therapy, the Company has entered into a strategic collaboration for the marketing, distribution and customer service of the Astrom CPS with Cobe BCT, Inc. (collectively with Cobe Laboratories, Inc. "Cobe"), a subsidiary of Gambro AB and a leading provider of blood cell processing products.

The Astrom CPS is designed as a platform product which implements the Company's pioneering stem cell replication technology. The Company believes that the Astrom CPS can be modified to produce a wide variety of other cell types for selected emerging therapies being developed by other companies and institutions. The Company intends to develop additional strategic collaborations for the development of the Astrom CPS in certain of these other cell therapy market segments. In ex vivo gene therapy, the Company is also developing the

Astrom Gene Loader, which is being designed to address the production of gene-modified cells.

CELL THERAPY

Cell therapy or ex vivo gene therapy involves the use of human cells to treat

a medical disorder. The most common types of cell therapy, blood and platelet transfusions, have been widely used for many decades. More recently, bone marrow-derived and UCB cells have been used to restore the bone marrow and the blood and immune system cells which are damaged by chemotherapy and radiation therapy during the treatment of many types of cancer. Transplantation of these cells is known as stem cell therapy. Other cell therapies have recently been used for generating skin and cartilage tissue, and additional cell therapies are being developed by various companies and researchers to restore immune system cells as well as bone, kidney, liver, vascular and neuronal tissues.

Cell therapies require the collection of cells, either from the patient or a suitably matched donor. These cells are typically processed and stored for administration to the patient. Although cell therapy is being developed for use in an increasing number of diseases, widespread application of new cell therapies remains limited by the difficulties and expense associated with current cell collection and processing procedures. The problems of current cell collection techniques are exemplified in the area of stem cell therapy where the patient or donor undergoes invasive, time-consuming and costly procedures to collect the large volume of cells currently required for effective treatment. The Company believes an alternative to collecting the required therapeutic dose of cells is to grow these cells ex vivo from a small starting volume. However,

ex vivo cell expansion, when biologically possible, has typically required

costly techniques, facilities and operations to comply with U.S. Food and Drug Administration ("FDA") current good manufacturing practices ("cGMP"), which are not generally available in hospitals. As a result, cells needed for such therapies often require specialized cell production facilities which use labor-intensive, manual cell culture techniques.

In ex vivo gene therapy, genes are introduced into target cells in order to

selectively correct or modulate disease conditions, or to modify cells for
production of a therapeutic protein. The Company believes that the successful
practice of ex vivo gene therapy will require the development of processes and

products for the reliable, high-efficiency transfer of genes into cells and a
means to produce the necessary dose of the genetically modified cells under cGMP
conditions.

STEM CELL THERAPY

Stem cell therapy is used to treat cancer patients who undergo chemotherapy or radiation therapy at dose levels that are toxic to the hematopoietic system, which is comprised of the bone marrow and the cells of the blood and immune systems. The objective of stem cell therapy is to restore the hematopoietic system via the infusion and subsequent engraftment of healthy cells to replace bone marrow and result in the rapid recovery of neutrophils and platelets that have been destroyed by chemotherapy and radiation therapy. Stem cell therapy reduces the risk of life-threatening infections and bleeding episodes following cancer treatments. In order to treat many cancers, high intensity chemotherapy or radiation is often required, which may severely destroy ("myeloablation") or partially destroy ("myelosuppression") the patient's hematopoietic system.

Cells required for effective stem cell therapy include stem cells, to replenish depleted bone marrow and provide a long-term ongoing source of the multilineage progenitor cells of the blood and immune systems, and early and late stage hematopoietic progenitor cells, to provide for rapid neutrophil and platelet recoveries. Stromal accessory cells are believed to further augment the growth of bone marrow. In the adult, all of these cell types originate in the bone marrow. These cells are currently collected from the donor or patient directly through multiple syringe aspirations under anesthesia, known as bone marrow collection, or through blood apheresis following treatment with drugs which cause cells to be released or mobilized from the bone marrow into the blood. This latter technique is known as a peripheral blood progenitor cell ("PBPC") collection. See "--Current Stem Cell Collection Methods."

Recently, it has been demonstrated that the blood cells found in the umbilical cord of newborn infants include cells effective for stem cell therapy. This source of cells is being explored by physicians as a significant new development in stem cell therapy, but is currently limited by difficulties in obtaining sufficient quantities of these cells and by prolonged engraftment times for the cells once transplanted into the patient.

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 a new marrow. 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 take years following myeloablative cancer therapy. When the patient's hematopoietic system is malignant, such as in the case of leukemia, cells from a suitable donor are generally required in order to avoid reintroducing the disease during cell infusion. Such donor derived transplants are termed "allogeneic" transplants. Procedures using cells derived from the patient are termed "autologous" transplants.

STEM CELL THERAPY MARKET OPPORTUNITY

The benefits of stem cell therapy in the treatment of cancer patients have been well established over the past two decades. Stem cell therapy, in the form of bone marrow transplantation, was originally used in patients who had received treatment for blood and bone marrow cancers such as leukemia, and genetic diseases of the blood. However, because stem cell therapy has been shown to promote the rapid recovery of hematopoietic function, it is now being increasingly used to enable patients with other forms of cancer to receive high dose or multicycle chemotherapy and radiation treatments. These high-intensity therapies have a greater probability of eradicating dose-sensitive cancers but, because of their hematopoietic toxicity, cannot generally be given without stem cell therapy. As a result, some patients are treated with lower and less effective doses, and fewer cycles of therapy than might otherwise be used.

According to an industry source, approximately 32,000 stem cell therapy procedures were completed worldwide in 1995, and, according to another industry source, the number of such procedures utilizing donor-derived and patient-derived cells has been growing annually by approximately 15% and 20%, respectively. This growth has been driven by encouraging clinical results in the treatment of dose-sensitive solid tumors, such as breast and ovarian cancers. The Company expects that the

number of stem cell therapy procedures will continue to grow due to increased incidence and prevalence of cancer, continued clinical demand for myelotoxic cancer treatment, and the increased cost effectiveness of stem cell therapy treatments.

Stem cell therapy may also enhance the effectiveness of blood cell growth factors. The timing and extent of additional cycles of chemotherapy is often limited by the recovery of a patient's white blood cells and platelets because a delayed recovery of these cells can leave the patient susceptible to life-threatening infection and bleeding episodes, and this limitation may allow for the regrowth of residual tumor cells. Many cancer patients are routinely treated with growth factors including G-CSF, such as Neupogen and GM-CSF, such as Leukine, which enhance the development of mature circulating white blood cells and platelets from the early progenitor bone-marrow derived cells, thereby decreasing the time between cycles of therapy and the probability of infection. However, during high dose or multicycle therapy, the stem and progenitor cells on which these growth factors act are often depleted. Without these cells, growth factors have a limited or negligible effect. Stem cell therapy generally enhances the effectiveness of growth factors by introducing target stem and progenitor cells for growth factors to act upon such that patients generally exhibit a more rapid and consistent hematopoietic recovery.

CURRENT STEM CELL COLLECTION METHODS

Currently, the bone marrow-derived cells required for stem cell therapy are collected primarily either through the bone marrow harvest method or the PBPC collection method.

Bone Marrow Harvest

A traditional bone marrow harvest is a costly and invasive surgical procedure in which a physician removes approximately one liter of bone marrow from a patient or donor. This volume of bone marrow is removed using needles inserted into the cavity of the hip bone. The bone marrow harvest procedure typically requires between two to four hours of operating room time, with the physician often making more than 90 separate puncture sites in the hip bone to collect the necessary amount of bone marrow. Due to the length of the procedure and the trauma to the patient, general surgical anesthesia is administered and the patient is often hospitalized for a day. Frequently, the patient suffers pain from the procedure for several days after being discharged from the hospital. Furthermore, complications resulting from the general anesthesia or invasive nature of the procedure occur in a small percentage of patients. Bone marrow harvest provides a reliable source of stem and stromal accessory cells and has been the preferred source of cells in allogeneic transplants.

PBPC Mobilization and Collection

PBPC mobilization is a technique in which bone marrow-derived cells are harvested from a patient's or donor's circulating blood, rather than from bone marrow. In a PBPC mobilization procedure, the patient receives multiple injections of growth factors or cytotoxic drugs, or both, over the course of a week or more, which cause stem and progenitor cells resident in the bone marrow to mobilize into the circulating blood. The mobilized cells are then collected by connecting the patient to a blood apheresis device, which draws and returns large volumes of the patient's or donor's blood in order to selectively remove the therapeutic volume of stem and progenitor cells. Each collection procedure typically lasts for two to six hours and is typically repeated on two to five consecutive days, however, procedure time has decreased and is expected to continue to decrease as the procedure is further optimized. Specialized laboratory testing over the period of mobilization and cell harvesting is necessary to determine that a sufficient quantity of desired cells has been collected, adding to the cost of the procedure. The PBPC process has become the predominant procedure in autologous stem cell therapy.

Procedure Considerations

Although stem cell therapy is being utilized to treat more patients for a broader range of diseases, its availability continues to be limited by the high costs of procuring cells, the invasive nature of traditional cell procurement techniques, and by the technical difficulties related to those collection procedures. The Company believes that current charges for bone marrow harvest, processing and infusion are approximately \$10,000 to \$15,000 per procedure, with considerable variability between institutions. The Company believes that current charges for PBPC collection, including mobilization and infusion, are approximately \$12,000 to \$20,000 for a two to three cycle procedure, with considerable variability between institutions depending on the mobilization regimen and the total volume, time and number of aphereses required.

Overall costs of stem cell therapy include the costs of the cell collection and infusion procedures, and the costs associated with supporting the patient during post-transplant recovery. Post-transplant costs include hospitalization time, antibiotic support, management of adverse reactions to the large volume cell infusions, and infusions of platelets and red blood cells. Any new stem cell therapy process will generally need to provide similar recovery endpoints to be competitive with the current procedures. In this regard, PBPC procedures have gained popularity compared with bone marrow harvests because the number of platelet transfusions is reduced for some patients.

Recently, products to implement a cell isolation method known as CD34 selection have been developed by other companies in conjunction with bone marrow harvest and PBPC collections. CD34 selection is a process designed to isolate specific types of cells in order to decrease storage and infusion problems associated with the large volume of fluids collected in bone marrow or multiple apheresis procedures. CD34 selection is used after the initial collection of stem and progenitor cells and, therefore, does not address the difficulties or costs associated with the basic cell collection procedures. A future objective of CD34 selection is to assist in depleting tumor cells from the transplant cells collected, thereby expanding the availability of stem cell therapy to new patient populations.

UMBILICAL CORD BLOOD

UCB, which is collected directly from the umbilical cord of newborn infants, without pain or risk to the infant or the mother, is emerging as a new source of cells for stem cell therapy. UCB has been reported to have stem cell concentrations that are much higher than that typically obtained from traditional bone marrow and PBPC collection methods. After collection, UCB is typically frozen for later use in a stem cell therapy procedure. Storage of UCB samples involves small volumes of cells, compared to typical bone marrow or PBPC storage. Accordingly, the costs of collection and storage of UCB cells are comparatively low. This source of cells is also "tumor-free," such that UCB would be preferred for many current stem cell therapy procedures in metastatic cancer patients. Before UCB can become a major supply source for stem cell therapy, a coordinated UCB banking system must emerge. In this regard, several UCB banking institutions have been established to date, and the group is growing in both number and size. The establishment of these UCB banking institutions is an initial step which may lead to a coordinated UCB banking system.

Current disadvantages of UCB include the relatively low number of available cells which may contribute to prolonged engraftment times for the cells once transplanted into the patient. Unlike bone marrow or PBPC harvest, where the collection of more cells to meet a particular treatment is typically achievable, the number of cells available from a UCB donor is limited. This problem is exacerbated by the required cryopreservation of the cells, which causes significant cell loss. The resultant low cell number is believed to be responsible for the longer hematopoietic recovery times observed with UCB transplants, as compared with bone marrow or PBPC transplants. Further, because of the low cell number, UCB transplants are typically restricted to small patients. Therefore, increasing the number of therapeutic cells from a UCB sample may facilitate the more widespread use of UCB transplants. Aastrom believes that providing the transplant site with the capability to carry out the UCB cell expansion will be a major factor in the increased use of UCB for stem cell therapy and a significant business opportunity.

AASTROM TECHNOLOGY

Aastrom is developing proprietary process technologies that are pioneering the ex vivo production of human stem and progenitor cells. The Company has also

developed a proprietary cell culture device that mimics the biological and physical environment necessary for the growth of certain human cells and tissues, including bone marrow. The Company's initial product candidate, the Aastrom CPS, utilizes the Company's process technology and is designed to enable the ex vivo production of human stem and progenitor cells as an alternative to

bone marrow harvest and PBPC mobilization methods and to enhance the clinical utility of UCB cells. The Company believes that the Aastrom CPS may be used for other cell production processes, such as immunotherapy and solid tissue repair, which are being developed by third parties and, in combination with the Company's proprietary gene transfer process, may have application in the developing field of ex vivo gene therapy.

CORE TECHNOLOGY

Stem Cell Growth Process

Aastrom has developed proprietary process technologies for ex vivo production of therapeutic stem and progenitor cells as well as other key cells found in human bone marrow. The Company's proprietary process entails the placement of a stem cell mixture in a culture environment that mimics the biology and physiology of natural bone marrow. This process enables the stem and early and late-stage progenitor cells needed for an effective stem cell therapy procedure to be concurrently expanded. Growth factors can be added to stimulate specific cell lineages to grow 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. Currently available cell culture methods tend to result in a loss of stem cells, either through death or through differentiation into mature cells. The Company has exclusive rights to several issued U.S. patents that cover these processes and cell compositions. See "--Additional Stem Cell and Other Cell Therapies."

Aastrom Cell Culture Chamber

Aastrom has developed a proprietary cell culture chamber to implement the Company's process technology. The culture chamber produces cells on a clinical scale and allows for simple, sterile recovery of the cells for therapeutic use. The Company believes that the Aastrom cell culture chamber may also be used for growing other human therapeutic cells, such as T-Cells and dendritic cells used for immunotherapies, chondrocytes for cartilage replacement, and mesenchymal tissues for bone and cartilage replacement. The Company holds exclusive rights to issued U.S. patents and additional applications for its cell culture chamber device technology. See "--Additional Stem Cell and Other Cell Therapies."

Efficient Gene Transfer

Aastrom has developed proprietary processes and device technology that may enable increased efficiency of vector-mediated gene transfer into cells as compared to conventional procedures. This directed-motion gene transfer or gene loading technology is being pursued by the Company for application in most cell and tissue types and most vector technologies. The Company intends to develop products based upon its gene loading technology. Development of additional products, however, will require the Company to raise additional funds or to seek collaborative partners, or both, to finance related research and development activities, as to which there can be no assurance of success. Furthermore, due to the uncertainties involved, the Company is unable to estimate the length of time such development may take. If successfully developed into products, the Company believes that such products would facilitate the advancement of numerous gene therapy protocols into the clinic and ultimately the market. The Company has exclusive rights to three issued U.S. patents, and has additional applications pending, for this technology. See "Aastrom Product Candidates For Ex Vivo Gene Therapy."

THE AASTROM CPS

The Aastrom CPS is the Company's lead product under development. While potentially applicable to multiple cell therapy applications such as immunotherapy, solid tissue repair and ex vivo gene therapy, the Aastrom CPS is -----
being developed initially by the Company for stem cell therapy. The Aastrom CPS is a proprietary system that the Company believes will enable the large scale ex vivo production of a variety of therapeutic cells at healthcare facilities, -----
independent laboratories, transplant centers and blood banks, and has been designed to implement Aastrom's stem cell growth process as well as processes for the production of other cell types.

The Aastrom CPS is comprised of several components, including single-use Cell Cassettes and reagents and microprocessor-controlled instruments, which are at various stages of development. The Cell Cassette is a single-use cartridge which contains the Aastrom cell culture chamber and the related media supply waste reservoirs and harvest bag. The microprocessor-controlled instruments include the Incubator which controls the culture conditions for the operation of the Cell Cassette, and the Processor which automates the priming and harvesting of the cells from the Cell Cassette. The System Manager is a user interface computer that is being developed to simultaneously track and monitor the cell production process in over thirty CPS Incubators and record relevant process variables and operator actions. Prototype components of the Aastrom CPS are currently being used in clinical trials and ongoing development activities are directed at completing other production level components of the Aastrom CPS.

The Aastrom CPS 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 end product of the Aastrom CPS process is a blood-bag container with the cell product. The control and documentation features of the Aastrom CPS have been designed to meet cGMP requirements for the therapeutic production of cells.

AASTROM CPS FOR STEM CELL THERAPY

The Company's initial application for the Aastrom CPS is expected to be in the growing field of stem cell therapy, where the Company believes that the Aastrom CPS may address many of the limitations of existing procedures. The Aastrom CPS is based on a comparatively simple process in which a small volume of bone marrow cells are collected from the patient or donor using a needle aspiration procedure typically under a local anesthetic or sedative. This cell mixture is quantified, and an appropriate volume of cells is then inoculated into one or more Cell Cassettes with the necessary growth media. Growth-factor-stimulated cells are produced using the Aastrom CPS in approximately 12 to 13 days, with no further patient involvement. Depending upon the cell quantity necessary for a therapeutic application, single or multiple Cell Cassettes may be required, with a different volume requirement of starting cells taken from the patient at the initial visit. The Aastrom CPS has been designed to minimize operator involvement during the cell production process, and the steps required before and after the Aastrom CPS are standard laboratory procedures. Cells derived from UCB may also serve as a tumor-free source of stem and progenitor cells for expansion in the Aastrom CPS.

Potential Advantages of Aastrom CPS

The Company believes that the Aastrom CPS, if approved for commercial sale by the FDA and foreign regulatory agencies, may provide certain improvements and efficiencies over traditional cell collection and infusion processes. The following table, which sets forth estimates based on a 1996 survey conducted by the Company of 11 stem cell transplant physicians at different transplant institutions throughout the United States, compares estimated patient care episodes and procedure time for currently established cell collection and infusion techniques with the Aastrom CPS method of cell procurement:

| Cell Source | CARE EPISODES(1) | PROCEDURE TIME (HOURS)(1) |
|---|------------------|---------------------------|
| Bone Marrow Harvest (2)..... | 8 | 16 |
| PBPC Mobilization and Collection (3)... | 21 | 39 |
| Aastrom CPS (4)..... | 2 | 1-3 |

- (1) Includes all outpatient, inpatient, and home care episodes.
- (2) Includes operating room procedure and all preparatory and recovery procedures.
- (3) Based on an average of three rounds of apheresis following cell mobilization injections.
- (4) Projections, based on data accumulated during the Company's research and clinical trials.

The Company believes that the Aastrom CPS may provide the following benefits when compared to current cell collection and infusion methods:

Cost-Effectiveness. The Company believes the Aastrom CPS has the potential

to cost-effectively replace the labor intensive and invasive cell collection and infusion procedures currently employed for stem cell therapy and to reduce physician, staff and patient time requirements.

Reduced Patient and Physician Burden. Cell production with the Aastrom CPS

is expected to require the collection of a small volume of starting material compared to current collection procedures, eliminating the requirement for general surgical anesthesia, multiple drug injections or blood apheresis. Patient benefits are expected to include fewer needle sticks than with current cell collection and infusion methods and a reduction in overall patient procedure time. Additionally, Aastrom's process for cell expansion is expected to minimize the time requirement for physicians compared with bone marrow harvest.

Enhanced Multicycle High-Dose Chemotherapy. The long restoration period for

the hematopoietic system following myeloablative therapy effectively limits patients to one opportunity for cell collection prior to cancer therapy. The Aastrom CPS may enhance the practice of multicycle, high-dose chemotherapy by providing the ability to produce a therapeutic dose of cells from a small starting volume. The initial cell collection can be divided into multiple samples and stored frozen until expansion at a later time is required.

Reduced Quantity of Lymphocytes. The Company believes its approach to stem

cell therapy may provide an additional benefit over current methods by depleting potentially harmful cells such as T-cells and B-cells. These cells are believed to be primarily responsible for graft-versus-host disease, a common manifestation of allogeneic transplants in which the grafted donor's cells attack the host's tissues and organs.

Tumor Cell Purging. 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. Additionally, patients may have undetected tumor cells present in their marrow or PBPC transplant, which could re-establish cancer in the patient following transplant. The Company's initial 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 Aastrom CPS compared with bone marrow

harvest or PBPC transplants may provide approximately 10 to 70 fold less tumor cells in a transplant. Further, in an evaluation of seven tumor-contaminated bone marrow samples that were expanded with the Aastrom CPS process, the presence of breast cancer cells in each sample was either substantially reduced or was no longer detectable. The Company believes 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.

CLINICAL DEVELOPMENT

The Company's clinical development plan is initially to obtain regulatory approval in the United States to market the Aastrom CPS for autologous stem cell therapy and UCB transplantation, and in Europe for more general cell therapy applications. The Company also intends to pursue approval of the Aastrom CPS for additional clinical indications.

The Company believes that the Aastrom CPS for stem cell therapy will be regulated as a medical device and that the Company will be required to submit a Pre-Market Approval ("PMA") application to, and obtain approval from, the FDA to allow it to market this product in the United States. In order to obtain PMA registration, the Company will be required to complete clinical trials under an IDE. See "--Government Regulation--Devices."

Aastrom is currently conducting a pre-pivotal stem cell therapy clinical trial at four U.S. sites. This clinical trial is designed to demonstrate that cells produced using the Aastrom CPS can alone provide hematopoietic recovery in accordance with trial endpoints in breast cancer patients who have received myeloablative chemotherapy. Bone marrow or mobilized PBPC obtained from the patients by traditional methods will be available for precautionary reasons at defined clinical stages.

Initial patient data from one trial site have been presented and demonstrate that cells produced in the Aastrom CPS can lead to engraftment of stem cells in patients within a recovery time frame that is comparable with that of conventional bone marrow transplantation following ablative chemotherapy. These patients started to recover their white blood cell counts within a median time of approximately seven days post-transplant and reached safe levels of neutrophils at approximately 16 days and platelets at approximately 23 days. Prior to implementing the trial protocol used for these patients, the Company had evaluated the cells produced in the Aastrom CPS in Stage IV breast cancer patients who had received significant prior cytotoxic therapy for their advanced cancer.

The Company has also initiated clinical trials at one site for adult patients and at another site for pediatric patients to evaluate the use of the Aastrom CPS to expand cells obtained from UCB for use in patients who have received myeloablative radiation or chemotherapy.

The objective of the current and anticipated future trials is to establish the protocols for pivotal trials of the Aastrom CPS in stem cell therapy. Provided that these pre-pivotal trials provide further evidence of the feasibility and safety of cells produced in the Aastrom CPS, the Company anticipates initiating pivotal clinical trials at multiple sites no earlier than late 1997, with patient enrollment to support a PMA filing, although this schedule is subject to numerous risks and uncertainties.

Aastrom, in partnership with Cobe, has initiated two clinical sites in Europe to evaluate the use of Aastrom CPS cells to promote hematopoietic recovery in breast cancer patients undergoing aggressive myelosuppressive or myelotoxic chemotherapy. Assuming the successful completion of these and other clinical trials, the Company intends to seek approval to market the Aastrom CPS in Europe through CE Mark Registration. See "--Government Regulation--Regulatory Process in Europe."

The ongoing trials were preceded by earlier studies designed to evaluate safety and process feasibility. Aastrom completed the first feasibility trial of its cell production system technology at the M.D. Anderson Cancer Center in October 1995. In this trial, ten breast cancer patients, who were subjected to myeloablative chemotherapy, were treated with cells obtained from a standard bone marrow harvest and with cells produced from a sample of such cells with a predecessor of the Aastrom CPS. The patients exhibited standard clinical recoveries, providing evidence of the clinical safety of cells obtained from the Company's cell production process and of the feasibility of cell production with a predecessor of the Aastrom CPS by clinical personnel at an investigational site. With this study completed, a five-patient study was then conducted to begin to evaluate the use of cells obtained from the Company's cell production process alone in the transplant setting.

The results from these patients provided evidence of the clinical safety of the Aastrom CPS-produced cells in patients and that the hematopoietic recovery endpoints specified for the trial are achievable. Four of these five patients received the delayed administration of the precautionary bone marrow pursuant to the trial protocol. Following further review by the FDA, the IDE was amended to expand the trail to the four additional sites where the clinical trail is now ongoing. The amended IDE provided for the enrollment of Stage II, III and IV patients, and a delayed use of the precautionary bone marrow.

In a dose-ranging study conducted by the University of Michigan (the "University") in 1993, ex vivo produced cells utilizing the Company's

proprietary cell production technology were infused into seven patients with non-Hodgkin's lymphoma after they received myeloablative chemotherapy. These patients also received cells obtained from either an autologous bone marrow harvest or PBPC procedure. No safety issues attributable to the infused cells were observed in this trial and the patients exhibited recovery profiles consistent with traditional transplantation techniques.

The preliminary results of the Company's pre-pivotal trials may not be predictive of results that will be obtained from subsequent patients in the trials or from more extensive trials. Further, there can be no assurance that the Company's pre-pivotal or pivotal trials will be successful, or that PMA registration or required foreign regulatory approvals for the Aastrom CPS will be obtained in a timely fashion, or at all. See "Business Risks--Uncertainties Related to Clinical Trials."

ADDITIONAL STEM CELL AND OTHER CELL THERAPIES

The Company believes that the Aastrom CPS hardware and single-use Cell Cassettes may be developed to serve as platform products for application in a variety of other emerging cell therapies in addition to stem cell therapy. The Company believes that the Aastrom CPS has the potential to supplant current manual cell culture methods to produce therapeutic quantities of cell types such as T-cells, chondrocytes, mesenchymal cells, keratinocytes, neuronal cells and dendritic cells. 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 Aastrom CPS in these therapies may include: (i) reducing labor and capital costs; (ii) enhancing process reliability; (iii) automating quality assurance; (iv) reducing the need for specialized, environmentally controlled facilities; and (v) providing greater accessibility of these procedures to care providers and patients and, in certain cases, providing a more biologically active cell product.

Modification of such processes and application of the Company's products to the expansion of other cell types may require substantial additional development of specialized cell culture environments which may need to be incorporated within the Company's existing Cell Cassettes. Such modifications may require the Company to raise substantial additional funds, or to seek additional collaborative partners, or both. There can be no assurance that the Company will be able to successfully modify or develop existing or future products to enable such additional cell production processes. The Company's 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 the Company's processes or product candidates will find successful application in such therapies. In addition, the Company 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 the Company 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--Future Capital Needs; Uncertainty of Additional Funding."

Immunotherapies

Immunotherapy involves using cells of the immune system to eradicate a disease target. T-cell lymphocytes and dendritic cells are being actively investigated by other companies for this purpose, and the Company anticipates that many of these procedures will require ex vivo cell production.

T-cells, a class of lymphocyte white blood cells, play a critical role in the human immune system and are responsible for the human immune response in a broad spectrum of diseases, including cancers and infectious diseases. Cytotoxic T-lymphocytes ("CTLs") is a new process that involves collecting T-cells from a patient and culturing them in an environment

resulting in T-cells with specificity for a particular disease target. Clinical trials by third parties have been initiated 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.

Dendritic cells (the potent antigen presenting cells) are believed to play an important role in the function of the immune system. Researchers believe that cultured dendritic cells could augment the natural ability of a patient to present antigens from the infectious agents to the immune system and aid in the generation of a cytotoxic T-cell response to the infectious agent.

Solid Tissue Cell Therapies

One of the newest areas 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 therapeutic quantity of chondrocytes is produced from this surgical biopsy. The cells are then implanted into the patient's 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. The Company believes that the Aastrom CPS may have the potential to reduce costs associated with the cell production procedure and, if successfully developed by the Company for this application, may eventually facilitate the transfer of the cell production capability away from specialized facilities directly to the clinical care sites.

Other Stem Cell Therapies

Autoimmune Diseases. Stem cell therapy is under clinical investigation by third parties for the treatment of other diseases. Clinical studies have suggested a potential role for stem cell therapy in treatment of autoimmune diseases such as rheumatoid arthritis, multiple sclerosis and lupus erythematosus. The generic cause of these diseases is a malfunctioning immune system, including T-lymphocytes. Clinical trials in which the patient receives treatment resulting in immune ablation (usually involving myelotoxic cancer drugs or radiation), followed by stem cell therapy to restore the bone marrow and cells of the blood and immune system, have demonstrated remission of the autoimmune disease in some patients.

Organ Transplantation. Recently, a number of academic and corporate researchers and companies have identified the potential use of stem cell therapy to facilitate successful solid organ and tissue transplants between human donors and recipients, as well as using organs from non-human species for transplantation into humans. These proposed applications are based on the observation that donor-specific bone marrow, infused concurrent with or prior to the organ transplant, can provide for reduction of the normal immune rejection response by the transplant recipient (e.g. heart, lung, liver or kidney transplants).

A major limitation to the use of stem cell therapy in solid organ transplant is the limited availability of sufficient amounts of bone marrow to obtain a desired therapeutic response of immune tolerization. This limitation is particularly problematic when cadaveric donor organs are used, which has traditionally been the source of cells for these procedures. Bone marrow is also often available from the cadaveric donor, but only in a limited amount. Normally this amount may be sufficient for one transplant, but a donor might provide multiple organs for transplant into multiple recipients. Aastrom believes that the ability to expand the available bone marrow ex vivo will enhance the use of

stem cell therapy for such transplant procedures and may pursue development of its products for application in such therapy in the future.

AASTROM PRODUCT CANDIDATES FOR EX VIVO GENE THERAPY

A novel form of cell therapy is ex vivo gene therapy. For this type of cell therapy, cells procured from the patient or a donor are genetically modified prior to their infusion into the patient. Analogous to other cell therapies, the ability to produce a therapeutic dose of these gene-modified cells is a major limitation to the commercialization of these cell therapies. This limitation is further exacerbated by the additional requirement that the cells be genetically modified under conditions that are sterile and comply with GMP.

Gene therapy is a therapeutic modality that holds the potential to significantly impact the delivery of healthcare and the delivery of therapeutically useful protein-based drugs within the body. Gene therapies are generally targeted at the introduction of a missing normal gene into otherwise defective human tissue, or the introduction of novel biologic capability

into the body via the introduction of a gene not ordinarily present (for example, genes providing for the enhanced recognition and destruction or inhibition of the HIV-1 virus). The major developmental focus of the ex vivo

gene therapy industry has been to identify the therapeutic gene of interest, insert it into a suitable vector that can be used to transport and integrate the gene into the DNA of the target cell, and then cause the gene to become expressed. The Company believes that for ex vivo gene therapy to progress to

clinical applications, a process to produce a sufficient quantity of therapeutic cells is required as is an efficient means to insert the gene vector into target cells. Gene therapy is still in an early stage of development by third parties. The Company's business opportunity is dependent upon the successful development and regulatory approval of individual gene therapy applications. No assurance can be given that such applications will be developed or approved or that the Company's processes or product candidates will find successful applications in such therapies. Successful development of the Company's processes and product candidates for application in ex vivo gene therapy will require substantial

additional research and development, including clinical testing, and will be subject to the Company's ability to finance such activities on acceptable terms, if at all. See "Business Risks--Future Capital Needs; Uncertainty of Additional Funding."

THE AASTROM CPS FOR GENE THERAPY (GT-CPS)

The Aastrom CPS has been designed to produce cells for therapy and the Company believes that the Aastrom CPS may be useful in many potential ex vivo gene

therapy applications. Further, the Company anticipates that its proprietary stem cell production process technology implemented by the Aastrom CPS may provide the conditions for clinical scale stem cell division, and enable or enhance the introduction of therapeutic genes into stem cell DNA. The Company believes that its technology may also enable expansion of more mature progeny of these stem cells to create a gene therapy cell product with potential short and long term therapeutic effect.

The Company has two principal objectives for the development of Aastrom GT-CPS: (i) the enablement of stem cell gene therapies for a variety of hematologic and other disorders, based on the GT-CPS's ability to enable large scale stem cell division ex vivo; and (ii) the enablement of gene transfer and therapeutic

cell production by local and regional primary patient care facilities and ancillary service laboratories.

THE AASTROM GENE LOADER

The Aastrom Gene Loader product technology, which is under development, is being designed to enhance the efficiency and reliability of the transfer of new therapeutic genes, which are carried by vectors, into the target cell. This process, which is typically inefficient in many human cells inhibits many ex vivo gene therapies from moving forward in the clinic. The Aastrom Gene Loader is being designed to incorporate the Company's proprietary directed motion gene transfer technology. Complete product development is expected to require additional funding sources or collaborations with others, or both.

The Company believes that these issues represent a general bottleneck for other companies pursuing ex vivo gene therapy clinical applications. The

Company's technology under development may favorably influence these gene therapy applications, the development of which are impeded due to low transduction efficiencies and the resultant need for use of extreme quantities of gene vectors and/or target "delivery" tissues.

STRATEGIC RELATIONSHIPS

On October 22, 1993, the Company entered into a Distribution Agreement (the "Distribution Agreement") with Cobe for Cobe to be the Company's exclusive, worldwide marketing, distribution and service provider for the Aastrom CPS for stem cell therapy applications (the "Stem Cell Therapy Applications"). Under the terms of the Company's Distribution Agreement with Cobe, other than with respect to sales to affiliates, the Company is precluded from selling the Aastrom CPS to customers for stem cell therapy applications. The Company has, however, reserved the right to sell the Aastrom CPS for: (i) all diagnostic or other non-therapeutic clinical applications; (ii) all gene therapy or gene transfer applications, including those for stem cells; (iii) all non-human applications; (iv) certain permitted clinical research applications; and (v) all applications that are labeled not for human use. The Company has also reserved the unconditional right to sell other products under development, including but not limited to products based upon its gene loading technology. The initial term of the Distribution Agreement expires on October 22, 2003, and Cobe has the option to extend the term for an additional ten-year period. The Company is responsible for the expenses to obtain FDA and other regulatory approval in the United States, while

Cobe is responsible for the expenses to obtain regulatory approval in foreign countries to allow for worldwide marketing of the Aastrom CPS for Stem Cell Therapy Applications. See "Business Risks--Consequences of Cobe Relationship."

Under the terms of the Distribution Agreement, the Company will realize approximately 58% to 62% of the net sales price at which Cobe ultimately sells the Aastrom CPS for Stem Cell Therapy Applications, subject to certain negotiated discounts and volume-based adjustments and subject to the obligation of the Company to make aggregate royalty payments of up to 5% to certain licensors of its technology. The Company is also entitled to a premium on United States sales in any year in which worldwide sales exceed specified levels.

The Distribution Agreement may be terminated by Cobe upon twelve months prior notice to the Company in the event that any person or entity other than Cobe beneficially owns more than 50% of the Company's outstanding Common Stock or voting securities. The Distribution Agreement may also be terminated by Cobe at any time after December 31, 1997 if Cobe determines that commercialization of the Aastrom CPS for stem cell therapy on or prior to December 31, 1998 is unlikely.

In conjunction with the Distribution Agreement, the Company also entered into a Stock Purchase Agreement with Cobe (the "Cobe Stock Agreement"), whereby Cobe acquired certain option, registration, preemptive and other rights pertaining to shares of the Company's stock. Pursuant to such preemptive rights, Cobe elected to purchase 714,200 shares of Common Stock in the Company's initial public offering in February 1997. See "Description of Capital Stock--Rights of Cobe" and "Certain Transactions."

The Company has entered into a Strategic Planning Consulting Services and Collaboration Agreement (the "Consulting Agreement") with Burrill & Company, LLC ("Burrill"), pursuant to which Burrill will advise the Company on potential strategic alliances and seek to identify potential collaborations. Pursuant to the Consulting Agreement, Burrill will be paid a monthly retainer of \$10,000 and will be reimbursed for expenses incurred pursuant to an approved budget. Aastrom has issued Burrill an immediately exercisable warrant to purchase 100,000 shares of Common Stock at an exercise price of \$7.24 and a second warrant, which vests over a one-year period, to purchase 100,000 shares at an exercise price of \$7.24. The Consulting Agreement is terminable by either party following periods of up to 30 days following notice.

The Consulting Agreement also provides for payments to Burrill that are based on the timing and amount of proceeds Aastrom may receive from any future strategic alliances. In the event that the Company enters into strategic alliances (which exclude minor technology license agreements and customary manufacturing or supply agreements that do not involve equity investments in Aastrom, as well as performance pursuant to any of Cobe's existing agreements with Aastrom), the Company will pay Burrill a success fee ranging from 4% to 7.5% of the proceeds in connection with the strategic alliance. In addition to the success fee, Aastrom will issue to Burrill additional warrants to purchase up to 500,000 shares of Common Stock, depending upon the achievement of certain milestones.

MANUFACTURING

The Company has no current intention of internally manufacturing its product candidates and, accordingly, is developing relationships with third party manufacturers which are FDA registered as suppliers for the manufacture of medical products.

In May 1994, the Company entered into a Collaborative Product Development Agreement with SeaMED Corporation, ("SeaMED"). Pursuant to this agreement, the Company and SeaMED will collaborate on the further design of certain instrument components in the Aastrom CPS, and enable SeaMED to manufacture pre-production units of the instrument components for laboratory and clinical evaluation. The Company is paying SeaMED for its design and pre-production work on a "time and materials" basis, utilizing SeaMED's customary hourly billing rates and actual costs for materials. Subject to certain conditions, the Company has committed to enter into a manufacturing agreement with SeaMED for commercial manufacture of the instrument components for three years after shipment by SeaMED of the first commercial unit pursuant to a pricing formula set forth in the agreement. The Company retains all proprietary rights to its intellectual property which is utilized by SeaMED pursuant to this agreement.

In November 1994, the Company entered into a Collaborative Product Development Agreement with Ethox Corporation ("Ethox"). Pursuant to this agreement, the Company and Ethox collaborated on the design of certain bioreactor assembly and custom tubing kit components of the Aastrom CPS. The Company is paying Ethox for its design and production work on a "time and materials" basis, utilizing Ethox's customary hourly billing rates and actual costs for materials. The Company retains all proprietary rights to its intellectual property which are utilized by Ethox pursuant to this agreement.

In March 1996, the Company entered into a five-year License and Supply Agreement with Immunex Corporation ("Immunex") to purchase and resell certain cytokines and ancillary materials for use in conjunction with the Aastrom CPS. The agreement required the Company to pay Immunex an initial up-front fee of \$1,500,000 to be followed by subsequent annual renewal payments equal to \$1,000,000 per year during the term of the agreement in addition to payment for supplies purchased by the Company. In August 1997, the Company and Immunex amended the agreement to expand the Company's territorial rights to use and sell such materials to a worldwide basis. Unless earlier terminated or renewed by the Company for an additional five-year term, the agreement will expire in April 2001. The 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 the Company of cytokines and ancillary materials if the Company fails to purchase a minimum amount of its forecasted annual needs from Immunex after notice to the Company and expiration of a specified cure period. The Company also has the right to terminate the agreement at any time subject to the payment to Immunex of a specified amount for liquidated damages. In the event that Immunex elects to cease to supply to the Company cytokines and ancillary materials or is prevented from supplying such materials to the Company by reason of force majeure, limited manufacturing rights will be transferred to the Company under certain circumstances. There is, however, no assurance that the Company could successfully manufacture the compounds itself or identify others that could manufacture these compounds to acceptable quality standards and costs, if at all.

In December 1996, the Company entered into a Collaborative Supply Agreement with Anchor Advanced Products, Inc., Mid-State Plastics Division ("MSP"). Under this agreement, MSP will conduct both pre-production manufacturing development and commercial manufacturing and assembly of the Cell Cassette component of the Aastrom CPS for the Company. During the initial phase of the seven-year agreement, the Company will pay MSP for its development activities on a time and materials basis. Upon reaching certain commercial manufacturing volumes, MSP will be paid by the Company on a per unit basis for Cell Cassettes delivered to the Company under a pricing formula specified in the agreement. Throughout the term of this agreement, the Company has agreed to treat MSP as its preferred supplier of Cell Cassettes, using MSP as its supplier of at least 60% of its requirements for Cell Cassettes.

There can be no assurance that the Company will be able to continue its present arrangements with its suppliers, supplement existing relationships or establish new relationships or that the Company will be able to identify and obtain the ancillary materials that are necessary to develop its product candidates in the future. The Company's dependence upon third parties for the supply and manufacture of such items could adversely affect the Company's ability to develop and deliver commercially feasible products on a timely and competitive basis. See "Business Risks--Manufacturing and Supply Uncertainties; Dependence on Third Parties."

PATENTS AND PROPRIETARY RIGHTS

The Company's success depends in part on its ability, and the ability of its licensors, to obtain patent protection for its products and processes. The Company has exclusive rights to twelve issued U.S. patents and one patent with respect to which the Company has received notice of allowance that 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. Patents equivalent to two of

these U.S. patents have also been issued in other jurisdictions: one in Australia and another in Canada and under the European Patent Convention. These twelve issued patents, in addition to the one patent with respect to which the Company has received notice of allowance, are due to expire beginning in 2006, through 2014. In addition, the Company and its exclusive licensors have filed applications for patents in the United States and equivalent applications in certain other countries claiming other aspects of the Company's products and processes, including a number of U.S. patent applications and corresponding applications in other countries related to various components of the Aastron CPS.

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 of the Company or its licensors will be issued, that the scope of any patent protection will exclude competitors or provide competitive advantages to the Company, that any of the patents that have been or may be issued to the Company or its 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 the Company. Furthermore, there can be no assurance that others have not developed or will not develop similar products, duplicate any of the Company's products or design around any patents that have been or may be issued to the Company or its licensors. Since patent applications in the United States are maintained in secrecy until patents issue, the Company also cannot be certain that others did not first file applications for inventions covered by the Company's and its licensors' pending patent applications, nor can the Company be certain that it will not infringe any patents that may issue to others on such applications.

The Company relies on certain licenses granted by the University of Michigan and Dr. Cremonese for the majority of its patent rights. If the Company breaches such agreements or otherwise fails to comply with such agreements, or if such agreements expire or are otherwise terminated, the Company may lose its rights under the patents held by the University of Michigan and Dr. Cremonese, which would have a material adverse effect on the Company's business, financial condition and results of operations. See "--Research and License Agreements."

The Company also relies on trade secrets and unpatentable know-how which it seeks to protect, in part, by confidentiality agreements. It is the Company's policy to require its employees, consultants, contractors, manufacturers, outside scientific collaborators and sponsored researchers, and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with the Company. These agreements provide that all confidential information developed or made known to the individual during the course of the individual's relationship with the Company is to be kept confidential and not disclosed to third parties except in specific limited circumstances. The Company also requires signed confidentiality or material transfer agreements from any company that is to receive its confidential data. In the case of employees, consultants and contractors, the agreements generally provide that all inventions conceived by the individual while rendering services to the Company shall be assigned to the Company as the exclusive property of the Company. There can be no assurance, however, that these agreements will not be breached, that the Company would have adequate remedies for any breach, or that the Company's trade secrets or unpatentable know-how will not otherwise become known or be independently developed by competitors.

The Company's success will also depend in part on its ability to develop commercially viable products without infringing the proprietary rights of others. The Company has 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 effect on the Company's ability to market its products or maintain its competitive position with respect to its products. If the Company's 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, the Company may be subject to infringement actions. In such event, the Company may challenge the validity of such patents or other proprietary rights or be required to obtain licenses from such companies in order to develop, manufacture or market its products. There can be no assurances that the Company 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 the Company's proposed products or the inability to proceed with the development, manufacture or sale of products requiring such licenses, which could have a material adverse effect on the Company's business, financial condition and results of operations. If the Company is required to defend itself against charges of patent infringement or to protect its own proprietary rights against third parties, substantial costs will be incurred regardless of whether the Company is successful. Such proceedings are typically protracted with no certainty of success. An adverse outcome could subject the Company to significant liabilities to third parties and force the Company to curtail or cease its development and sale of its products and processes.

Certain of the Company's and its licensors' research has been or is being funded in part by the Department of Commerce and by a Small Business Innovation Research Grant obtained from the Department of Health and Human Services. As a result of such funding, the U.S. Government has certain rights in the technology developed with the funding. These rights include a non-exclusive, paid-up, worldwide license under such inventions for any governmental purpose. In addition, the government has the right to require the Company 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) if the licensee does not pursue reasonable commercialization of a needed product using the invention, the government may force the granting of a license to a third party who will make and sell the needed product; and (iii) the U.S. Government may use the invention for its own needs.

RESEARCH AND LICENSE AGREEMENTS

In August 1989, the Company entered into a Research Agreement (the "Research Agreement") with the University, pursuant to which the Company funded a research project at the University under the direction of Stephen G. Emerson, M.D., Ph.D., as the principal inventor, together with Michael F. Clarke, M.D., and Bernhard O. Palsson, Ph.D., as co-inventors. Pursuant to the Research Agreement, the Company was granted the right to acquire an exclusive, worldwide license to utilize all inventions, know-how and technology derived from the research project. By Extension Agreements, the Company and the University extended the scope and term of the Research Agreement through December 1994.

In March 1992, the Company and the University entered into the License Agreement, as contemplated by the Research Agreement. There have been clarifying amendments to the License Agreement, in March 1992, October 1993 and June 1995. Pursuant to this License Agreement, (i) the Company 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's research project or which resulted from certain further research conducted through December 1994, and (ii) the Company is obligated to pay to the University a royalty equal to 2% of the net sales of products which are covered by the University's patents. Unless it is terminated earlier at the Company's option or due to a material breach by the Company, the License Agreement will continue in effect until the latest expiration date of the patents to which the License Agreement applies.

In July 1992, the Company entered into a License Agreement with Joseph G. Cremonese pursuant to which the Company obtained exclusive worldwide license rights for all fields of use, to utilize U.S. Patent No. 4,839,292, entitled "Cell Culture Flask Utilizing a Membrane Barrier," which patent was issued to Dr. Cremonese on June 13, 1989, and to utilize any other related patents that might be issued to Dr. Cremonese. Pursuant to the License Agreement, the Company has reimbursed Dr. Cremonese for \$25,000 of his patent costs. Under the terms of the License Agreement, the Company is to pay to Dr. Cremonese a royalty of 3% of net sales of the products which are covered by said patent, subject to specified minimum royalty payments ranging from \$20,000 to \$50,000 per year, commencing in calendar year 1997. Unless earlier terminated, the License Agreement will continue in effect until the latest expiration date of the patents to which the License Agreement applies, which latest expiration date is currently August 2009. The License Agreement may be terminated by either party upon

default by the other party of any of its obligations under the agreement without cure after expiration of a 30-day notice period. The Company also has the right to terminate the License Agreement at any time without cause upon 30 days prior written notice to Dr. Cremonese.

GOVERNMENT REGULATION

The Company's research and development activities and the manufacturing and marketing of the Company's products are subject to the laws and regulations of governmental authorities in the United States and other countries in which its 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, the Company is 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 the Company's knowledge, it is the first to develop a 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 the Company's products is uncertain.

The Company's products are potentially subject to regulation as medical devices under the Federal Food, Drug, and Cosmetic Act, and as biological products under the Public Health Service Act, or both. Different regulatory requirements may apply to the Company's products depending on how they are categorized by the FDA under these laws. To date, the FDA has indicated that it intends to regulate the Aastrom CPS product for stem cell therapy as a Class III medical device through the Center for Biologics Evaluation and Research. However, there can be no assurance that FDA will ultimately regulate the Aastrom CPS as a medical device.

Further, it is unclear whether the FDA will separately regulate the cell therapies derived from the Aastrom CPS. The FDA is still in the process of developing its requirements with respect to somatic cell therapy and gene cell therapy products and has recently issued draft documents concerning the regulation of umbilical cord blood stem cell products, as well as cellular and tissue-based products. If the FDA adopts the regulatory approach set forth in the draft document, the FDA may require separate regulatory approval for such cells in some cases. The FDA also recently proposed a new type of license, called a biologic license application ("BLA"), for autologous cells manipulated ex vivo and intended for structural repair or reconstruction. This proposal may

indicate that the FDA will extend a similar approval requirement to other types of autologous cellular therapies, such as autologous cells for stem cell therapy. Any such additional regulatory or approval requirements could significantly delay the introduction of the Company's product candidates to the market, and have a material adverse impact on the Company.

Approval of new medical devices and biological products is a lengthy procedure leading from development of a new product through preclinical and clinical testing. This process takes a number of years and the expenditure of significant resources. There can be no assurance that the Company's product candidates will ultimately receive regulatory approval.

Regardless of how the Company's 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, recordkeeping, 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 the Company to enter into government supply contracts, withdrawal of previously approved applications and criminal prosecution.

DEVICES

In order to obtain FDA approval of a new medical device sponsors must generally submit proof of safety and efficacy. In some cases, such proof entails extensive clinical and preclinical 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 the Company may encounter significant difficulties or costs in its efforts to obtain FDA approvals which could delay or preclude the Company from marketing any products it may develop. The FDA may also require postmarketing 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 the Company will have the exclusive right to exploit such technologies.

If human clinical trials of a proposed device are required and the device presents significant risk, the manufacturer or distributor of the device will have to file an IDE submission with the FDA prior to commencing human clinical trials. The IDE submission must be supported by data, typically including the results of pre-clinical and laboratory testing. If the IDE submission is granted, human clinical trials may commence at a specified number of investigational sites with the number of patients approved by the FDA.

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 recordkeeping regulations, GMPs, 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 postmarket 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 prior to marketing and distribution. The FDA also has the authority to require clinical testing of Class I and Class II devices.

If a manufacturer or distributor of medical devices cannot establish that a proposed device is substantially equivalent, the manufacturer or distributor must submit a PMA application to the FDA. A PMA application must be supported by extensive data, including preclinical and human clinical trial data, to prove the safety and efficacy of the device. Upon receipt, the FDA conducts a preliminary review of the PMA application. If sufficiently complete, the submission is declared filed by the FDA. By regulation, the FDA has 180 days to review a PMA application once it is filed, although PMA application reviews more often occur over a significantly protracted time period, and may take approximately one year or more from the date of filing to complete.

Some of the Company's products may be classified as Class II or Class III medical devices. The Company has submitted several IDEs for the Aastrom CPS, and is currently conducting pre-pivotal clinical studies under these IDEs. The Company believes that the Aastrom CPS product will be regulated by the FDA as a Class III device, although there can be no assurance that the FDA will not choose to regulate this product in a different manner.

The Company and any contract manufacturer are required to be registered as a medical device manufacturer with the FDA. As such, they will be inspected on a routine basis by the FDA for compliance with the FDA's GMP regulations. These regulations will require that the Company and any contract manufacturer manufacture products and maintain documents in a prescribed manner with respect to manufacturing, testing, distribution, storage, design control and service activities, and that adequate design and service controls are implemented. The Medical Device Reporting regulation requires that the Company provide information to the FDA on deaths or serious injuries alleged to be associated with the use of its 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.

BIOLOGICAL PRODUCTS -----

For certain of the Company's new products which may be regulated as biologics, the FDA requires (i) preclinical laboratory and animal testing, (ii) submission to the FDA of an investigational new drug ("IND") 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 product license application ("PLA") and establishment license application ("ELA") and (v) review and approval of the PLA and ELA 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 the Company is 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 effects. 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 the Company 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 PLA 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 effects be reported to the FDA and may also require post-marketing testing to monitor for adverse effects, which can involve significant expense.

Under current requirements, facilities manufacturing biological products must be licensed. To accomplish this, an ELA must be filed with the FDA. The ELA 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 cGMP and the ability to consistently manufacture the product in the facility in accordance with the PLA. If the FDA finds the inspection unsatisfactory, it may decline to approve the ELA, resulting in a delay in production of products. Although reviewed separately, approval of both the PLA and ELA must be received prior to commercial marketing of a cellular biologic.

As part of the approval process for human biological products, each manufacturing facility must be registered and inspected by 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 Company believes that the Aastrom CPS will be regulated in Europe as a Class IIb medical device, under the authority of the new Medical Device Directives ("MDD") being implemented by European Union ("EU") member countries. This classification applies to medical laboratory equipment and supplies including, among other products, many devices that are used for the collection and processing of blood for patient therapy. Certain ancillary products (e.g., biological reagents) used with the Aastrom CPS may be considered 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 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 charged with 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, although there is a general trend among EU member countries not to impose additional requirements beyond those specified for CE Mark certification.

COMPETITION

The biotechnology and medical device industries are characterized by rapidly evolving technology and intense competition. The Company's 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 those of the Company. 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 those of the Company. 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. The Company's product development efforts are primarily directed toward obtaining regulatory approval to market the Aastrom CPS for stem cell therapy. That market is currently dominated by the bone marrow harvest and PBPC collection methods. The Company's clinical data, although early, suggests that cells expanded in the Aastrom CPS using its current process will enable hematopoietic recovery within the time frames currently achieved by bone marrow harvest, however, neutrophil and platelet recovery times may be slower than with PBPC collection methods. The Company is evaluating techniques and methods to optimize the cells produced in the Aastrom CPS to reduce the recovery time of neutrophils and platelets in patients. There can be no assurance that if such procedure optimization does not lead to recovery times equal to or faster than those of PBPC collection methods, such outcome would not have a material adverse effect on the Company's business, financial condition and results of operations. In addition, the bone marrow harvest and PBPC collection methods have been widely practiced for a number of years and, recently, the patient costs associated with these procedures have begun to decline. There can be no assurance that the Aastrom CPS method, if approved for marketing, will prove to be competitive with these established collection methods on the basis of hematopoietic recovery time, cost or otherwise. The Company is 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 which the Company has targeted for product development. In particular, the Company is aware that competitors such as Amgen, Inc., CellPro, Incorporated, Novartis, A.G., Baxter Healthcare Corp. and Rhne-Poulenc Rorer Inc. ("RPR") are in advanced stages of development of technologies and products for use in stem cell therapy and other market applications currently being pursued by the Company. In addition, Cobe, a significant shareholder of the Company, is a market leader in the blood cell processing products industry and, accordingly, a potential competitor of the Company. There can be no assurance that developments by others will not render the Company's product candidates or technologies obsolete or noncompetitive, that the Company will be able to keep pace with new technological developments or that the Company's product candidates will be able to supplant established products and methodologies in the therapeutic areas that are targeted by the Company. The foregoing factors could have a material adverse effect on the Company's business, financial condition and results of operations.

The Company's products under development are expected to address a broad range of existing and new markets. The Company believes that its stem cell therapy products will, in large part, face competition by existing procedures rather than novel new products. The Company's competition will be determined in part by the potential indications for which the Company's 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 the Company or its 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. The Company's competitive position will also depend on its 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. The Company expects its products, if approved for sale, to compete primarily on the basis of product efficacy, safety, patient convenience, reliability, value and patent position.

EMPLOYEES

As of August 31, 1997, the Company employed approximately 72 individuals full-time. A significant number of the Company's management and professional employees have had prior experience with pharmaceutical, biotechnology or medical product companies. None of the Company's employees are covered by collective bargaining agreements, and management considers relations with its employees to be good.

Executive Officers of the Company

The executive officers of the Company, and their respective ages as of August 31, 1997, are as follows:

| NAME ---- | AGE --- | POSITION ----- |
|---------------------------------|------------|--|
| R. Douglas Armstrong, Ph.D..... | 44 | President and Chief Executive Officer |
| James Maluta..... | 50 | Vice President, Product Development |
| Todd E. Simpson..... | 36 | Vice President, Finance & Administration, Chief Financial Officer, Secretary and Treasurer |
| Walter C. Ogier..... | 40 | Vice President, Marketing |
| Thomas E. Muller, Ph.D..... | 61 | Vice President, Regulatory Affairs |
| Alan K. Smith, Ph.D..... | 42 | Vice President, Research |

R. Douglas Armstrong, Ph.D. joined the Company in June 1991 as a director and as its President and Chief Executive Officer. From 1987 to 1991, Dr. Armstrong served in different capacities, including as Executive Vice President and a Trustee of the La Jolla Cancer Research Foundation ("LJCRF"), a 250-employee scientific research institute located in San Diego, California. Dr. Armstrong received his doctorate in Pharmacology and Toxicology from the Medical College of Virginia, and has held faculty and staff positions at Yale University, University of California, San Francisco, LJCRF and University of Michigan. Dr. Armstrong also serves on the Board of Directors of Nephros Therapeutics, Inc.

James Maluta joined the Company in August 1992 as Vice President, Product Development. Mr. Maluta has a broad background in the development and manufacturing of medical devices, with 25 years of experience in the industry, principally with OHMEDA and with Cobe BCT, Inc. While with Cobe BCT, Inc., Mr. Maluta was Program Manager for the Cobe Spectra Apheresis System, a device for blood cell processing and apheresis. Mr. Maluta held other engineering management positions and also was director of Quality Assurance for Cobe BCT. Mr. Maluta received his degree in electrical engineering from the University of Wisconsin, Madison.

Todd E. Simpson joined the Company in January 1996 as Vice President, Finance and Administration and Chief Financial Officer and is also the Company's Secretary and Treasurer. Prior to that, Mr. Simpson was Treasurer of Integra LifeSciences Corporation ("Integra"), a biotechnology company, which acquired Telios Pharmaceuticals, Inc. ("Telios") in August 1995 in connection with the reorganization of Telios under Chapter 11 of the U.S. Bankruptcy Code. Mr. Simpson served as Vice President of Finance and Chief Financial Officer of Telios up until its acquisition by Integra and held various other financial positions at Telios after joining that company in February 1992. Telios was a publicly-held company engaged in the development of pharmaceutical products for the treatment of dermal and ophthalmic wounds, fibrotic disease, vascular disease, and osteoporosis. From August 1983 through February 1992, Mr. Simpson practiced public accounting with the firm of Ernst & Young, LLP. Mr. Simpson is a Certified Public Accountant and received his B.S. degree in Accounting and Computer Science from Oregon State University.

Walter C. Ogier joined the Company in March 1994 as Director of Marketing and was promoted to Vice President, Marketing during 1995. Prior to that, Mr. Ogier was at Baxter Healthcare Corporation's Immunotherapy Division, where he served as Director, Business Development from 1992 to 1994 and as Manager, Marketing and Business Development in charge of the company's cell therapy product lines from 1990 to 1992. Mr. Ogier previously held positions with Ibbottson Associates and with the Business Intelligence Center at SRI International (formerly Stanford Research Institute). Mr. Ogier received his B.A. degree in Chemistry from Williams College in 1979 and his Masters of Management degree from the Yale School of Management in 1987.

Thomas E. Muller, Ph.D. joined the Company in May 1994 as Vice President, Regulatory Affairs. Prior to that, Dr. Muller was Director, Biomedical Systems with W.R. Grace & Company in Lexington, Massachusetts. Prior to this, Dr. Muller was Vice President, Engineering and Director of Research and Development with the Renal Division of Baxter Healthcare in Deerfield, Illinois. Dr. Muller has also served as Adjunct Professor at Columbia University and as Visiting Professor at the University of Gent, Belgium. Dr. Muller graduated from the Technical University in Budapest, Hungary, in 1956 with a B.S. in Chemical Engineering. Dr. Muller received his M.S. degree in 1959 and was awarded a Ph.D. in 1964, both in Polymer Chemistry, from McGill University.

Alan K. Smith, Ph.D. joined the Company in November 1995 as Vice President, -----
 Research. Previously, Dr. Smith was Vice President of Research and Development at Geneic Sciences, Inc., a developmental stage bone marrow transplantation company. Prior to that, Dr. Smith held the position of Director, Cell Separations Research and Development of the Immunotherapy Division of Baxter Healthcare Corporation. In this capacity, he was responsible for the research and development activities for a stem cell concentration system approved for clinical use in Europe and currently in pivotal clinical trials in the United States. Dr. Smith has also held positions as Research and Development Manager at BioSpecific Technologies, as Director of Biochemistry at HyClone Laboratories and as a member of the Board of Directors of Dallas Biomedical. Dr. Smith received his B.S. degree in Chemistry from Southern Utah State College in 1976 and a Ph.D. in Biochemistry from Utah State University in 1983.

ITEM 2. PROPERTIES

The Company leases approximately 20,000 square feet of office and research and development space in Ann Arbor, Michigan under a lease agreement expiring in May 1998. The lease is renewable at the option of the Company for up to an additional five-year term. The Company believes that its facilities will be adequate for its currently anticipated needs. Contract manufacturing or additional facilities will be required in the future to support expansion of research and development and to manufacture products.

ITEM 3. LEGAL PROCEEDINGS

The Company is not party to any material legal proceedings, although from time to time it may become involved in disputes in connection with the operation of its business.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

No matters were submitted to a vote of the Company's security holders during the fourth quarter of the Company's fiscal year ended June 30, 1997.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED SHAREHOLDER MATTERS

The Company effected an initial public offering of its Common Stock during February 1997 at a price of \$7.00 per share. Commencing on February 4, 1997, the Company's Common Stock has been quoted on the Nasdaq National Market under the symbol "ASTM." The following table sets forth, for the periods indicated, the high and low sales prices per share of Common Stock as reported on the Nasdaq National Market:

| YEAR ENDED JUNE 30, 1997 ----- | HIGH ---- | LOW --- |
|-------------------------------------|--------------|------------|
| 3rd Quarter (from February 4, 1997) | 7 5/8 | 5 3/4 |
| 4th Quarter | 8 1/2 | 3 1/2 |

As of August 31, 1997, there were approximately 140 shareholders of record of the Common Stock. The Company has never declared or paid any cash dividends on its Common Stock and does not anticipate paying such cash dividends in the foreseeable future. The Company currently anticipates that it will retain all future earnings, if any, for use in the development of its business.

ITEM 6. SELECTED FINANCIAL DATA

The statement of operations data presented below for the five years ended June 30, 1997 and for the period from the Company's inception on March 24, 1989 ("Inception") to June 30, 1997 and the balance sheet data at June 30, 1993, 1994, 1995, 1996 and 1997, were derived from the audited financial statements of the Company.

The data set forth below should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the financial statements and notes thereto appearing elsewhere in this Report.

| | YEAR ENDED JUNE 30, | | | | | INCEPTION TO JUNE 30, 1997 |
|---|---------------------|---------------|---------------|---------------|----------------|----------------------------------|
| | 1993 | 1994 | 1995 | 1996 | 1997 | |
| STATEMENT OF OPERATIONS DATA: | | | | | | |
| Revenues: | | | | | | |
| Research and development agreements..... | \$ -- | \$ 49,000 | \$ 396,000 | \$ 1,342,000 | \$ 230,000 | \$ 2,017,000 |
| Grants..... | 784,000 | 823,000 | 121,000 | 267,000 | 148,000 | 2,143,000 |
| Total revenues..... | 784,000 | 872,000 | 517,000 | 1,609,000 | 378,000 | 4,160,000 |
| Costs and expenses: | | | | | | |
| Research and development..... | 2,600,000 | 5,627,000 | 4,889,000 | 10,075,000 | 13,357,000 | 38,432,000 |
| General and administrative..... | 1,153,000 | 1,565,000 | 1,558,000 | 2,067,000 | 1,953,000 | 9,042,000 |
| Total costs and expenses..... | 3,753,000 | 7,192,000 | 6,447,000 | 12,142,000 | 15,310,000 | 47,474,000 |
| Loss from operations..... | (2,969,000) | (6,320,000) | (5,930,000) | (10,533,000) | (14,932,000) | (43,314,000) |
| Other income (expense): | | | | | | |
| Interest income..... | 148,000 | 245,000 | 279,000 | 678,000 | 676,000 | 2,252,000 |
| Interest expense..... | (26,000) | (65,000) | (66,000) | (62,000) | (32,000) | (251,000) |
| Net loss..... | \$(2,847,000) | \$(6,140,000) | \$(5,717,000) | \$(9,917,000) | \$(14,288,000) | \$(41,313,000) |
| Net loss per share(1)..... | \$ (.52) | \$ (.82) | \$ (.66) | \$ (.98) | \$ (1.26) | |
| Weighted average number of shares outstanding(1)..... | | | | | | |
| | 5,480,000 | 7,461,000 | 8,644,000 | 10,103,000 | 11,315,000 | |

| | JUNE 30, | | | | |
|--|--------------|--------------|---------------|---------------|---------------|
| | 1993 | 1994 | 1995 | 1996 | 1997 |
| BALANCE SHEET DATA: | | | | | |
| Cash, cash equivalents and short-term investments..... | \$ 3,085,000 | \$ 6,730,000 | \$ 11,068,000 | \$ 10,967,000 | \$ 17,007,000 |
| Working capital..... | 2,744,000 | 6,187,000 | 10,319,000 | 9,851,000 | 15,600,000 |
| Total assets..... | 4,156,000 | 8,227,000 | 12,551,000 | 12,673,000 | 18,410,000 |
| Long-term capital lease obligations..... | 311,000 | 425,000 | 412,000 | 189,000 | 65,000 |
| Deficit accumulated during the development stage..... | (5,251,000) | (11,391,000) | (17,108,000) | (27,025,000) | (41,313,000) |
| Total shareholders' equity..... | 3,268,000 | 6,985,000 | 11,186,000 | 10,850,000 | 16,583,000 |

(1) See Note 1 of Notes to Financial Statements for information concerning the computation of net loss per share and shares used in computing pro forma net loss per share.

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

This section of this Report on Form 10-K contains, in addition to historical information, forward-looking statements that involve risks and uncertainties. The Company's actual results may differ materially from those 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."

OVERVIEW

Since its Inception, the Company has been in the development stage and engaged in research and product development, conducted both on its own behalf and in connection with various collaborative research and development agreements with other entities. The Company does not expect to generate positive cash flows from operations for at least the next several years and, until product sales commence, the Company expects that its revenue sources will continue to be limited to grant revenue, research funding and milestone payments and licensing fees from potential future corporate collaborators. The timing and amount of such future cash payments and revenues, if any, will be subject to significant fluctuations, based in part on the success of the Company's research activities, the receipt of necessary regulatory approvals, the timing of the achievement of certain other milestones and the extent to which associated costs are reimbursed under grant or other arrangements. Substantially all of the Company's revenues from product sales, if any, will be subject to the Company's obligation to make aggregate royalty payments of up to 5% to certain licensors of its technology. Further, under the Company's Distribution Agreement with Cobe, Cobe will perform marketing and distribution activities and in exchange will receive approximately 38% to 42% of the Company's product sales in the area of stem cell therapy, subject to negotiated discounts and volume-based adjustments. Research and development expenses may fluctuate due to the timing of expenditures for the varying stages of the Company's research and clinical development programs. Research and development expenses will increase as product development programs and applications of the Company's products progress through research and development stages. Under the Company's License Agreement with Immunex, annual renewal fees of \$1,000,000 are payable in each of the next three fiscal years. Under the Company's Distribution Agreement with Cobe, regulatory approval activities for the Company's products for stem cell therapies outside of the United States will be conducted, and paid for, by Cobe. As a result of these and other factors, the Company's results of operations have fluctuated and are expected to continue to fluctuate significantly from year to year and from quarter to quarter and therefore may not be comparable to or indicative of the result of operations for any future periods.

Over the past several years, the Company's net loss has primarily increased, consistent with the growth in the Company's scope and size of operations. In the near term, the Company plans additional moderate growth in employee headcount necessary to address increasing requirements in the areas of product development, research, clinical and regulatory affairs, quality systems and administration. Assuming capital is available to finance such growth, the Company's operating expenses will continue to increase as a result. At least until such time as the Company enters into arrangements providing research and development funding or initiates product sales, the net loss will continue to increase as well. The Company has never been profitable and does not anticipate having net income for at least the next several years. Through June 30, 1997, the Company had an accumulated deficit of \$41,313,000. There can be no assurance that the Company will be able to achieve profitability on a sustained basis, if at all.

RESULTS OF OPERATIONS

Years Ended June 30, 1997, 1996 and 1995

Total revenues were \$378,000 in 1997, \$1,609,000 in 1996 and \$517,000 in 1995. Grant revenues decreased to \$148,000 in 1997 from \$267,000 in 1996 and were \$121,000 in 1995, reflecting the timing of grant awards and related research activities, to the extent that such associated costs are reimbursed under the grants. Grant revenues accounted for 39%, 17% and 23% of total revenues for the years ended June 30, 1997, 1996 and 1995, respectively, and are recorded on a cost-reimbursement basis. Revenues from research and development agreements totaled \$230,000 in 1997, \$1,342,000 in 1996 and \$396,000 in 1995, reflecting research funding received by the Company under its collaboration with RPR which commenced in September 1995 and ended in September 1996. Revenues from RPR accounted for 52%, 83% and 48% of such revenue in 1997, 1996 and 1995, respectively.

Total costs and expenses were \$15,310,000 in 1997, \$12,142,000 in 1996 and \$6,447,000 in 1995. The increases in costs and expenses in 1997 and 1996 are primarily the result of increases in research and development expense to \$13,357,000 in 1997 from \$10,075,000 in 1996 and \$4,889,000 in 1995. Research and development expense includes charges of \$1,000,000 and \$1,500,000 for the years ended June 30, 1997 and 1996, respectively, representing license fee payments pursuant to the Company's supply agreement with Immunex. The increase in research and development expense reflects an increase in research, clinical development and product development activities. General and administrative expenses were \$1,953,000 in 1997, \$2,067,000 in 1996 and \$1,558,000 in 1995. General and administrative expenses, which decreased slightly in 1997 compared to 1996, are expected to increase as a result of increasing finance, legal and other administrative and marketing expenses in support of the Company's increasing product development and research activities.

Interest income was \$676,000 in 1997, \$678,000 in 1996 and \$279,000 in 1995. The fluctuations in interest income are due primarily to corresponding changes in the levels of cash, cash equivalents and short-term investments for such periods. Interest expense was \$32,000 in 1997, \$62,000 in 1996 and \$66,000 in 1995, reflecting decreasing amounts outstanding under capital leases during these periods.

The Company's net loss was \$14,288,000 in 1997, \$9,917,000 in 1996 and \$5,717,000 in 1995. The Company expects to report substantial net losses for at least the next several years.

The Company has not generated any profits to date and therefore has not paid any federal income taxes since inception. At June 30, 1997, the Company's federal tax net operating loss and tax credit carryforwards were \$40,420,000 and \$971,000, respectively, which will expire from 2004 through 2012, if not utilized. The Company underwent an ownership change in October 1993, which has resulted in a limitation under which the Company can utilize a portion of its federal net operating loss carryforward amounting to \$1,153,000 per year. As of June 1997, the portion of the Company's net operating loss that remains subject to this limitation is \$2,490,000 and therefore is not expected to ultimately effect the Company's ability to utilize this benefit. If certain changes in ownership should occur again in the future, the Company's ability to utilize its net operating loss and tax credit carryforwards may become subject to further annual limitation.

LIQUIDITY AND CAPITAL RESOURCES

The Company has financed its operations since Inception primarily through public and private sales of its equity securities, which, from Inception through June 30, 1997, have totaled approximately \$57,906,000, 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 the Company to maintain adequate levels of cash and other liquid investments. Under the Company's primary equipment leasing agreement, the lessor is granted a security interest in all of the Company's property and assets.

The Company's combined cash, cash equivalents and short-term investments totaled \$17,007,000 at June 30, 1997, an increase of \$6,040,000 from June 30, 1996. The primary uses of cash, cash equivalents and short-term investments during the year ended June 30, 1997 included \$13,214,000 to finance the Company's operations and working capital requirements, \$424,000 in capital equipment additions and \$223,000 in scheduled debt payments. On February 7, 1997, the Company completed an underwritten initial public offering of 3,000,000 shares of its Common Stock at an offering price of \$7.00 per share. On March 5, 1997, the underwriters elected to purchase an additional 250,000 shares of Common Stock pursuant to the underwriters' over-allotment option at a price of \$7.00 per share. Proceeds from the offering, net of underwriters' commissions and expenses, were \$19,885,000. The Company plans to continue its policy of investing excess funds in short-term, investment-grade, interest-bearing instruments.

The Company's future cash requirements will depend on many factors, including continued scientific progress in its 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. The Company does not expect to generate a positive cash flow from operations for at least the next several years due to the expected increase in spending for research and development programs and the expected cost of commercializing its product candidates. The Company intends to seek additional funding through research and development agreements with suitable corporate collaborators, grants and through public or private financing

transactions. The Company expects that its primary sources of capital for the foreseeable future will be through collaborative arrangements and through the public or private sale of its 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 the Company's ability to raise additional funding, including, but not limited to, market volatility of the Company's 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, the Company may be required to delay, reduce the scope of, or eliminate one or more of its research and development programs, which may have a material adverse effect on the Company's business. See "Business Risks--Future Capital Needs; Uncertainty of Additional Funding" and Notes to Financial Statements.

RECENT ACCOUNTING PRONOUNCEMENT

During March 1997, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 128, "Earnings Per Share" ("SFAS 128"), which amends the standards for computing earnings per share previously set forth in Accounting Principles Board Opinion No. 15, "Earnings per Share" ("APB 15"). SFAS 128, which will be adopted by the Company for the period ending December 31, 1997, will not have a material effect on the computation of the Company's historical net loss per share amounts.

BUSINESS RISKS

The Company's business is subject to a number of risks and uncertainties, including those discussed below.

UNCERTAINTIES RELATED TO PRODUCT DEVELOPMENT AND MARKETABILITY

The Company has not completed the development or clinical trials of any of its cell culture technologies or product candidates and, accordingly, has not begun to market or generate revenue from their commercialization. Furthermore, the Company's technologies and product candidates are based on cell culture processes and methodologies which are not widely employed. Commercialization of the Company's lead product candidate, the Aastrom CPS, will require substantial additional research and development by the Company as well as substantial clinical trials. There can be no assurance that the Company will successfully complete development of the Aastrom CPS or its other product candidates, or successfully market its technologies or product candidates, which lack of success would have a material adverse effect on the Company's business, financial condition and results of operations.

The Company or its collaborators may encounter problems and delays relating to research and development, regulatory approval and intellectual property rights of the Company's technologies and product candidates. There can be no assurance that the Company's research and development programs will be successful, that its cell culture technologies and product candidates will facilitate the ex vivo

production of cells with the expected biological activities in humans, that its technologies and product candidates, if successfully developed, will prove to be safe and efficacious in clinical trials, that the necessary regulatory approvals for any of the Company's technologies or product candidates and the cells produced in such products will be obtained or, if obtained, will be as broad as sought, that patents will issue on the Company's patent applications or that the Company's intellectual property protections will be adequate. The Company's product development efforts are primarily directed toward obtaining regulatory approval to market the Aastrom CPS as an alternative to the bone marrow harvest and PBPC stem cell collection methods. These stem cell collection methods have been widely practiced for a number of years, and there can be no assurance that any of the Company's technologies or product candidates will be accepted by the marketplace as readily as these or other competing processes and methodologies, or at all. The failure by the Company to achieve any of the foregoing would have a material adverse effect on the Company's business, financial condition and results of operations.

UNCERTAINTIES RELATED TO CLINICAL TRIALS

The approval of the FDA will be required before any commercial sales of the Company's product candidates may commence in the United States, and approvals from foreign regulatory authorities will be required before international sales may commence. Prior to obtaining necessary regulatory approvals, the Company will be required to demonstrate the safety and efficacy of its processes and product candidates and the cells produced by such processes and in such products for application in the treatment of humans through extensive preclinical studies and clinical trials. The Company is currently conducting pre-pivotal clinical trials to demonstrate the safety and biological activity of patient-derived or UCB cells produced in the Company's prototype of the Aastrom CPS in a limited number of patients with breast cancer. If the results from these pre-pivotal trials are successful, the Company intends to seek clearance from the FDA to commence pivotal clinical trials. The results of preclinical studies and clinical trials of the Company's product candidates, however, may not necessarily be predictive of results that will be obtained from subsequent or more extensive clinical trials. Further, there can be no assurance that pre-pivotal or pivotal clinical trials of any of the Company's product candidates will demonstrate the safety, reliability and efficacy of such products, or of the cells produced in such products, to the extent necessary to obtain required regulatory approvals or market acceptance.

The ability of the Company to complete its clinical trials in a timely manner is dependent upon many factors, including the rate of patient enrollment. Patient enrollment is a function of many factors, including the size of the patient population, the proximity of suitable patients to clinical sites and the eligibility criteria for the study. The Company has experienced delays in patient accrual in its current pre-pivotal clinical trials. Further delays in patient accrual, in the Company's current pre-pivotal clinical trials or in future clinical trials, could result in increased costs associated with clinical trials or delays in receiving regulatory approvals and commercialization, if any. Furthermore, the progress of clinical investigations with the Aastrom CPS and the Company's other product candidates will be monitored by the FDA, which has the authority to cease clinical investigations, at any time, due to patient safety or other considerations. Any of the foregoing would have a material adverse

effect on the Company's business, financial condition and results of operations. See "--Uncertainty of Regulatory Approval; Extensive Government Regulation."

The Company's current pre-pivotal trials are designed to demonstrate specific biological safety and activity of cells produced in the Aastrom CPS, but is not designed to demonstrate long-term sustained engraftment of such cells. The patients enrolled in this pre-pivotal trial will have undergone extensive chemotherapy treatment prior to the infusion of cells produced in the Aastrom CPS. Such treatments will have substantially weakened these patients and may have irreparably damaged their hematopoietic systems. Due to these and other factors, it is possible that one or more of these patients may die or suffer severe complications during the course of the pre-pivotal trial. Further, there can be no assurance that patients receiving cells produced with the Company's technologies and product candidates will demonstrate long-term engraftment in a manner comparable to cells obtained from current stem cell therapy procedures, or at all. The failure to adequately demonstrate the safety or efficacy of the Company's technologies and product candidates, including long-term sustained engraftment, or the death of, or occurrence of severe complications in, one or more patients could substantially delay, or prevent, regulatory approval of such product candidates and have a material adverse effect on the Company's business, financial condition and results of operations.

MANUFACTURING AND SUPPLY UNCERTAINTIES; DEPENDENCE ON THIRD PARTIES

The Company does not operate and has no current intention to operate manufacturing facilities for the production of its product candidates. The Company currently arranges for the manufacture of its product candidates and their components, including certain cytokines, serum and media, with third parties, and expects to continue to do so in the foreseeable future. The Company has entered into collaborative product development and supply agreements with SeaMED, Ethox and MSP for the collaborative development and manufacture of certain components of the Aastrom CPS and is dependent upon those suppliers to manufacture its products. The Company is also dependent upon Immunex, Life Technologies, Inc. and Biowittaker for the supply of certain cytokines, serum and media to be used in conjunction with the Aastrom CPS. With regard to cytokines that are not commercially available from other sources, Immunex is currently the Company's sole supplier and few alternative supply sources exist. Apart from SeaMED, Ethox, MSP and Immunex, the Company currently does not have contractual commitments from any of these manufacturers or suppliers. There can be no assurance that the Company's supply of such key cytokines, components and other materials will not become limited, be interrupted or become restricted to certain geographic regions. Additionally, there can be no assurance that the Company will not require additional cytokines, components and other materials to manufacture, use or market its product candidates, or that necessary key components will be available for use on a sustained basis, if at all, by the Company in the markets in which it intends to sell its products. There can also be no assurance that the Company will be able to obtain alternative components and materials from other manufacturers of acceptable quality, or on terms or in quantities acceptable to the Company or that the Company will not require additional cytokines, components and other materials to manufacture or use its product candidates. In the event that any of the Company's key manufacturers or suppliers fail to perform their respective obligations or the Company's supply of such cytokines, components or other materials become limited or interrupted, the Company would not be able to market its product candidates on a timely and cost-competitive basis, if at all, which would have a material adverse effect on the Company's business, financial condition and results of operations.

Certain of the compounds used by the Company in its current stem cell expansion process involve the use of animal-derived products. The availability of these compounds for clinical and commercial use may become limited by suppliers or restricted by regulatory authorities, which may impose a potential competitive disadvantage for the Company's products compared to competing products and procedures. There can be no assurance that the Company will not experience delays or disadvantages related to the future availability of such materials. Any restriction on the use of such materials could have a material adverse effect on the Company's business, financial condition and results of operations, and there can be no assurance that the Company will be able to develop or obtain alternative compounds.

Like SeaMED, Ethox and MSP, other suppliers would need to meet FDA manufacturing requirements and undergo rigorous facility and process validation tests required by federal and state regulatory authorities. Any significant delays in the completion and validation of such facilities could have a material adverse effect on the ability of the Company to complete clinical trials and to market its products on a timely and profitable basis, which in turn would have a material adverse effect on the Company's business, financial condition and results of operations.

There can also be no assurance that the Company will be able to continue its present arrangements with its suppliers, supplement existing relationships or establish new relationships or that the Company will be able to identify and obtain the ancillary materials that are necessary to develop its product candidates in the future. The Company's dependence upon third parties for the supply and manufacture of such items could adversely affect the Company's ability to develop and deliver commercially feasible products on a timely and competitive basis.

HISTORY OF OPERATING LOSSES; ANTICIPATION OF FUTURE LOSSES

The Company is a development stage company and there can be no assurance that its product applications for cell therapy will be successful. The Company has not yet completed the development and clinical trials of any of its product candidates and, accordingly, has not yet begun to generate revenues from the commercialization of any of its product candidates. Aastrom was incorporated in 1989 and has experienced substantial operating losses since inception. As of June 30, 1997, the Company has incurred net operating losses totaling approximately \$41.3 million. Such losses have resulted principally from costs incurred in the research and development of the Company's cell culture technologies and the Aastrom CPS, general and administrative expenses, and the prosecution of patent applications. The Company expects to incur significant and increasing operating losses for at least the next several years, primarily owing to the expansion of its research and development programs, including preclinical studies and clinical trials. The amount of future losses and when, if ever, the Company will achieve profitability, are uncertain. The Company's ability to achieve profitability will depend, among other things, on successfully completing the development of its product candidates, obtaining regulatory approvals, establishing manufacturing, sales and marketing arrangements with third parties, and raising sufficient funds to finance its activities. No assurance can be given that the Company's product development efforts will be successful, that required regulatory approvals will be obtained, that any of the Company's product candidates will be manufactured at a competitive cost and will be of acceptable quality, or that the Company will be able to achieve profitability or that profitability, if achieved, can be sustained.

LIMITED SALES AND MARKETING CAPABILITIES; DEPENDENCE ON COLLABORATIVE RELATIONSHIPS

The Company has limited internal sales, marketing and distribution capabilities. If any of the Company's product candidates are successfully developed and the necessary regulatory approvals are obtained, the Company intends to market such products through collaborative relationships with companies that have established sales, marketing and distribution capabilities. The Company has established a strategic alliance with Cobe for the worldwide distribution of the Aastrom CPS for stem cell therapy and related uses. Cobe has the right to terminate its Distribution Agreement with the Company upon twelve months notice upon a change of control of the Company, other than to Cobe, or at any time after December 31, 1997, if Cobe determines that commercialization of the Aastrom CPS for stem cell therapy on or prior to December 31, 1998 is unlikely. See "--Consequences of Cobe Relationship."

The amount and timing of resources that Cobe commits to its strategic alliance activities with the Company are, to a significant extent, outside of the control of the Company. There can be no assurance that Cobe will pursue the marketing and distribution of the Company's products, continue to perform its obligations under its agreements with the Company or that the Company's strategic alliance with Cobe will result in the successful commercialization and distribution of the Company's technologies and product candidates. There can also be no assurance that Cobe will be successful in its efforts to market and distribute the Company's products for stem cell therapy. The suspension or termination of the Company's strategic alliance with Cobe or the failure of the strategic alliance to be successful would have a material adverse effect on the Company's business, financial condition and results of operations.

Subject to the contractual requirements of the Cobe relationship, the Company will seek to enter into other agreements relating to the development and marketing of product candidates and in connection with such agreements may rely upon corporate partners to conduct clinical trials, seek regulatory approvals for, manufacture and market its potential products. There can be no assurance that the Company will be able to establish collaborative relationships for the development or marketing of the Company's product candidates on acceptable terms, if at all, or, if such relationships are established, that they will be successful or sustained on a long-term basis. The inability of the Company to establish such collaborative relationships may require the Company to curtail its development or marketing activities with regard to its potential products which would have a material adverse effect on the Company's business, financial condition and results of operations.

FUTURE CAPITAL NEEDS; UNCERTAINTY OF ADDITIONAL FUNDING

To date, Aastrom has funded its operations primarily through the sale of equity securities and corporate collaborations. In order to grow and expand its business, and to introduce its product candidates into the marketplace, the Company will need, among other things, to raise additional funds. The development of the Company's products for the expansion of additional cell types will require the Company to raise additional funds or to seek collaborative partners, or both, to finance related research and development activities.

The Company's future capital requirements will depend upon many factors, including, but not limited to, continued scientific progress in its research and development programs, costs and timing of conducting clinical trials and seeking regulatory approvals and patent prosecutions, competing technological and market developments, possible changes in existing collaborative relationships, the ability of the Company to establish additional collaborative relationships, and effective commercialization activities and facilities expansions if and as required. Because of the Company's potential long-term funding requirements, it may attempt to access the public or private equity markets if and whenever conditions are favorable, even if it does not have an immediate need for additional capital at that time. There can be no assurance that any such additional funding will be available to the Company on reasonable terms, or at all. If adequate funds are not available, the Company may be required to delay or terminate research and development programs, curtail capital expenditures, and reduce business development and other operating activities. If the Company is not successful in finding, entering into and maintaining arrangements with collaborative partners, its development efforts could be delayed. Furthermore, there can be no assurance that the Company will be able to implement collaborative development agreements under acceptable terms, if at all. Any of the foregoing capital constraints would have a material adverse effect on the Company's business, financial condition and results of operations. See "Management's Discussion and Analysis of Financial Condition and Results of Operations--Liquidity and Capital Resources."

UNCERTAINTY OF REGULATORY APPROVAL; EXTENSIVE GOVERNMENT REGULATION

The Company's research and development activities, preclinical studies, clinical trials, and the anticipated manufacturing and marketing of its product candidates are subject to extensive regulation by the FDA and other regulatory authorities in the United States. These activities are also regulated in other countries where the Company intends to test and market its product candidates. The approval of the FDA will be required before any commercial sales of the Company's product candidates may commence in the United States. Additionally, the Company will be required to obtain approvals from foreign regulatory authorities before international sales may commence.

The Company's products are potentially subject to regulation as medical devices under the Federal Food, Drug, and Cosmetic Act, or as biological products under the Public Health Service Act, or both. Different regulatory requirements may apply to the Company's products depending on how they are categorized by the FDA under these laws. To date, the FDA has indicated that it intends to regulate the Aastrom CPS for stem cell therapy as a Class III medical device through the Center for Biologics Evaluation and Research. However, there can be no assurance that the FDA will ultimately regulate the Aastrom CPS for stem cell therapy as a medical device or that regulatory approval for such product will be obtained in a timely fashion or at all.

Further, it is unclear whether the FDA will separately regulate the cell therapies derived from the Aastrom CPS. The FDA is in the process of developing its requirements with respect to somatic cell therapy and gene cell therapy products, and recently proposed a new type of license for autologous cells manipulated ex vivo and intended for structural repair or reconstruction;

autologous cells are cells obtained from, and administered to, the same patient. This proposal may indicate that the FDA will impose a similar approval requirement on other types of autologous cellular therapies, such as autologous cells for stem cell therapy. Any such additional regulatory or approval requirement could significantly delay the introduction of the Company's product candidates to the market, and have a material adverse effect on the Company's business, financial condition and results of operations. Until the FDA issues definitive regulations covering the Company's product candidates, the regulatory guidelines or requirements for approval of such product candidates will continue to be subject to significant uncertainty.

Before marketing, the Aastrom CPS or other product candidates developed by the Company must undergo an extensive regulatory approval process. The regulatory process, which includes preclinical studies and clinical trials to establish safety and efficacy, takes many years and requires the expenditure of substantial resources. Data obtained from preclinical and clinical activities are susceptible to varying interpretations which could delay, limit or prevent FDA approval. In addition, delays or rejections may be encountered based upon changes in FDA policy for medical product approvals during the period of product development and FDA regulatory review of applications submitted by the Company for product approval. Similar delays may also be encountered in foreign countries. There can be no assurance that, even after the expenditures of substantial time and financial resources, regulatory approval will be obtained for any products developed by the Company. Moreover, if regulatory approval of a product is obtained, such approval may be subject to limitations on the indicated uses for which it may be marketed. Further, even if such regulatory approval is obtained, a marketed product, its manufacturer and its manufacturing facilities are subject to continual review and periodic inspections by the FDA, and later discovery of previously unknown problems with a product, manufacturer or facility may result in restrictions on such product or manufacturer, including a withdrawal of the product from the market. Failure to comply with the applicable regulatory requirements can, among other things, result in fines, suspensions of regulatory approvals, product recalls, operating restrictions and criminal prosecution. Further, additional government regulation may be established which could prevent or delay regulatory approval of the Company's products.

The Company believes that the Aastrom CPS will be regulated in Europe as a Class IIB medical device, under the authority of the new Medical Device Directives ("MDD") being implemented by European Union ("EU") member countries. In order for the Company to market its products in Europe, it must obtain a CE Mark from a Notified Body to certify that the Company and its operations comply with certain minimum quality standards and compliance procedures, or, alternatively, that its manufactured products meet a more limited set of requirements. There can be no assurance that the Company and its suppliers will be able to meet these minimum requirements, or, if met, that the Company and its suppliers will be able to maintain such compliance. The result of such non-compliance would have a material adverse effect on the Company's business, financial condition and results of operations. There can be no assurance, however, that the Aastrom CPS will be regulated in Europe as a Class IIB medical device, and, if the Aastrom CPS is not so regulated, the Company could be forced to obtain additional regulatory approvals and could be subjected to additional regulatory requirements and uncertainty, which would have a material adverse effect on the Company's business, financial condition and results of operations. See "Business--Government Regulation."

CONSEQUENCES OF COBE RELATIONSHIP

Cobe is the largest single shareholder of the Company, beneficially owning approximately 24% of the outstanding shares of Common Stock as of August 31, 1997. In addition, Cobe has certain preemptive rights to maintain its relative percentage ownership and voting interest in the Company and has an option, until February 2000, to purchase from the Company an amount of Common Stock equal to 30% of the Company's fully diluted shares after the exercise of such option, at a purchase price equal to 120% of the public market trading price of the Company's Common Stock. If such option is exercised, Cobe would significantly increase its ownership interest in the Company and, as a consequence of such share ownership, obtain effective control of the Company. Such effective control would include the ability to influence the outcome of shareholder votes, including votes concerning the election of directors, the amendment of provisions of the Company's Restated Articles of Incorporation or Bylaws, and the approval of mergers and other significant transactions. Cobe also has been granted a "right of first negotiation" in the event that the Company determines to sell all, or any material portion, of its assets to another company or to merge with another company. Furthermore, the Company has agreed to use reasonable and good faith efforts to cause a nominee designated by Cobe to be elected to the Board of Directors for as long as Cobe owns at least 15% of the outstanding Common Stock. In addition, Edward C. Wood, Jr., the President of Cobe BCT, is a director of the Company. The agreements establishing the Company's relationship with Cobe provide the Company with an option (the "Put Option") to require Cobe to purchase the lesser of 20%, or \$5,000,000, in an initial public offering ("IPO") or a private offering meeting certain minimum requirements. In the event that the Company exercises the Put Option, Cobe then has the option to purchase up to 40% of that offering. While the Put Option was not exercised by the Company in connection with the IPO, Cobe voluntarily elected to purchase an additional 714,200 shares of Common Stock in the IPO, for an aggregate purchase price of approximately \$5,000,000. The Put Option does not apply to any public offerings, and the Company and Cobe are evaluating whether or not the Put Option remains in effect as to any future private offerings of the Company's equity securities. The existence of the foregoing rights or the exercise of such control by Cobe could have the effect of delaying, deterring or

preventing certain takeovers or changes in control of the management of the Company, including transactions in which shareholders might otherwise receive a premium for their shares over then current market prices.

COMPETITION AND TECHNOLOGICAL CHANGE

The Company is engaged in the development of medical products and processes which will face competition in a marketplace characterized by rapid technological change. Many of the Company's competitors have significantly greater resources than the Company, and have developed and may develop product candidates and processes that directly compete with the Company's products. Moreover, competitors that are able to achieve patent protection, obtain regulatory approvals and commence commercial sales of their products before the Company, and competitors that have already done so, may enjoy a significant competitive advantage. The Company's product development efforts are primarily directed toward obtaining regulatory approval to market the Aastrom CPS for stem cell therapy. That market is currently dominated by the bone marrow harvest and PBPC collection methods. The Company's clinical data, although early, suggests that cells expanded in the Aastrom CPS using its current process will enable hematopoietic recovery within the time frames currently achieved by bone marrow harvest, however, neutrophil and platelet recovery times may be slower than with PBPC collection methods. The Company is evaluating techniques and methods to optimize the cells produced in the Aastrom CPS to reduce the recovery time of neutrophils and platelets in patients. There can be no assurance that if such procedure optimization does not lead to recovery times equal to or faster than those of PBPC collection methods, such outcome would not have a material adverse effect on the Company's business, financial condition and results of operations. In addition, the bone marrow harvest and PBPC collection methods have been widely practiced for a number of years and, recently, the patient costs associated with these procedures have begun to decline. There can be no assurance that the Aastrom CPS method, if approved for marketing, will prove to be competitive with these established collection methods on the basis of hematopoietic recovery time, cost or otherwise. The Company also is 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 which the Company has targeted for product development. In particular, the Company is aware that competitors such as Amgen, Inc., CellPro, Incorporated, Novartis, A.G., Baxter Healthcare Corp. and RPR are in advanced stages of development of technologies and products for use in stem cell therapy and other market applications currently being pursued by the Company. In addition, Cobe, a significant shareholder of the Company, is a market leader in the blood cell processing products industry and, accordingly, a potential competitor of the Company. There can be no assurance that developments by others will not render the Company's product candidates or technologies obsolete or noncompetitive, that the Company will be able to keep pace with new technological developments or that the Company's product candidates will be able to supplant established products and methodologies in the therapeutic areas that are targeted by the Company. The foregoing factors could have a material adverse effect on the Company's business, financial condition and results of operations.

UNCERTAINTY REGARDING PATENTS AND PROPRIETARY RIGHTS

Aastrom's success depends in part on its ability, and the ability of its licensors, to obtain patent protection for its products and processes, preserve its trade secrets, defend and enforce its rights against infringement and operate without infringing the proprietary rights of third parties, both in the United States and in other countries. 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 of the Company or its licensors will be issued, that the scope of any patent protection will exclude competitors or provide competitive advantages to the Company, that any of the patents that have been or may be issued to the Company or its 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 the Company. Furthermore, there can be no assurance that others have not developed or will not develop similar products, duplicate any of the Company's products or design around any patents that have been or may be issued to the Company or its licensors. Since patent applications in the United States are maintained in secrecy until patents issue, the Company also cannot be certain that others did not first file applications for inventions covered by the Company's and its licensors' pending patent applications, nor can the Company be certain that it will not infringe any patents that may issue to others on such applications. The Company relies on certain licenses granted by the University of Michigan and Dr. Cremonese for the majority of its patent rights. If the Company breaches such agreements or otherwise fails to comply with such agreements, or if such agreements expire or are otherwise terminated, the Company may lose its rights under the patents held by the University of Michigan and Dr. Cremonese, which would have a material adverse effect on the Company's business, financial condition and results of operation. See "Business--Patents and Proprietary Rights--Research and License

Agreements." The Company also relies on trade secrets and unpatentable know-how which it seeks to protect, in part, by confidentiality agreements with its employees, consultants, suppliers and licensees. There can be no assurance that these agreements will not be breached, that the Company would have adequate remedies for any breach, or that the Company's trade secrets or unpatentable know-how will not otherwise become known or be independently developed by competitors.

The Company's success will also depend in part on its ability to develop commercially viable products without infringing the proprietary rights of others. The Company has 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 effect on the Company's ability to market its products or maintain its competitive position with respect to its products. If the Company's 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, the Company may be subject to infringement actions. In such event, the Company may challenge the validity of such patents or other proprietary rights or be required to obtain licenses from such companies in order to develop, manufacture or market its products. There can be no assurance that the Company 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 the Company's proposed products or the inability to proceed with the development, manufacture or sale of products requiring such licenses, which could have a material adverse effect on the Company's business, financial condition and results of operations. If the Company is required to defend itself against charges of patent infringement or to protect its own proprietary rights against third parties, substantial costs will be incurred regardless of whether the Company is successful. Such proceedings are typically protracted with no certainty of success. An adverse outcome could subject the Company to significant liabilities to third parties, and force the Company to curtail or cease its development and sale of its products and processes. See "Business--Patents and Proprietary Rights."

NO ASSURANCE OF THIRD PARTY REIMBURSEMENT

The Company's ability to successfully commercialize its product candidates will depend in part on the extent to which payment for the Company's products and related treatments will be available from government healthcare programs, such as Medicare and Medicaid, as well as private health insurers, health maintenance organizations and other third party payors. Government and other third-party payors are increasingly attempting to contain health care costs, in part by challenging the price of medical products and services. 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. Since reimbursement approval is required from each payor individually, seeking such approvals is a time-consuming and costly process which will require the Company to provide scientific and clinical support for the use of each of the Company's products to each payor separately. Significant uncertainty exists as to the payment status of newly approved medical products, and there can be no assurance that adequate third-party payments will be available to enable the Company to establish or maintain price levels sufficient to realize an appropriate return on its investment in product development. If adequate payment levels are not provided by government and third-party payors for use of the Company's products, the market acceptance of those products will be adversely affected.

There can be no assurance that reimbursement in the United States or foreign countries will be available for any of the Company's product candidates, that any reimbursement granted will be maintained, or that limits on reimbursement available from third-party payors will not reduce the demand for, or negatively affect the price of, the Company's products. The unavailability or inadequacy of third-party reimbursement for the Company's product candidates would have a material adverse effect on the Company. Finally, the Company is unable to forecast what additional legislation or regulation relating to the healthcare industry or third-party coverage and reimbursement may be enacted in the future, or what effect such legislation or regulation would have on the Company's business.

HAZARDOUS MATERIALS

The Company's research and development activities involve the controlled use of hazardous materials, chemicals and various radioactive compounds. The Company is subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of such materials and certain waste products. In the event of any contamination or injury from these materials, the Company could be held liable for any damages that result and any such liability could exceed

the resources of the Company. Furthermore, the failure to comply with current or future regulations could result in the imposition of substantial fines against the Company, suspension of production, alteration of its manufacturing processes or cessation of operations. There can be no assurance that the Company will not be required to incur significant costs to comply with any such laws and regulations in the future, or that such laws or regulations will not have a material adverse effect on the Company's business, financial condition and results of operations. Any failure by the Company to control the use, disposal, removal or storage of, or to adequately restrict the discharge of, or assist in the cleanup of, hazardous chemicals or hazardous, infectious or toxic substances could subject the Company to significant liabilities, including joint and several liability under certain statutes. The imposition of such liabilities would have a material adverse effect on the Company's business, financial condition and results of operations.

POTENTIAL PRODUCT LIABILITY; AVAILABILITY OF INSURANCE

The Company is, and will continue to be, subject to the risk of product liability claims alleging that the use of its products has adverse effects on patients. This risk exists for product candidates tested in human clinical trials as well as products that are sold commercially, if any. Further, given the medical conditions for which the Aastrom CPS is expected to be utilized, any product liability claim could entail substantial compensatory and punitive damages. The assertion of product liability claims against the Company could result in a substantial cost to, and diversion of efforts by, the Company. There can be no assurance that the Company would prevail in any such litigation or that product liability claims, if made, would not result in a recall of the Company's products or a change in the indications for which they may be used. The Company maintains product liability insurance coverage up to an aggregate of \$5,000,000 for claims arising from the use of its product candidates in clinical trials. There can be no assurance that the Company will be able to maintain such insurance or obtain product liability insurance in the future to cover any of its product candidates which are commercialized or that such existing or any future insurance and the resources of the Company would be sufficient to satisfy any liability resulting from product liability claims. Consequently, a product liability claim or other claim with respect to uninsured or underinsured liabilities could have a material adverse effect on the Company's business, financial condition and results of operations.

DEPENDENCE ON KEY PERSONNEL

The success of the Company depends in large part upon the Company's ability to attract and retain highly qualified scientific and management personnel. The Company faces competition for such personnel from other companies, research and academic institutions and other entities. There can be no assurance that the Company will be successful in hiring or retaining key personnel. See "Business--Employees" and "--Executive Officers of the Company."

CONTROL BY EXISTING MANAGEMENT AND SHAREHOLDERS

As of August 31, 1997, the Company's directors, executive officers, and certain principal shareholders, including Cobe, affiliated with members of the Board of Directors and their affiliates beneficially owned approximately 36% of the outstanding shares of Common Stock. Accordingly, such shareholders, acting together, may have the ability to exert significant influence over the election of the Company's Board of Directors and other matters submitted to the Company's shareholders for approval. The voting power of these holders may discourage or prevent certain takeovers or changes in control of the management of the Company unless the terms are approved by such holders. See "Principal Shareholders."

POSSIBLE STOCK PRICE VOLATILITY

The price of the Company's Common Stock has experienced significant volatility. The trading price of the Common Stock and the price at which the Company may sell securities in the future could be subject to wide fluctuations in response to announcements of clinical results, research activities, technological innovations or new products by the Company or competitors, changes in government regulation, developments concerning proprietary rights, variations in the Company's operating results, announcements by the Company of regulatory developments, litigation, disputes concerning patents or proprietary rights or public concern regarding the safety, efficacy or other implications of the products or methodologies to be developed by the Company or its collaborators or enabled by the Company's technology, general market conditions, the liquidity of the Company or its ability to raise additional funds, and other factors or events. In addition, the stock market has

experienced extreme fluctuations in price and volume. This volatility has significantly affected the market prices for securities of emerging biotechnology companies for reasons frequently unrelated to or disproportionate to the operating performance of the specific companies. These market fluctuations, as well as shortfalls in revenue or earnings as compared with public market analysts' expectations, changes in such analysts' recommendations or projections and fluctuations in the stock markets generally may adversely affect the market price of the Common Stock. In addition, since the Company's initial public offering in February 1997, the average daily trading volume of the Common Stock on the Nasdaq National Market has generally been relatively low. There can be no assurance that a more active trading market will develop in the future.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The Company's financial statements as of June 30, 1996 and 1997, for each of the three years in the period ended June 30, 1997 and for the period from Inception to June 30, 1997 and the report of independent accountants are included in this Report as listed in Item 14(a).

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

See Item 14(b) of this Report.

PART III

Certain information required by Part III is omitted from this Report, in that on October 10, 1997, the Company filed its Proxy Statement with the Securities and Exchange Commission pursuant to Regulation 14A in connection with its Annual Meeting of Shareholders to be held on November 12, 1997 (the "Proxy Statement"), and certain information included therein is incorporated herein by reference.

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

The information relating to the directors of the Company is incorporated by reference to the Proxy Statement as set forth under the caption "General Information -- Board of Directors." Information relating to the executive officers of the Company is set forth in Part I of this Report under the caption "Executive Officers of the Company."

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 equity securities of the Company 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.

Balance Sheets -- As of June 30, 1996 and 1997

Statements of Operations -- For the years Ended June 30, 1995, 1996 and 1997, and from March 24, 1989 (Inception) to June 30, 1997

Statements of Shareholders' Equity -- From March 24, 1989 (Inception) to June 30, 1997

Statements of Cash Flows -- For the years Ended June 30, 1995, 1996 and 1997, and from March 24, 1989 (Inception) to June 30, 1997

Notes to Financial Statements

2. FINANCIAL STATEMENT SCHEDULE:

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:

On July 16, 1997, the Company filed with the Securities and Exchange Commission a Current Report on Form 8-K, dated July 9, 1997, which contains disclosure under Item 4 concerning a change in the Company's independent auditors. A letter from Coopers & Lybrand L.L.P., dated July 15, 1997, was filed as an exhibit to such report.

REPORT OF INDEPENDENT ACCOUNTANTS

To the Board of Directors and Shareholders of
Aastrom Biosciences, Inc.

In our opinion, the accompanying balance sheets and the related statements of operations, of shareholders' equity and of cash flows present fairly, in all material respects, the financial position of Aastrom Biosciences, Inc. (a development stage company) at June 30, 1996 and 1997, and the results of its operations and its cash flows for each of the three years in the period ended June 30, 1997, and for the period from March 24, 1989 (Inception) to June 30, 1997, in conformity with generally accepted accounting principles. 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 generally accepted auditing standards 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 the opinion expressed above.

PRICE WATERHOUSE LLP

Detroit, Michigan
August 15, 1997

AASTROM BIOSCIENCES, INC.
(A DEVELOPMENT STAGE COMPANY)

BALANCE SHEETS

| | June 30, | |
|--|------------------|------------------|
| | 1996 | 1997 |
| ASSETS | | |
| CURRENT ASSETS: | | |
| Cash and cash equivalents.. | \$10,967,000 | \$ 1,943,000 |
| Short-term investments..... | -- | 15,064,000 |
| Receivables..... | 81,000 | 229,000 |
| Prepaid expenses..... | 437,000 | 126,000 |
| | ----- | ----- |
| Total current assets..... | 11,485,000 | 17,362,000 |
| PROPERTY, NET..... | 1,188,000 | 1,048,000 |
| | ----- | ----- |
| Total assets..... | \$12,673,000 | \$18,410,000 |
| | ===== | ===== |
| LIABILITIES AND SHAREHOLDERS' EQUITY | | |
| CURRENT LIABILITIES: | | |
| Accounts payable and accrued expenses..... | \$ 1,192,000 | \$ 1,508,000 |
| Accrued employee expenses... | 97,000 | 130,000 |
| Current portion of capital lease obligations..... | 223,000 | 124,000 |
| Deferred revenue..... | 122,000 | -- |
| | ----- | ----- |
| Total current liabilities.. | 1,634,000 | 1,762,000 |
| CAPITAL LEASE OBLIGATIONS..... | 189,000 | 65,000 |
| COMMITMENTS (Note 7) | | |
| SHAREHOLDERS' EQUITY: | | |
| Preferred Stock, no par value; shares authorized - 9,951,765 and 5,000,000, respectively; shares issued and outstanding - 9,451,766 and 0, respectively. | 34,218,000 | -- |
| Common Stock, no par value; shares authorized - 18,500,000 and 40,000,000, respectively; shares issued and outstanding - 1,886,479 and 13,275,208, respectively..... | 324,000 | 58,073,000 |
| Deficit accumulated during the development stage..... | (27,025,000) | (41,313,000) |
| Shareholder notes receivable... | (167,000) | (167,000) |
| Stock purchase rights..... | 3,500,000 | -- |
| Unrealized losses on investments..... | -- | (10,000) |
| | ----- | ----- |
| Total shareholders' equity.... | 10,850,000 | 16,583,000 |
| | ----- | ----- |
| Total liabilities and shareholders' equity..... | \$ 12,673,000 | \$ 18,410,000 |
| | ===== | ===== |

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

AASTROM BIOSCIENCES, INC.
(A DEVELOPMENT STAGE COMPANY)

STATEMENT OF OPERATIONS

| | YEAR ENDED JUNE 30, | | | MARCH 24, 1989 (INCEPTION) TO JUNE 30, 1997 |
|--|----------------------|----------------------|-----------------------|--|
| | 1995 | 1996 | 1997 | |
| REVENUES: | | | | |
| Research and development agreements..... | \$ 396,000 | \$ 1,342,000 | \$ 230,000 | \$ 2,017,000 |
| Grants..... | 121,000 | 267,000 | 148,000 | 2,143,000 |
| Total revenues..... | 517,000 | 1,609,000 | 378,000 | 4,160,000 |
| COSTS AND EXPENSES: | | | | |
| Research and development..... | 4,889,000 | 10,075,000 | 13,357,000 | 38,432,000 |
| General and administrative..... | 1,558,000 | 2,067,000 | 1,953,000 | 9,042,000 |
| Total costs and expenses..... | 6,447,000 | 12,142,000 | 15,310,000 | 47,474,000 |
| LOSS FROM OPERATIONS..... | (5,930,000) | (10,533,000) | (14,932,000) | (43,314,000) |
| OTHER INCOME (EXPENSE): | | | | |
| Interest income..... | 279,000 | 678,000 | 676,000 | 2,252,000 |
| Interest expense..... | (66,000) | (62,000) | (32,000) | (251,000) |
| Other income..... | 213,000 | 616,000 | 644,000 | 2,001,000 |
| NET LOSS..... | <u>\$(5,717,000)</u> | <u>\$(9,917,000)</u> | <u>\$(14,288,000)</u> | <u>\$(41,313,000)</u> |
| NET LOSS PER SHARE..... | <u>\$ (.66)</u> | <u>\$ (.98)</u> | <u>\$ (1.26)</u> | |
| Weighted average number of common and common equivalent shares outstanding..... | <u>8,644,000</u> | <u>10,103,000</u> | <u>11,315,000</u> | |

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

AASTROM BIOSCIENCES, INC.
(A DEVELOPMENT STAGE COMPANY)

STATEMENTS OF SHAREHOLDERS' EQUITY

| | Preferred Stock | | Common Stock | | Deficit accumulated during the development stage | Shareholder notes receivable |
|---|-----------------|--------------|--------------|------------|--|------------------------------|
| | Shares | Amount | Shares | Amount | | |
| BALANCE, MARCH 24, 1989 (Inception)..... | -- | \$ -- | -- | \$ -- | \$ -- | \$ -- |
| Non-cash issuance of Common Stock..... | | | 454,545 | -- | | |
| Issuance of Series A Preferred Stock at \$1.00 per share in August 1989..... | 1,500,000 | 1,500,000 | | | | |
| Issuance of Series A Preferred Stock in March 1991 at \$1.00 per share, net of issuance costs of \$5,000..... | 1,000,000 | 995,000 | | | | |
| Issuance of Series B Preferred Stock in April 1992 at \$2.00 per share, net of issuance costs of \$46,000..... | 3,030,000 | 6,014,000 | | | | |
| Issuance of Common Stock for services..... | | | 33,333 | 10,000 | | |
| Issuance of Series C Preferred Stock in October 1993 at \$1,000 per share, net of issuance costs of \$175,000 | 10,000 | 9,825,000 | | | | |
| Exercise of stock options. | | | 1,229,482 | 230,000 | | (198,000) |
| Net loss..... | | | | | (11,391,000) | |
| BALANCE, JUNE 30, 1994..... | 5,540,000 | 18,334,000 | 1,717,360 | 240,000 | (11,391,000) | (198,000) |
| Issuance of Series D Preferred Stock in April and May 1995 at \$4.00 per share, net of issuance costs of \$81,000 | 2,500,001 | 9,919,000 | | | | |
| Exercise of stock options. | | | 39,103 | 8,000 | | |
| Retirement of Common Shares outstanding..... | | | (25,000) | (7,000) | | |
| Unrealized loss on investments..... | | | | | | |
| Net loss..... | | | | | (5,717,000) | |
| BALANCE, JUNE 30, 1995..... | 8,040,001 | 28,253,000 | 1,731,463 | 241,000 | (17,108,000) | (198,000) |
| Issuance of Series E Preferred Stock in January 1996 at \$4.25 per share, net of issuance costs of \$35,000..... | 1,411,765 | 5,965,000 | | | | |
| Exercise of stock options. | | | 130,016 | 53,000 | | |
| Issuance of Common Stock at \$1.20 per share..... | | | | 25,000 | 30,000 | |
| Issuance of Stock Purchase Rights for cash in September 1995 and March 1996..... | | | | | | |
| Repurchase of Series D Preferred Stock at \$4.00 per share..... | (62,500) | (250,000) | | | | |
| Sale of Series D Preferred Stock at \$4.00 per share..... | 62,500 | 250,000 | | | | |
| Principal payment received under shareholder note receivable..... | | | | | | 31,000 |
| Unrealized gain on investments..... | | | | | | |
| Net loss..... | | | | | (9,917,000) | |
| BALANCE, JUNE 30, 1996..... | 9,451,766 | 34,218,000 | 1,886,479 | 324,000 | (27,025,000) | (167,000) |
| Exercise of stock options. | | | 40,307 | 26,000 | | |
| Issuance of Series E Preferred Stock at \$17.00 per share..... | 205,882 | 3,500,000 | | | | |
| Issuance of Common Stock at \$7.00 per share, net of issuance costs of \$2,865,000..... | | | 3,250,000 | 19,885,000 | | |
| Conversion of Preferred Stock..... | (9,657,648) | (37,718,000) | 8,098,422 | 37,718,000 | | |
| Compensation expense related to stock options granted..... | | | | 120,000 | | |

| | | | | | | |
|---------------------------------------|----|-------|--------------|--------------|----------------|--------------|
| Unrealized losses on investments..... | | | | | (14,288,000) | |
| Net loss..... | | | | | | |
| BALANCE, JUNE 30, 1997..... | -- | \$ -- | \$13,275,208 | \$58,073,000 | \$(41,313,000) | \$ (167,000) |

| | Stock purchase rights | Unrealized gain (losses) on investments | Total shareholders' equity |
|--|-----------------------|---|----------------------------|
| BALANCE, MARCH 24, 1989 (Inception)..... | -- | \$ -- | \$ -- |
| Non-cash issuance of Common Stock..... | | | -- |
| Issuance of Series A Preferred Stock at \$1.00 per share in August 1989..... | | | 1,500,000 |
| Issuance of Series A Preferred Stock in March 1991 at \$1.00 per share, net of issuance costs of \$5,000..... | | | 995,000 |
| Issuance of Series B Preferred Stock in April 1992 at \$2.00 per share, net of issuance costs of \$46,000..... | | | 6,014,000 |
| Issuance of Common Stock for services..... | | | 10,000 |
| Issuance of Series C Preferred Stock in October 1993 at \$1,000 per share, net of issuance costs of \$175,000..... | | | 9,825,000 |
| Exercise of stock options.. | | | 32,000 |
| Net loss..... | | | (11,391,000) |
| BALANCE, JUNE 30, 1994..... | -- | -- | 6,985,000 |
| Issuance of Series D Preferred Stock in April and May 1995 at \$4.00 per share, net of issuance costs of \$81,000..... | | | 9,919,000 |
| Exercise of stock options.. | | | 8,000 |
| Retirement of Common Shares outstanding..... | | | (7,000) |
| Unrealized loss on investments..... | | (2,000) | (2,000) |
| Net loss..... | | | (5,717,000) |
| BALANCE, JUNE 30, 1995..... | -- | (2,000) | 11,186,000 |
| Issuance of Series E Preferred Stock in January 1996 at \$4.25 per share, net of issuance costs of \$35,000..... | | | 5,965,000 |
| Exercise of stock options.. | | | 53,000 |
| Issuance of Common Stock at \$1.20 per share..... | | | 30,000 |
| Issuance of Stock Purchase Rights for cash in September 1995 and March 1996..... | 3,500,000 | | 3,500,000 |
| Repurchase of Series D Preferred Stock at \$4.00 per share..... | | | (250,000) |
| Sale of Series D Preferred Stock at \$4.00 per share..... | | | 250,000 |
| Principal payment received under shareholder note receivable..... | | | 31,000 |
| Unrealized gain on investments..... | | 2,000 | 2,000 |
| Net loss..... | | | (9,917,000) |
| BALANCE, JUNE 30, 1996..... | 3,500,000 | -- | 10,850,000 |
| Exercise of stock options.. | | | 26,000 |
| Issuance of Series E Preferred Stock at \$17.00 per share..... | (3,500,000) | | -- |
| Issuance of Common Stock at \$7.00 per share, net of issuance costs of \$2,865,000..... | | | 19,885,000 |
| Conversion of Preferred Stock..... | | | -- |
| Compensation expense related to stock options granted..... | | | 120,000 |
| Unrealized losses on | | | |

| | | | |
|-----------------------------|-------|-------------|--------------|
| investments..... | | (10,000) | (10,000) |
| Net loss..... | | | (14,288,000) |
| | ----- | ----- | ----- |
| BALANCE, JUNE 30, 1997..... | \$ -- | \$ (10,000) | \$16,583,000 |
| | ===== | ===== | ===== |

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

AASTROM BIOSCIENCES, INC.
(A DEVELOPMENT STAGE COMPANY)

STATEMENT OF CASH FLOWS

| | YEAR ENDED JUNE 30, | | | MARCH 24, 1989 (INCEPTION) TO JUNE 30, 1997 |
|--|---------------------|---------------|----------------|--|
| | 1995 | 1996 | 1997 | |
| OPERATING ACTIVITIES: | | | | |
| Net loss..... | \$ (5,717,000) | \$(9,917,000) | \$(14,288,000) | \$(41,313,000) |
| Adjustments to reconcile net loss to net cash used for operating activities: | | | | |
| Depreciation and amortization..... | 329,000 | 536,000 | 564,000 | 1,831,000 |
| Loss on property held for resale..... | -- | -- | -- | 110,000 |
| Amortization of discounts and premiums on investments..... | (9,000) | (110,000) | (84,000) | (203,000) |
| Stock compensation expense..... | -- | -- | 120,000 | 130,000 |
| Changes in assets and liabilities: | | | | |
| Receivables..... | 132,000 | 18,000 | (148,000) | (229,000) |
| Prepaid expenses..... | (59,000) | (332,000) | 311,000 | (126,000) |
| Accounts payable and accrued expenses..... | (40,000) | 864,000 | 316,000 | 1,508,000 |
| Accrued employee expenses..... | 28,000 | (33,000) | 33,000 | 130,000 |
| Deferred revenue..... | 79,000 | (103,000) | (122,000) | -- |
| Net cash used for operating activities..... | (5,257,000) | (9,077,000) | (13,298,000) | (38,162,000) |
| INVESTING ACTIVITIES: | | | | |
| Organizational costs..... | -- | -- | -- | (73,000) |
| Purchase of short-term investments..... | (10,981,000) | -- | (19,190,000) | (31,138,000) |
| Maturities of short-term investments..... | 3,567,000 | 8,500,000 | 4,200,000 | 16,267,000 |
| Capital purchases..... | (118,000) | (445,000) | (424,000) | (2,142,000) |
| Proceeds from sale of property held for resale..... | -- | -- | -- | 400,000 |
| Net cash provided by (used for) investing activities..... | (7,532,000) | 8,055,000 | (15,414,000) | (16,686,000) |
| FINANCING ACTIVITIES: | | | | |
| Issuance of Preferred Stock..... | 9,919,000 | 5,965,000 | -- | 34,218,000 |
| Issuance of Common Stock..... | 1,000 | 83,000 | 19,911,000 | 20,027,000 |
| Payments received for stock purchase rights..... | -- | 3,500,000 | -- | 3,500,000 |
| Payments received under shareholder notes..... | -- | 31,000 | -- | 31,000 |
| Principal payments under capital lease obligations.. | (214,000) | (270,000) | (223,000) | (985,000) |
| Net cash provided by financing activities..... | 9,706,000 | 9,309,000 | 19,688,000 | 56,791,000 |
| NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS.... | (3,083,000) | 8,287,000 | (9,024,000) | 1,943,000 |
| CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD..... | 5,763,000 | 2,680,000 | 10,967,000 | -- |
| CASH AND CASH EQUIVALENTS AT END OF PERIOD..... | \$ 2,680,000 | \$10,967,000 | \$ 1,943,000 | \$ 1,943,000 |
| SUPPLEMENTAL CASH FLOW INFORMATION: | | | | |
| Interest paid..... | \$ 66,000 | \$ 62,000 | \$ 32,000 | \$ 251,000 |
| Additions to capital lease obligations..... | 270,000 | -- | -- | 1,174,000 |

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

AASTROM BIOSCIENCES, INC.
(A DEVELOPMENT STAGE COMPANY)
NOTES TO FINANCIAL STATEMENTS

1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Aastron Biosciences, Inc. (the Company) was incorporated in March 1989 (Inception) under the name Ann Arbor Stromal, Inc. The Company changed its name in 1991 concurrent with the commencement of employee-based operations. The Company is in the development stage with its principal business activities being research and product development, conducted both on its own behalf and in connection with various collaborative research and development agreements with other companies, involving the development of processes and instrumentation for the ex vivo production of human stem cells and their progeny, and hematopoietic and other tissues.

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 maintain adequate levels of funding.

SIGNIFICANT REVENUE RELATIONSHIPS - Two companies accounted for 49% and 28% of total revenues for the year ended June 30, 1995 and one company accounted for 83% and 52% of total revenues for the year ended June 30, 1996 and 1997, respectively. One company accounted for 43% of total revenues for the period from Inception to June 30, 1997. Grant revenues consist of grants sponsored by the U.S. government.

CASH AND CASH EQUIVALENTS - Cash and cash equivalents include cash and short-term investments with original maturities of three months or less.

SHORT-TERM INVESTMENTS - Short-term investments consist of U.S. government securities and commercial paper with original maturities of over three months but less than one year. Short-term investments are classified as available-for-sale, and are presented at market value, with unrealized gains and losses on investments reflected as a component of shareholders' equity.

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.

PROPERTY - Property is recorded at cost and depreciated or amortized using the straight-line method over the estimated useful life of the asset (primarily five years), or the remaining lease term, if shorter, with respect to leasehold improvements and certain capital lease assets.

REVENUE RECOGNITION - Revenue from grants and research agreements is recognized on a cost reimbursement basis consistent with the performance requirements of the related agreement. Funding received in advance of costs incurred is presented as deferred revenue in the accompanying financial statements.

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 \$146,000, \$1,294,000 and \$154,000 for the years ended June 30, 1995, 1996 and 1997, respectively, and \$1,642,000 for the period from Inception to June 30, 1997.

STOCK COMPENSATION - The Company adopted the disclosure provisions of Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation" (SFAS 123) as of July 1, 1996. 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 in accounting for its plans and does not recognize compensation expense for its employee stock-based compensation plans as prescribed in SFAS 123.

AASTROM BIOSCIENCES, INC.
(A DEVELOPMENT STAGE COMPANY)
NOTES TO FINANCIAL STATEMENTS--(CONTINUED)

INCOME TAXES - The Company recognizes deferred tax assets and liabilities for

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

NET LOSS PER SHARE - Net loss per share is computed using the weighted average

number of common and common equivalent shares outstanding during the period. Common equivalent shares are not included in the per share calculation where the effect of their inclusion would be anti-dilutive. However, common and common equivalent shares issued during the twelve month period preceding the filing of the registration statement for the Company's initial public offering which was completed in February 1997, (the IPO) at a price below the expected offering price are considered to be cheap stock and are included in the calculation for periods prior to the IPO, as if they were outstanding for all periods using the treasury stock method, as applicable, even though their inclusion is anti-dilutive. Due to the automatic conversion of all outstanding shares of Preferred Stock into Common Stock upon the completion of the IPO, Preferred Stock is assumed to have been converted into Common Stock at the time of issuance, except for those shares considered to be cheap stock which are treated as outstanding for all periods presented.

During March 1997, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 128, "Earnings Per Share" (SFAS 128) which amends the standards for computing earnings per share previously set forth in Accounting Principles Board Opinion No. 15 "Earnings per Share" (APB 15). SFAS 128, which will be adopted by the Company for the period ending December 31, 1997, will not have a material effect on the computation of net loss per share for the periods presented in the accompanying financial statements.

USE OF ESTIMATES - The preparation of financial statements in accordance with

generally accepted accounting principles requires management to make estimates that affect the amounts reported in the financial statements and disclosures made in the accompanying notes to financial statements. 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 generally 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 adopted Statement of Financial Accounting

Standards No. 121 (SFAS 121) as of July 1, 1996 and 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. Adoption of this pronouncement has not significantly impacted the accompanying financial statements as no impairment losses have been identified by the Company.

2. SHORT-TERM INVESTMENTS

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

| | Cost | Gross Unrealized Gains | Gross Unrealized Losses | Estimated Fair Value |
|---------------------------------|--------------|------------------------------|-------------------------------|-------------------------|
| June 30, 1997: | | | | |
| U.S. Government Securities..... | \$13,574,000 | \$1,000 | \$(11,000) | \$13,564,000 |
| Commercial Paper..... | 1,500,000 | -- | -- | 1,500,000 |
| | \$15,074,000 | \$1,000 | \$(11,000) | \$15,064,000 |

AASTROM BIOSCIENCES, INC.
(A DEVELOPMENT STAGE COMPANY)
NOTES TO FINANCIAL STATEMENTS--(CONTINUED)

3. PROPERTY

Property consists of the following:

| | June 30, | |
|--|--------------|--------------|
| | 1996 | 1997 |
| Machinery and equipment..... | \$ 1,337,000 | \$ 1,425,000 |
| Office equipment..... | 482,000 | 733,000 |
| Leasehold improvements..... | 520,000 | 605,000 |
| | ----- | ----- |
| | 2,339,000 | 2,763,000 |
| Less accumulated depreciation and amortization..... | (1,151,000) | (1,715,000) |
| | ----- | ----- |
| | \$ 1,188,000 | 1,048,000 |
| | ===== | ===== |

Equipment under capital leases totaled \$1,131,000 at June 30, 1996 and 1997, with related accumulated amortization of \$622,000 and \$844,000, respectively (Note 7).

4. SHAREHOLDERS' EQUITY

INITIAL PUBLIC OFFERING - In February 1997, the Company completed an

underwritten initial public offering of 3,000,000 shares of its Common Stock at an offering price of \$7.00 per share. In March 1997, the underwriters elected to purchase an additional 250,000 shares of Common Stock pursuant to the underwriters' over-allotment option at a price of \$7.00 per share. Proceeds from the offering, net of underwriters' commissions and expenses, were \$19,885,000.

PREFERRED STOCK - The Company had the following classes of preferred stock

outstanding as of June 30, 1996. As a result of the IPO, all 9,657,648 shares of previously outstanding preferred stock were automatically converted into 8,098,422 shares of Common Stock.

| | Shares Authorized | Shares Issued and Outstanding | Liquidation Preference |
|-----------------------------|----------------------|----------------------------------|---------------------------|
| Series A..... | 2,500,000 | 2,500,000 | \$ 2,500,000 |
| Series B..... | 3,030,000 | 3,030,000 | 6,060,000 |
| Series C..... | 10,000 | 10,000 | 10,000,000 |
| Series D..... | 3,000,000 | 2,500,001 | 10,000,000 |
| Series E..... | 1,411,765 | 1,411,765 | 6,000,000 |
| | ----- | ----- | ----- |
| Balance, June 30, 1996..... | 9,951,765 | 9,451,766 | \$34,560,000 |
| | ===== | ===== | ===== |

No dividends have ever been declared or paid.

COBE LABORATORIES, INC. STOCK PURCHASE RIGHTS - In connection with the purchase

of the Series C Convertible Preferred Stock by Cobe Laboratories, Inc. (Cobe) in October 1993, Cobe received a preemptive right to purchase a pro-rata portion of any newly issued shares of stock by the Company in order to maintain its then current percentage ownership interest. Any such purchase of newly issued shares shall be at the net price to the Company after deducting underwriters' discounts and commissions, if any. The agreements establishing the Company's relationship with Cobe provide the Company with an option (the Put Option) to require Cobe to purchase the lesser of 20%, or \$5,000,000, in an initial public offering or a private offering meeting certain minimum requirements. In the event that the Company exercises the Put Option, Cobe then has the

AASTROM BIOSCIENCES, INC.
(A DEVELOPMENT STAGE COMPANY)
NOTES TO FINANCIAL STATEMENTS--(CONTINUED)

option to purchase up to 40% of that offering. While the Put Option was not exercised by the Company in connection with the IPO, Cobe elected to purchase an additional \$5,000,000 in Common Stock as part of the IPO. The Company and Cobe are evaluating whether or not the Put Option remains in effect as it relates to the Company's ability to exercise the option in a subsequent private offering of its equity securities.

Cobe has an option to purchase additional shares from the Company equal to 30% of the total number of shares outstanding assuming exercise of the option. Such option, which is exercisable until February 2000, must be exercised in full with the purchase price of the shares equal to 120% of the public market trading price as determined by the 30-day average market price preceding the date of exercise of the option.

The Company has granted Cobe a right of first negotiation in the event the Company receives any proposal concerning, or otherwise decides to pursue, a merger, consolidation or other transaction in which all or a majority of the Company's equity securities or substantially all of the Company's assets, or any material portion of the assets of the Company used by the Company in performing its obligation under the Distribution Agreement (Note 6), would be acquired by a third party outside of the ordinary course of business.

STOCK OPTION PLANS - The Company has various stock option plans which provide

for the issuance of nonqualified and incentive stock options to acquire up to 2,986,594 shares of Common Stock. Such options may be granted by the Company's Board of Directors to certain of the Company's founders, 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.

For certain options granted, the Company recognizes compensation expense for the difference between the deemed value for accounting purposes and the option exercise price on the date of grant. During the year ended June 30, 1997, compensation expense totaling approximately \$120,000 has been charged with respect to these options. Additional future compensation expense with respect to the issuance of such options totals approximately \$135,000 and will be recognized through December 2001.

As permitted by SFAS 123, the Company continues to apply APB 25 and related interpretations in accounting for its stock option plans and does not recognize compensation expense for its employee stock-based compensation plans as prescribed in SFAS 123. If the Company had elected to recognize compensation expense based upon the fair value at the grant dates for stock option awards granted in 1996 and 1997, in accordance with SFAS No. 123, the pro forma net loss and net loss per share would be as follows.

| | June 30, | |
|----------------------------|-------------|--------------|
| | 1996 | 1997 |
| Net Loss: | | |
| As reported..... | \$9,917,000 | \$14,288,000 |
| Pro forma..... | 9,942,000 | 14,793,000 |
| Net Loss per common share: | | |
| As reported..... | \$ (.98) | \$ (1.26) |
| Pro forma..... | (.98) | (1.31) |

The fair value of options was estimated at the date of grant using the Black-Scholes option pricing model with the following assumptions; no dividend yields, 40% volatility, risk free interest rates ranging from 5.2% to 6.8% and expected option lives of three to five years.

AASTROM BIOSCIENCES, INC.
(A DEVELOPMENT STAGE COMPANY)
NOTES TO FINANCIAL STATEMENTS--(CONTINUED)

The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options which have no vesting restrictions and are fully transferable. In addition, option valuation models require the use of highly subjective assumptions including the expected stock price volatility. Because the Company's employee stock options have characteristics significantly different from those of traded options, and because changes in subjective assumptions can materially affect the fair value estimates, in management's opinion, the existing models do not necessarily provide a reliable single measure of the fair value of its employee stock based compensation plans.

The following table summarizes option activity under the Company's stock option plans:

| | Options Outstanding ----- | Options Available For Grant ----- | Weighted Average Exercise Price Per Share ----- | Options Exercisable At Period End ----- |
|-----------------------------|---------------------------------|---|--|--|
| March 24, 1989 (Inception) | | | | |
| Options authorized..... | -- | 1,703,261 | | |
| Options granted..... | 1,727,111 | (1,727,111) | \$.31 | |
| Options exercised..... | (1,229,482) | -- | \$.19 | |
| Options canceled..... | (103,964) | 103,964 | \$.66 | |
| | ----- | ----- | | |
| Balance, June 30, 1994..... | 393,665 | 80,114 | \$.61 | 77,682 |
| Options authorized..... | -- | 333,333 | | |
| Options granted..... | 55,333 | (55,333) | \$1.20 | |
| Options exercised..... | (39,103) | -- | \$.21 | |
| Options canceled..... | (60,230) | 60,230 | \$.34 | |
| | ----- | ----- | | |
| Balance, June 30, 1995..... | 349,665 | 418,344 | \$.78 | 108,492 |
| Options authorized..... | -- | 800,000 | | |
| Options granted..... | 155,337 | (155,337) | \$1.44 | |
| Options exercised..... | (130,016) | -- | \$.14 | |
| Options canceled..... | (44,690) | 44,690 | \$.85 | |
| | ----- | ----- | | |
| Balance, June 30, 1996..... | 330,296 | 1,107,697 | \$1.20 | 101,021 |
| Options authorized..... | -- | 150,000 | | |
| Options granted..... | 785,200 | (785,200) | \$6.78 | |
| Options exercised..... | (40,307) | -- | \$.65 | |
| Options canceled..... | (16,818) | 16,818 | \$1.83 | |
| | ----- | ----- | | |
| Balance, June 30, 1997..... | 1,058,371 ===== | 489,315 ===== | \$5.36 | 483,376 |

OUTSIDE DIRECTORS' STOCK OPTION PLAN - The Company has an outside directors'

stock option plan which provides for the issuance of options to purchase up to 150,000 shares of Common Stock to outside directors. Under this plan, non-qualified options to purchase 5,000 shares of Common Stock are granted to each outside director on the day of the Annual Shareholders' meeting. These options generally vest over a one-year period and expire ten years after the date of grant. As of June 30, 1997, options to purchase 30,000 shares of Common Stock at \$7.00 per share are outstanding under this plan, of which options to purchase 10,002 shares of Common Stock are exercisable.

AASTROM BIOSCIENCES, INC.
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NOTES TO FINANCIAL STATEMENTS--(CONTINUED)

The following table summarizes information about stock-based compensation plans outstanding as of June 30, 1997:

| 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 - \$1.20 | 260,170 | 7.7 | \$1.15 | 135,542 | \$1.11 |
| \$3.20 - \$3.88 | 58,418 | 9.2 | \$3.24 | 4,501 | \$3.20 |
| \$7.00 - \$7.13 | 739,783 | 9.6 | \$7.00 | 343,333 | \$7.00 |
| | ----- 1,058,371 ===== | | | ----- 483,376 ===== | |

The weighted average fair value of options granted during the year ended June 30, 1997 was \$6.78 per share.

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 ending 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. The initial purchase date under this plan is August 31, 1997, accordingly, no shares have been sold under this plan as of June 30, 1997.

STOCK PURCHASE WARRANTS - The Company has issued warrants to purchase 69,444

shares of Common Stock which expire on October 15, 2000. These warrants may be exercised, in whole or in part, at a price equal to the lesser of (a) \$9.00 per share, which price increases by \$3.00 per share on February 3, 1998, 1999 and 2000; or (b) 85% of the fair market value of the Company's Common Stock at the time of exercise.

COMMON SHARES RESERVED - As of June 30, 1997, the Company has reserved shares of

Common Stock for future issuance as follows:

| | |
|---|-----------------------------|
| Issuance under stock option plans: | |
| 1992 Incentive and Non-Qualified Stock Option Plan..... | 1,397,686 |
| 1995 Outside Director Stock Option Plan..... | 150,000 |
| | ----- 1,547,686 |
| Issuance under 1996 Employee Stock Purchase Plan..... | 250,000 |
| Exercise of Stock Purchase Warrants..... | 69,444 |
| | ----- 1,867,130 ===== |

AASTROM BIOSCIENCES, INC.
(A DEVELOPMENT STAGE COMPANY)
NOTES TO FINANCIAL STATEMENTS--(CONTINUED)

5. INCOME TAXES

Deferred tax assets consist of the following:

| | June 30, | |
|--|---------------|----------------|
| | 1996 | 1997 |
| Net operating loss carryforwards..... | \$ 9,210,000 | \$ 14,150,000 |
| Tax credits and other..... | 440,000 | 1,162,000 |
| | 9,650,000 | 15,312,000 |
| Gross deferred tax assets..... | | |
| Deferred tax assets valuation allowance..... | \$(9,650,000) | \$(15,312,000) |
| | \$ -- | \$ -- |

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.

At June 30, 1997, the Company's Federal tax net operating loss and tax credit carryforwards were \$40,420,000 and \$971,000, respectively, which will expire from 2004 through 2012, if not utilized. The Company underwent an ownership change in October 1993 which has resulted in a limitation under which the Company can utilize a portion of its federal net operating loss carryforward amounting to \$1,153,000 per year. As of June 1997, the portion of the Company's net operating loss that remains subject to this limitation is \$2,490,000 and therefore is not expected to ultimately effect the Company's ability to utilize the benefit. If certain changes in ownership should occur again in the future, the Company's ability to utilize its net operating loss and tax credit carryforwards may become subject to further annual limitation.

6. 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). Under the terms of this research agreement, as amended, the Company agreed to reimburse the University for certain research costs through the date of its expiration in December 1994. Payments made to the University under the aforementioned agreements totaled \$121,000 and \$2,521,000 for the years ended June 30, 1995 and for the period from Inception to June 30, 1997, respectively, which amounts are included in research and development expense in the accompanying Statements of Operations. As part of this relationship, the Company issued to the University 454,545 shares of Common Stock in August 1989. No value has been assigned to these shares in the accompanying financial statements. In March 1992, and as provided for under the research agreement, the Company 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.

COBE BCT, INC. - In connection with the issuance of the Series C Preferred Stock to Cobe in October 1993, the Company and Cobe BCT, Inc. (Cobe BCT), an affiliate of Cobe, entered into an agreement which grants to Cobe BCT exclusive worldwide distribution and marketing rights to the Company's Cell Production System (CPS) for stem cell therapy applications (Distribution Agreement). The term of the Distribution Agreement is ten years, with an option, exercisable by Cobe BCT, to extend the term for an additional ten years. Cobe has the right to terminate its Distribution Agreement with the Company with twelve months' notice upon a change of control of the Company, other than to Cobe, or at any time after December 31, 1997, if Cobe determines that commercialization of the Aastrom CPS for stem cell therapy on or prior to December 31, 1998 is unlikely. Pursuant to the Distribution Agreement, Cobe BCT will perform worldwide marketing and distribution activities of the CPS for use in stem cell therapy and will receive a share of the resulting net sales, as defined, ranging from 38% to 42%, subject to certain negotiated discounts and volume-based adjustments.

AASTROM BIOSCIENCES, INC.
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NOTES TO FINANCIAL STATEMENTS--(CONTINUED)

The agreements establishing this collaboration provided for payments totaling \$5,000,000 to be made by Cobe BCT upon the Company meeting certain development milestones. In May 1995, the Company accepted, as part of the sale of the Series D Preferred Stock, an equity investment of \$5,000,000 from Cobe in lieu of those future milestone payments.

LICENSE AND ROYALTY AGREEMENTS - In July 1992, the Company licensed certain cell culture technology under which it obtained an exclusive worldwide license to the technology in exchange for a royalty payable of up to 3% of net sales on products containing the licensed technology.

In March 1996, the Company executed a license agreement which provides for the use of licensed products in the CPS. Pursuant to this license agreement, the Company recorded a charge to research and development expense of \$1,500,000 representing the license fee payable upon execution of the agreement. The license agreement provides for annual renewal fees of \$1,000,000 over the five year license term, if renewed by the Company, and can be extended at the Company's option for an additional five years.

RHONE-POULENC RORER, INC. - In September 1995, the Company entered into a research and development collaboration with Rhone-Poulenc Rorer, Inc. (RPR), granting RPR a right to license the Company's CPS for Lymphoid cell applications. Pursuant to the agreements establishing this collaboration, RPR was obligated to fund certain research costs associated with the development of the CPS for Lymphoid cell applications and was entitled to make equity purchases of up to \$12,500,000 subject to the Company's satisfaction of certain milestones and RPR's decision to exercise certain options. In September 1996, RPR notified the Company of its intent to not exercise its additional options under the collaboration. This notification was made after RPR had determined that for strategic reasons it would not pursue Lymphoid cell therapy applications, including those being pursued under the collaboration the Company. The Company received \$3,500,000 in equity payments and recognized \$1,538,000 in research revenue under this collaboration. As a result of this termination, no further equity payments or research funding is due from RPR and RPR's license rights to the Company's CPS for Lymphoid cell applications have been terminated.

7. COMMITMENTS

The Company leases certain machinery and equipment and office equipment under capital leases. Obligations under these leasing arrangements bear interest at rates ranging from 9.7% to 12.1% and mature through May 1999. Additionally, the Company leases its facility under an operating lease which expires in May 1998, at which time the Company has the option to renew the lease for an additional period of up to five years.

Future minimum payments under capital leases and non-cancelable operating leases are as follows:

| | CAPITAL LEASES | OPERATING LEASES |
|--|-------------------|---------------------|
| Year Ending June 30, | ----- | ----- |
| 1998..... | \$138,000 | \$435,000 |
| 1999..... | 69,000 | -- |
| | ----- | ----- |
| Total minimum lease payments..... | 207,000 | \$435,000 |
| | | ===== |
| Less amount representing interest..... | (18,000) | |
| | ----- | |
| Obligations under capital lease..... | \$189,000 | |
| | ===== | |

Certain of the Company's capital lease agreements contain restrictive provisions which require that the Company's total assets exceed its total liabilities by at least \$1,000,000. Should the Company fall out of compliance with this provision, and a

AASTROM BIOSCIENCES, INC.
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NOTES TO FINANCIAL STATEMENTS--(CONTINUED)

waiver cannot be obtained from the lessor, remaining amounts due under the lease agreements become immediately due and payable.

Rent expense for the years ended June 30, 1995, 1996 and 1997, was \$241,000, \$338,000 and \$456,000, respectively, and for the period from Inception to June 30, 1997 was \$1,278,000.

8. EMPLOYEE SAVINGS PLAN

The Company has a 401(k) plan that became effective in January 1994. The plan 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, 1997, the Company has made no contributions to the plan.

SIGNATURES

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

Date: October 20, 1997 AASTROM BIOSCIENCES, INC.

By: /s/ R. Douglas Armstrong

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

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below on October 20, 1997 by the following persons in the capacities indicated.

| Signature ----- | Title ----- |
|--|--|
| /s/ R. DOUGLAS ARMSTRONG ----- R. Douglas Armstrong, Ph.D. | President, Chief Executive Officer and Director Principal Executive Officer) |
| /s/ TODD E. SIMPSON ----- Todd E. Simpson | Vice President, Finance & Administration, Chief Financial Officer, Secretary and Treasurer (Principal Financial and Accounting Officer) |
| /s/ ROBERT J. KUNZE ----- Robert J. Kunze | Chairman of the Board and Director |
| /s/ STEPHEN G. EMERSON ----- Stephen G. Emerson, M.D., Ph.D. | Director |
| /s/ G. BRADFORD JONES ----- G. Bradford Jones | Director |
| /s/ HORST R. WITZEL ----- Horst R. Witzel, Dr.-Ing. | Director |
| /s/ EDWARD C. WOOD ----- Edward C. Wood, Jr. | Director |

EXHIBIT INDEX

| EXHIBIT NUMBER - - - - - | Description of Document ----- |
|--------------------------------|--|
| 3.1* | Restated Articles of Incorporation of the Company. |
| 3.2** | Bylaws, as amended. |
| 4.1** | Specimen Common Stock Certificate. |
| 4.2** | Amended and Restated Investors' Rights Agreement, dated April 7, 1992. |
| 10.1**# | Form of Indemnification Agreement. |
| 10.2**# | Amended and Restated 1992 Incentive and Non-Qualified Stock Option Plan and forms of agreements thereunder. |
| 10.3**# | 1996 Outside Directors Stock Option Plan and forms of agreements thereunder. |
| 10.4**# | 1996 Employee Stock Purchase Plan and form of agreement thereunder. |
| 10.5** | Stock Purchase Agreement, dated October 22, 1993, between Cobe Laboratories, Inc. and the Company and amendment thereto dated October 29, 1996. |
| 10.6**+ | Distribution Agreement, dated October 22, 1993, between Cobe BCT, Inc. and the Company and amendments thereto dated March 29, 1995, September 11, 1995 and October 29, 1996. |
| 10.7** | Lease Agreement, dated May 18, 1992, between Domino's Farms Holdings, L.P. and the Company and amendments thereto dated February 26, 1993, October 3, 1994, November 16, 1994 and July 29, 1996. |
| 10.8**# | Promissory Note, dated November 18, 1993, for \$120,000 loan by the Company to R. Douglas Armstrong, Ph.D. and amendment thereto dated October 30, 1996. |
| 10.9**# | Promissory Note, dated October 20, 1993, for \$47,303 loan by the Company to Stephen G. Emerson, M.D., Ph.D. and amendment thereto dated October 30, 1996. |
| 10.10** | Clinical Trial Agreement dated August 28, 1996 between the Company and Loyola University Medical Center Cancer Center. |
| 10.11** | Stock Purchase Commitment Agreement, dated October 15, 1996, between the State Treasurer of the State of Michigan and the Company. |
| 10.12** | Convertible Loan Commitment Agreement, dated October 15, 1996, between the State Treasurer of the State of Michigan and the Company. |
| 10.13** | Letter Agreement, dated November 11, 1996, between the Company and Cobe Laboratories, Inc. |
| 10.14** | Termination Agreement, dated November 14, 1996, between the Company and Rhone-Poulenc Rorer Inc. |
| 10.15** | Stock Purchase Agreement, dated November 14, 1996, between the Company and Rhone-Poulenc Rorer Inc. |
| 10.16** | Collaborative Supply Agreement, dated December 16, 1996, between the Company and Anchor Advanced Products, Inc. Mid-State Plastics Division. |
| 10.17**# | 1989 Stock Option Plan and form of agreement thereunder. |
| 10.18**# | Ancillary Stock Option Plan and form of agreement thereunder. |
| 10.19**# | 401(k) Plan. |

- 10.20**# Form of Employment Agreement.
- 10.21** License Agreement, dated July 17, 1992, between J.G. Cremonese and the Company and related addenda thereto dated July 14, 1992 and July 7, 1993.
- 10.22**+ Collaborative Product Development Agreement, dated May 10, 1994, between SeaMED Corporation and the Company.
- 10.23**+ Collaborative Product Development Agreement, dated November 8, 1994, between Ethox Corporation and the Company.
- 10.24**+ License and Supply Agreement, dated April 1, 1996, between Immunex Corporation and the Company.
- 10.25** Clinical Trial Agreement, dated April 19, 1996, between the Company and the University of Texas M.D. Anderson Cancer Center.
- 10.26** License Agreement, dated March 13, 1992, between the Company and the University of Michigan and amendments thereto dated March 13, 1992, October 8, 1993 and June 21, 1995.
- 10.27**# Employee Proprietary Information and Invention Agreement, effective June 1, 1991, between the Company and R. Douglas Armstrong, Ph.D.
- 10.28**# Employment Agreement, dated June 19, 1992, between the Company and James Maluta.
- 10.29**# Employment Agreement, dated December 8, 1995, between the Company and Todd E. Simpson.
- 10.30**# Employment Agreement, dated February 10, 1994, between the Company and Walter C. Ogier.
- 10.31**# Employment Agreement, dated April 19, 1994, between the Company and Thomas E. Muller, Ph.D.
- 10.32**# Employment Agreement, dated October 26, 1995, between the Company and Alan K. Smith, Ph.D.
- 10.33**# Consulting Agreement, dated June 1, 1995, between the Company and Stephen G. Emerson, M.D., Ph.D.
- 10.34** Form of Subscription Agreement for the purchase of Series D Preferred Stock (Enterprise Development Fund L.P., Enterprise Development Fund II, L.P. and Northwest Ohio Venture Fund Limited Partnership).
- 10.35** Stock Purchase Agreement, dated January 8, 1996, among the Company, SBIC Partners, L.P. and the State Treasurer of the State of Michigan.
- 10.36** Form of Subscription Agreement for the purchase of Series D Preferred Stock (Brentwood Associates V, L.P., Candice E. Appleton Family Trust, Candis J. Stern, Helmut F. Stern, H&Q Life Science Technology Fund, H&Q London Ventures, State Treasurer of the State of Michigan and Windpoint Partners II, Limited Partnership).
- 10.37** Subscription Agreement, dated December 11, 1995, between the Company and Northwest Ohio Venture Fund Limited Partnership.
- 10.38# Second Amendment to Promissory Note payable to the Company by Stephen G. Emerson, M.D., Ph.D., dated June 30, 1997.
- 10.39# Second Amendment to Promissory Note payable to the Company by R. Douglas Armstrong, Ph.D., dated June 30, 1997.
- 10.40**** Amendment to License and Supply Agreement, dated August 25, 1997, between Immunex Corporation and the Company.

- 10.41% Strategic Planning Consulting Services and Collaboration Agreement, dated October 7, 1997, between Burrill & Company, LLC and the Company.
- 11.1**** Statement regarding computation of net loss per share.
- 16.1*** Letter from Coopers & Lybrand L.L.P., dated July 15, 1997.
- 23.1 Consent of Price Waterhouse LLP.
- 27.1**** Financial Data Schedule.

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- * Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended December 31, 1996, as filed on March 7, 1997.
- ** Incorporated by reference to the Company's Registration Statement on Form S-1 (No. 333-15415), declared effective on February 3, 1997.
- *** Incorporated by reference to the Company's Current Report on Form 8-K, as filed on July 16, 1997.
- **** Incorporated by reference to the Company's Annual Report on Form 10-K for the year ended June 30, 1997, as filed on September 25, 1997.
- % Incorporated by reference to the Company's Registration Statement on Form S-1 (No. 333-37439), as filed on October 8, 1997.
- + Confidential treatment has been granted as to a portion of this exhibit.
- # Management contract or compensatory plan or arrangement covering executive officers or directors of the Company.

CONSENT OF INDEPENDENT ACCOUNTANTS

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 (No. 333-25021) of Aastrom Biosciences, Inc. of our report dated August 15, 1997 appearing on page 39 of this Form 10-K/A.

/s/ PRICE WATERHOUSE LLP

PRICE WATERHOUSE LLP

Battle Creek, Michigan
October 20, 1997