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BIOTRANSPLANT INC  
Form 10-K  
March 15, 2002

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SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549  
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FORM 10-K

FOR ANNUAL AND TRANSITION REPORTS  
PURSUANT TO SECTIONS 13 OR 15(D) OF THE  
SECURITIES EXCHANGE ACT OF 1934

(MARK ONE)

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

FOR THE FISCAL YEAR ENDED: DECEMBER 31, 2001  
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 NO. 000-28324  
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BIOTRANSPLANT INCORPORATED

(Exact name of registrant as specified in its charter)

DELAWARE  
(State or other jurisdiction of  
incorporation or organization)

04-3119555  
(I.R.S. Employer Identification No.)

CHARLESTOWN NAVY YARD, BUILDING 75  
THIRD AVENUE, CHARLESTOWN, MA  
(Address of principal executive  
offices)

02129  
(Zip Code)

REGISTRANT'S TELEPHONE NUMBER, INCLUDING AREA CODE: (617) 241-5200  
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Securities registered pursuant to Section 12(b) of the Act: NONE

Securities registered pursuant to Section 12(g) of the Act: COMMON STOCK, \$.01 PAR VALUE

(Title of each class)

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 /X/ 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 the Form 10-K. / /

The aggregate market value of voting Common Stock held by non-affiliates of the registrant was \$107,802,498 based on the last reported sale price of the Common Stock on the Nasdaq consolidated transaction reporting system on March 11, 2002.

Number of shares of the registrant's class of Common Stock outstanding as of March 11, 2002: 21,295,528.

Documents Incorporated By Reference: None

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### PART I

#### ITEM 1. BUSINESS

##### OVERVIEW

We discover, develop and commercialize therapeutics, therapeutic devices and therapeutic regimens designed to suppress undesired immune responses and enhance the body's ability to accept donor cells, tissues and organs. We believe that our patented products and product candidates, either alone, in combination or with modified conventional therapies, will address significant unmet medical needs in autoimmune diseases, cancer and transplantation.

**MEDI-507.** We have developed a novel and proprietary humanized monoclonal antibody, MEDI-507, that we believe will be effective in the treatment of a number of T cell-mediated diseases. We have exclusively licensed MEDI-507 for use as a stand-alone agent to MedImmune, Inc., which is developing it under the name Siplizumab. MedImmune has announced completion of enrollment of multiple Phase II clinical trials of Siplizumab for the treatment of moderate to severe psoriasis. We are also independently developing MEDI-507 as a component of transplantation systems.

**ELIGIX-TM- HDM CELL SEPARATION SYSTEMS.** Our Eligix HDM Cell Separation Systems use monoclonal antibodies to remove unwanted cells from bone marrow, peripheral blood stem cell and donor leukocyte grafts used in transplantation procedures. Our BCell Separation System, BCell-SC, and our initial TCell Separation System, CD8-DLI, have received CE Mark approval and are sold in Europe by Gambro BCT, our European sales and distribution partner. We expect to receive CE Mark approval for our CD8-SC Cell Separation System in late 2002.

**ALLOMUNE SYSTEMS.** We are currently developing our AlloMune Systems as

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multiple-component proprietary therapeutic regimens intended to re-educate a patient's immune system to prevent the rejection of transplanted cells, tissues and organs. MEDI-507 is an important component of our AlloMune Systems, and we are developing the next generation of AlloMune Systems to incorporate our Eligix HDM Cell Separation Systems. We are currently conducting a multi-center Phase I/II clinical trial of our AlloMune System for Cancer for the treatment of refractory lymphoma. A physician-sponsored investigational new drug pilot clinical study using our AlloMune System for Transplantation for human kidney transplantation has also been started.

**XENOTRANSPLANTATION.** Our joint venture with Novartis Pharma AG, Immerge BioTherapeutics, is researching the use of MEDI-507 and other proprietary technologies as part of a xenotransplantation system. Xenotransplantation is the transplantation of cells, tissues or organs from one species to another. Immerge BioTherapeutics is currently conducting animal studies to test the use of miniature swine organs in swine-to-primate transplantation.

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### PRODUCTS AND PRODUCTS UNDER DEVELOPMENT

The following table summarizes the status of our products and products under development:

PRODUCTS AND PRODUCTS UNDER DEVELOPMENT	APPLICATION	STATUS*	COLLABORATOR/ DISTRIBUTOR
MEDI-507 (Siplizumab)	Psoriasis	Phase II completed enrollment	MedImmune
Eligix HDM Cell Separation Systems BCell Separation System PURGING OF MALIGNANT B CELLS BCell-SC	Autologous bone marrow transplantation	EUROPE: CE Mark approval received in 2001; launched in the fourth quarter of 2001 U.S.: Phase III**	Gambro  None
TCell Separation Systems DEPLETION OF CD8+ T CELLS CD8-DLI	Donor leukocyte infusions, or DLIs	EUROPE: CE Mark approval received in 2001; launched in the fourth quarter of 2001 U.S.: Phase III planned for late 2002**	Gambro  None
CD8-SC	Allogeneic bone marrow transplantation	EUROPE: CE Mark approval expected in late 2002 U.S.: Preclinical Investigator sponsored Phase I/II	Gambro  None
AlloMune Systems AlloMune System for Cancer	Refractory Lymphoma  Refractory Hematological	Phase I/II  Physician IND	None  Massachusetts Gener

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AlloMune System for Transplantation	Malignancies Kidney Transplantation	Physician IND	Hospital Massachusetts General Hospital
Xenotransplantation	Animal to human transplantation	Preclinical	Joint Venture with Novartis (Immerge)

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\* Preclinical means that the product is being evaluated or optimized in laboratory and/or animal models. Phase I means an investigational new drug application, or IND, or an investigational device exemption, or IDE, has been filed with the United States Food and Drug Administration and that the product candidate is in clinical trials to evaluate safety in healthy volunteers. An investigator sponsored clinical trial is a trial that is being sponsored by the investigator or institution where the trial is being conducted. Physician IND means that a physician has filed with the FDA to conduct a study under his or her own protocol. Phase I/II means the product candidate is in clinical trials for safety and initial indications of efficacy in patients. Phase II means that the product candidate is in clinical trials for safety and potential efficacy in patients. Phase III typically means the product candidate is in additional clinical trials for safety and efficacy in an expanded population.

\*\* We do not anticipate commercialization of the product candidate in the U.S. for a number of years.

MEDI-507

OVERVIEW

MEDI-507 is a novel and proprietary humanized monoclonal antibody that may be effective in treating T cell-mediated diseases. A monoclonal antibody is a single antibody that reacts to a specific antigen, or cell marker, and can trigger or block an immune response. T cells are white blood cells that are responsible for part of the body's primary immune response to foreign antigens. When T cells come in contact with foreign tissue, they become activated and proliferate. The T cells then attack and destroy the targeted foreign tissue, or, in the case of autoimmune disease, mistakenly attack the body's own tissue. This is noticeable in psoriasis, an autoimmune disease characterized by inflammation of, and dry, scaling, red lesions on, the skin. It is now well established that auto-reactive T cells drive this process. Similarly, in multiple sclerosis, rheumatoid arthritis and Crohn's disease, the T cells target the individual's own tissue and the resulting destruction of the tissue causes debilitating autoimmune symptoms. MEDI-507 strongly inhibits the immune response triggered by T cells by binding to CD2, which is a receptor found on T cells. By binding to CD2, MEDI-507 can either turn off the T cell responses or, through alternative dosing, selectively remove T cell populations from the body, while allowing other immune cells to respond normally to other antigens. We have exclusively licensed MEDI-507 for use as a stand-alone agent to MedImmune, which is developing the monoclonal antibody under the name Siplizumab primarily for the treatment of autoimmune diseases. We are entitled to royalties from MedImmune on sales of Siplizumab and future generations of stand-alone products.

Sources estimate that new therapeutic approaches will cause the market for autoimmune disorder treatments to grow to a value of over \$21 billion by 2006. Autoimmune disease is currently the third target category of illness in the industrialized world, behind heart disease and cancer, and is now the focus of intense research.

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### PSORIASIS

MedImmune is focusing its initial development efforts with Siplizumab on the treatment of moderate to severe psoriasis. Psoriasis is an autoimmune disease that leads to chronic inflammation of, and dry, scaling, red lesions on, the skin as well as other more serious consequences. More than seven million Americans suffer from psoriasis, and an estimated 150,000 to 260,000 new cases are diagnosed annually. Of these, an estimated 20% to 25% have moderate to severe psoriasis. Psoriasis can be a debilitating disease for which there is no known cure. The aggregate annual cost of outpatient treatment is estimated to be between \$1.6 billion and \$3.2 billion.

MedImmune has announced completion of Phase I and Phase I/II clinical trials to evaluate Siplizumab for moderate to severe psoriasis. Reported results from a pooled analysis of 79 patients in these clinical trials indicate that over 70% of patients achieved at least a 25% improvement in their Psoriasis Area and Severity Index, or PASI, score. Moreover, approximately 56% and 39% of patients receiving the highest doses achieved at least a 50% and at least a 75% improvement in PASI score, respectively. MedImmune is presently conducting a comprehensive Phase II program for the treatment of psoriasis that includes 44 sites and has a completed enrollment of more than 400 patients.

### OTHER INDICATIONS

MedImmune has indicated its intention to initiate Siplizumab clinical trials in psoriatic arthritis and rheumatoid arthritis and is also exploring other potential indications.

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### ELIGIX HDM CELL SEPARATION SYSTEMS

#### OVERVIEW

We developed our proprietary Eligix HDM Cell Separation Systems to remove unwanted populations of cells in bone marrow, peripheral blood stem cell, or PBSC, and donor leukocyte grafts used in transplantation procedures. Bone marrow contains cells, referred to as stem cells, that have the ability to develop into the different kinds of blood cells in the human body. When bone marrow containing these stem cells is collected from one individual and transplanted into a recipient who has been conditioned with irradiation or chemotherapy, the stem cells from the donor bone marrow take root, or engraft, into the bone marrow of the recipient and replace some or all of the recipient's blood cells. Alternatively, because it is often easier to collect the stem cells from peripheral blood rather than bone marrow, a donor can be treated with agents that induce the stem cells to migrate from the bone marrow into the blood and then the blood stem cells can be removed from the donor's blood. A preparation containing these blood stem cells can then be transplanted into the recipient in a procedure referred to as a peripheral blood stem cell transplant, with similar results as a bone marrow transplant. Bone marrow registry sources estimate that there were approximately 47,000 bone marrow and stem cell transplant procedures performed worldwide in 1998, the last year for which data were available to the registry.

There are two types of bone marrow transplantation that are currently performed: autologous bone marrow transplantation and allogeneic bone marrow transplantation. In autologous transplantation, doctors use the patient's own bone marrow cells, which are harvested prior to administration of high-dose chemotherapy and/or radiation, to reconstitute the patient's bone marrow cells following high-dose chemotherapy treatment and/or radiation. However, the patient is at risk for cancer relapse, with one cause of relapse being potential cancer cell contamination of the autologous bone marrow being returned to the

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patient. In allogeneic transplantation, the patient receives transplanted bone marrow cells or peripheral blood stem cells harvested from a healthy donor. However, differences in the antigens of donor and recipient significantly limit donor availability for allogeneic bone marrow transplantation. Even when the donor and the recipient are tissue-matched siblings, complications such as graft-versus-host disease, poor immune function, and graft failure can occur as a result of immune responses to minor antigen differences between donor and recipient, as well as from the side effects caused by the treatments used to overcome these differences.

Antigen differences between the donor and the recipient may complicate treatment of tumors which relapse following allogeneic bone marrow or PBSC transplants. Until recently, a second transplant was the primary treatment option for patients who had cancer relapses following allogeneic bone marrow or PBSC transplantations. The intention is to introduce an anti-tumor response with the immune cells contained in the second transplant. Unfortunately, this second treatment often results in a high incidence of treatment-related complications, including graft-versus-host disease. Graft-versus-host disease occurs when the donor's immune cells recognize the patient's cells as foreign and begin to attack the patient's normal cells, tissues and organs, even in the presence of therapeutic agents, with possible fatal consequences. A published study suggests that it is possible to infuse donor immune cells following an allogeneic transplant, and this treatment may induce remissions in patients who have relapsed after donor transplantations. Known as a donor leukocyte infusion, or DLI, this procedure has emerged as an effective treatment for patients receiving allogeneic bone marrow transplants for blood cancers.

The Eligix HDM Cell Separation Systems consist of high density microparticles, referred to as HDM, to which monoclonal antibodies specific for targeted cell surface antigens are coupled. Mixing HDM-conjugated-antibodies with blood or bone marrow EX VIVO, or outside the body, allows the binding of specific cells in the blood or bone marrow to the HDM. Once the specific cells are bound to the HDM, they are then removed from the blood or bone marrow by allowing the HDM to settle out from

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the blood or bone marrow by gravity. Removing cancerous cells from autologous bone marrow transplants may reduce the risk of relapse in blood cell cancers. Alternatively, removing the donor T cells that react with the recipient reduces the risk of graft-versus-host disease in allogeneic transplants. In addition to removing unwanted cells from blood or bone marrow such as cancerous cells or T cells reactive with the recipient's tissues, the Eligix HDM Cell Separation Systems can be used to isolate cells useful for activation of the immune system against specific targets. These cells include specific T cells or antigen presenting cells which can be increased in number in the laboratory and then reinfused into the patient for anti-viral or anti-tumor adoptive immunotherapy.

### BCELL SEPARATION SYSTEM

Our BCell Separation System is designed to effectively purge B cells from autologous bone marrow and stem cell transplantation procedures in patients undergoing high dose chemotherapy and/or radiation for B cell malignancies. A significant portion of blood cancers and lymphomas are of B cell origin, or consist of the cancerous counterparts to normal cells of B cell lineage. B cells are immune cells that are responsible for the production of antibodies in defense of viral and bacterial infections. In healthy individuals, B cells are only a minor fraction of the blood cells. However, in patients with B cell malignancies, B cells start to multiply uncontrollably and increase to numbers that are eventually detrimental to immune functions. Non-Hodgkins lymphoma, or NHL, is the most prevalent of these B cell cancers treated with high dose chemotherapy and/or radiation followed by an autologous bone marrow transplant.

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Currently, two thirds of patients diagnosed with intermediate or high grade NHL are not cured with conventional treatments. Of these patients, approximately one half are cured by autologous bone marrow transplantation following high dose chemotherapy and/or radiation. The remaining one half will likely relapse. A published study has demonstrated a reduced rate of relapse in NHL patients when the patients received autologous bone marrow that was effectively purged of malignant B cells.

Our BCell-SC Cell Separation System has received CE Mark approval, permitting its sale in the European Union. Pursuant to a distribution agreement with Gambro AB, this system is currently being marketed in Europe through Gambro. We are currently conducting a multi-center Phase III trial in the U.S. but do not anticipate commercialization of the product candidate in the U.S. for a number of years.

### TCELL SEPARATION SYSTEMS

**DONOR LEUKOCYTE INFUSION.** Our CD8-DLI Cell Separation System is a TCell Separation System developed to remove the CD8+ T cells from DLIs. By depleting the CD8+ T cells in the DLI, we believe the incidence of graft-versus-host disease in patients receiving DLIs will be reduced. The clinical utility of conventional DLI has been reduced by the incidence of graft-versus-host disease associated with the procedure. However, a published study suggests that when patients receive DLIs that have been depleted of CD8+ T cells, rates of acute graft-versus-host disease were reduced as compared to patients given conventional DLIs, without the CD8+ T cells depleted. In the same study, the anti-tumor efficacy of the DLI was retained in the patients receiving DLIs with the CD8+ T cells depleted.

Investigators who wish to perform such manipulation of DLI currently rely upon developing their own antibodies to deplete CD8+ T cells. We believe that our TCell Separation Systems will provide institutions with instruments and reagents produced by current good manufacturing practice that will ensure treatment consistency across institutions.

Our CD8-DLI Cell Separation System has received CE Mark approval, and, pursuant to our distribution agreement with Gambro, this system is being marketed in Europe through Gambro. We believe that our CD8-DLI Cell Separation System is currently the only product of its type which has

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received CE Mark approval and is commercially available in Europe. Pending FDA concurrence with our trial plan, we plan to begin a Phase III trial in late 2002, but we do not anticipate commercialization of the product candidate in the U.S. for a number of years.

**PERIPHERAL BLOOD STEM CELL TRANSPLANTATION.** We are developing our CD8-SC Cell Separation System to deplete CD8+ T cells from PBSC transplantation procedures in which patients receive PBSCs from a human leukocyte antigen, or HLA, matched donor for the treatment of blood cancers or tumors. HLA proteins are the major cell surface proteins used by the body's immune system for recognition and differentiation of "self" from "non-self." An individual possesses only a small, relatively unique set of HLA proteins. Each individual, other than identical twins, has unique HLA proteins. Following PBSC transplantations, many complications, such as graft-versus-host disease, poor immune function and transplant failure, often occur. The more different the HLA proteins of the donor and the recipient, the more frequent the occurrence of graft-versus-host disease. Reducing the incidence and/or severity of graft-versus-host disease will increase the pool of possible transplant recipients. We expect that by depleting the CD8+ T cells, which are the cells thought to be responsible for causing graft-versus-host disease, from the donor

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PBSC, our CD8-SC Cell Separation System will reduce the incidence and severity of graft-versus-host disease.

We expect to receive CE Mark approval for our CD8-SC Cell Separation System in late 2002. We are conducting pilot clinical studies in the U.S. under an investigator sponsored IDE and expect to file an IDE application, which we will sponsor, to begin Phase I clinical trials by the end of 2002.

### OTHER APPLICATIONS

We are pursuing research and development of additional Eligix HDM Cell Separation System candidates that expand the utility of this technology. We are developing these product candidates to separate additional specific subsets of cells from bone marrow or blood stem cell preparations. Particular indications currently in research and development are:

- the selection and activation of disease-specific immune cells to enhance a patient's immune response to disease;
- the selective activation of immune response against cancers and infectious diseases; and
- the removal of cells that interfere with the ability to achieve immune system tolerance for the prevention of rejection and resultant organ failure in solid organ and tissue transplants.

### ALLOMUNE SYSTEMS

#### OVERVIEW

We are currently developing our AlloMune Systems as multiple-component proprietary therapeutic regimens intended to re-educate a patient's immune system to accept transplanted cells, tissues and organs. This re-education is expected to be accomplished by establishing a state of mixed bone marrow chimerism between the patient and the donor in which the patient's immune system recognizes the donor's cells, tissues and organs as "self." Mixed bone marrow chimerism refers to bone marrow of a transplant recipient in which the cells of both the donor and the patient co-exist. We expect our AlloMune Systems to be less debilitating procedures for donor bone marrow transplantations in the treatment of blood cell cancers and to reduce the need for lifelong immunosuppressive therapy in connection with human organ transplants. We believe our AlloMune Systems are suitable for elderly and relatively infirm patients, as well as patients without tissue-matched donors, and, therefore, will enable a significant expansion of the pool of patients to be considered for transplantation.

The immune system is one of the major biological defense mechanisms protecting an individual against disease and invasion by disease-causing agents, referred to as pathogens. In the context of

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transplantation, the immune system can distinguish self from foreign, non-self, cells by recognizing specific markers on cells called antigens. The immune system is capable of producing a biological response to destroy and eliminate the cells carrying the foreign antigens.

When an individual receives a cell, tissue or organ transplant, the recipient's immune system generally recognizes the transplanted tissue as foreign and initiates an immune response, resulting in rejection of the foreign cell, tissue or organ. This immune response results from the recognition by the immune system of foreign antigens on the surface of the cells of the donor that



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are different from those of the recipient.

The current approach to preventing rejection in transplant patients is to administer a combination of immunosuppressive medications, which suppress the ability of T cells to recognize and respond to antigens. These medications, however, not only inhibit T cells from recognizing antigens of donor cells, tissues or organs, but also block the patient's T cells from recognizing other foreign antigens. As a result, the transplant recipient is vulnerable to viral, bacterial and fungal infections. In addition, long-term use of these immunosuppressive drugs can lead to cardiovascular disease, kidney and liver damage, as well as an increased incidence of some types of cancer such as skin and lip cancer and lymphomas.

To achieve mixed bone marrow chimerism, the doctor first blocks the patient's immune response to the new foreign antigens from the donor by giving the patient injections of an anti-T cell antibody, such as MEDI-507, which depletes the patient's mature T cells. The doctor performs this process prior to the transplantation of the donor bone marrow into the patient. Concurrent with the administration of the anti-T cell antibody, the patient receives doses of radiation or drugs to make space in the patient's bone marrow and allow the transplanted bone marrow to "seed" the newly created space. The doctor then injects bone marrow cells from the donor into the patient.

We believe that the creation of mixed bone marrow chimerism will cause the patient to tolerate the donor antigens and regard them as antigens of the patient. By regarding the donor's antigens as self, the patient's immune system retains its ability to respond to foreign pathogens without rejecting cells, tissues or organs transplanted from the bone marrow donor. In addition, in the case of blood cell cancers, the creation of mixed bone marrow chimerism allows the immune cells from the donor to preferentially attack only the cancer cells rather than all of the patient's own cells.

We also intend to incorporate our Eligix HDM Cell Separation Systems technology into our AlloMune Systems. We plan to use the Eligix HDM Cell Separation Systems technology to deplete T cells from allogeneic transplants. This procedure is expected to eliminate the specific T cells that are primarily responsible for graft-versus-host disease from the donor bone marrow or stem cells.

### ALLOMUNE SYSTEM FOR CANCER

We are developing our AlloMune System for Cancer as a treatment regimen for several types of blood cancers, such as lymphomas, leukemias and myelomas, as well as other malignancies. Our AlloMune System for Cancer is intended to re-program a patient's immune system so that a greater number of patients can benefit from potentially life-saving bone marrow transplantation with a lower risk of debilitating side effects. Our AlloMune System for Cancer will employ a less-intensive therapeutic regimen that does not destroy the patient's own bone marrow, thereby enabling more patients to tolerate the treatment. We believe that our AlloMune System for Cancer will make bone marrow transplants more successful by allowing the transplanted bone marrow to aggressively attack cancer cells but not the patient's own normal tissues.

In 2001, our clinical collaborators at Massachusetts General Hospital, or MGH, presented data at the annual meeting of the American Society for Hematology demonstrating that a prototype of our AlloMune System for Cancer, including a mild course of chemotherapy and antibody mediated T cell

depletion, in some cases by the use of MEDI-507, followed by bone marrow transplantation, was found to positively effect the treatment of large B-cell

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lymphoma, referred to as L-BCL, in patients. Patients with advanced chemotherapy refractory L-BCL normally have a poor prognosis with only a remote possibility of survival following conventional, harsh chemotherapeutic regimens. In this pilot trial, 20 patients with advanced L-BCL were treated. Eight of nineteen evaluable patients achieved a response, with five achieving a complete response and three achieving a partial response, including three of ten that received transplants from donors with HLA that matched that of the recipient and five of ten patients receiving transplants from partial HLA mismatched donors. Of these 20, five patients were alive and progression-free 13 to 52 months after transplant at the time of the presentation.

In further studies by our clinical collaborators at MGH presented at the same conference, 69 patients with a variety of refractory blood disorders had transplants using a similar mild regimen including T cell depletion of the recipient. Forty-six of these patients received a bone marrow transplant from an HLA-matched donor and 23 received a transplant from an HLA-mismatched donor. Thirty five percent of patients who maintained long-term full or partial donor chimerism achieved a complete anti-tumor response or complete remission. Even among 20 patients who subsequently lost chimerism, four patients, all with refractory non-Hodgkins lymphoma developed complete anti-tumor responses. Two of these patients relapsed at six to eight months post-transplant while the other two remain in complete remission more than two years after the transplant.

In early 2000, we initiated a Phase I/II clinical trial of our AlloMune System for Cancer to treat patients with therapy-resistant lymphoma under an investigational new drug application. We have completed enrollment of patients in this study and are in the process of analyzing the data. We expect to perform additional Phase I/II studies by the end of 2002.

### ALLOMUNE SYSTEM FOR TRANSPLANTATION

We are developing our AlloMune System for Transplantation to re-program a patient's immune system to accept a transplanted donor organ without the need for life-long immunosuppressive therapy. We expect our AlloMune System for Transplantation to establish a state of mixed bone marrow chimerism in which the patient and donor T cells will recognize the other's cells, tissues and organs as self.

In 2000, over 30,000 organ transplants were performed in patients suffering from end-stage kidney, liver, heart, pancreas, intestine and lung disease in the United States and Western Europe. We estimate that patients in the United States spend over \$5.0 billion annually on the transplantation of organs and tissues. Care subsequent to the transplant accounts for over half of the costs of organ transplantation. These post-transplant healthcare costs include costs associated with lifelong immunosuppressive therapy and hospitalizations due to complications resulting from the chronic use of immunosuppressive drugs, infections and transplant rejections. We expect that improvements in transplantation technology that reduce the wait for suitable organs and minimize infections and other complications will lower the overall cost, and improve the outcome of treating, end-stage organ disease.

Our clinical collaborators at MGH have initiated an investigator sponsored, institutional hospital review board-approved Phase I/II proof-of-principle evaluation of a prototype AlloMune System for Transplantation in humans. Physicians at MGH have treated two patients with end-stage kidney disease that developed as a result of refractory multiple myeloma, a blood cell cancer. The patients each received a simultaneous bone marrow and kidney transplant. As of February 2002, both patients had good kidney function with remission of the myeloma and without having received immunosuppressive drug therapy for more than three years in the case of the first patient, and more than 14 months in the case of the second patient.

## XENOTRANSPLANTATION

Xenotransplantation is intended to address the problems arising from the limited supply of available human cells, tissues and organs for transplantation by developing technologies to permit the transplantation of cells, tissues and organs from other species, such as swine, into humans.

There is a critical shortage of organs for transplantation worldwide. United Network of Organ Sharing reports that over 79,000 patients in the United States suffering from end-stage organ disease are currently on waiting lists for a lifesaving organ transplant. If an adequate supply of transplant organs were available and the complications of transplantation minimized, we estimate that an additional 100,000 critically ill patients annually could benefit from organ transplantation.

Since 1993, we have collaborated with Novartis to research and develop xenotransplantation products. In September 2000, we entered into a joint venture with Novartis, Immerge BioTherapeutics, to continue research on xenotransplantation products using the technology and intellectual property that we and Novartis had previously developed, both independently and in collaboration with one another. Immerge BioTherapeutics began operations in January 2001. The goal of the joint venture is to demonstrate the feasibility and safety of swine-to-primate transplantation leading to clinical trials by Novartis of xenotransplantation for the treatment of end-stage organ failure in humans. We expect that the joint venture will conduct this research in three general areas:

- First, the joint venture will seek to demonstrate proof of concept for organ survival in primate model systems in collaboration with researchers at MGH. These experiments will employ several technologies and procedures, including:
  - swine that carry human genes that inhibit hyperacute rejection, referred to as transgenic swine;
  - proprietary inbred miniature swine;
  - proprietary technology licensed from the Alberta Research Council, which removes natural antibodies from the recipient's blood prior to the transplant to reduce or eliminate hyperacute rejection;
  - immunosuppressive compounds; and
  - the transplantation of pig thymus tissue to re-program the recipient's immune system to recognize the donor tissue as self.
- Second, the joint venture will continue studies begun by us to examine the safety of swine-to-human xenotransplantation. Others have demonstrated that a type of porcine, or swine, virus, referred to as porcine endogenous retrovirus, has the potential to infect human cells. Studies conducted by us have documented that, on a consistent basis, some miniature swine do not infect human cells in culture with porcine endogenous retrovirus.
- Third, the joint venture will focus on adapting recent successes in porcine nuclear transfer technology in which a genetically modified miniature swine has been cloned with modifications that are believed to enhance the survival rates of swine organs in primates. In February 2002, the joint venture and a collaborative partner announced the birth of the first piglets genetically modified to lack the gene thought to be responsible for causing hyperacute rejection in swine-to-human

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transplantation. This was accomplished by knocking out, or eliminating, one of the two genes from this same strain of miniature swine that produce a key sugar molecule that is responsible for triggering the hyperacute rejection process that historically occurs following xenotransplantation. The hyperacute rejection response happens when human antibodies attach to these sugar molecules on the surface of the transplanted pig organ's cells. Once they attach, the antibodies kill the cells. If both genes that produce the sugar molecule can be successfully

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eliminated, it is believed that the hyperacute rejection process can not begin because there is no sugar for the antibodies to attach to.

### COLLABORATIONS AND AGREEMENTS

As part of our strategy, we have established alliances with pharmaceutical and other life science companies, academic institutions, scientists and government laboratories. Since inception, substantially all of our revenues have been derived from our strategic alliances. Currently, our principal strategic alliances are the following:

#### MEDIMMUNE

In October 1995, we formed a collaborative arrangement with MedImmune for the development and commercialization of products to treat and prevent transplant rejection and autoimmune diseases. The collaboration is based upon the development of products derived from the BTI-322 monoclonal antibody, MEDI-507 and future generations of products derived from these molecules. In connection with the collaboration, we granted MedImmune an exclusive worldwide license to develop and commercialize the BTI-322 monoclonal antibody and MEDI-507 and any products based on the BTI-322 monoclonal antibody or MEDI-507, other than the use of the BTI-322 monoclonal antibody or MEDI-507 in kits or systems for xenotransplantation or allogeneic transplantation. MedImmune paid us a \$2.0 million license fee at the time of formation of the collaboration and agreed to fund and assume responsibility for clinical testing and commercialization of any resulting products. MedImmune also provided \$2.0 million in non-refundable research support through December 31, 1997 and has agreed to make milestone payments which could total an additional \$11.0 million, all of which is repayable from royalties on the BTI-322 monoclonal antibody or MEDI-507. MedImmune has also agreed to pay royalties on any sales of the BTI-322 monoclonal antibody or MEDI-507 and future generations of products, if any. Royalties will largely depend upon the efforts of MedImmune to perform clinical testing, obtain regulatory approvals and market and sell the BTI-322 monoclonal antibody and MEDI-507. MedImmune controls the amount and timing of the resources devoted to these activities. MedImmune is currently developing MEDI-507 under the name Siplizumab.

#### DR. DAVID H. SACHS/MGH

In January 1991, we entered into a ten-year agreement with MGH, which was extended for an additional five-year term in December 2000, under which we fund a portion of the research of Dr. Sachs and other MGH personnel in the area of transplantation of cells, tissues and organs. In exchange for our research funding, MGH has granted us exclusive worldwide royalty-bearing rights to technology and inventions developed in the course of research funded by us, subject to a royalty to be paid to MGH and subject to customary retention rights of the United States government. We also have a right of first refusal in connection with any additional research proposals in the field of tissue and organ transplantation to be submitted by Dr. Sachs and his colleagues, who are funded by us, to other commercial sponsors.

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### NOVARTIS/BIOTRANSPLANT JOINT VENTURE

From 1993 through October 2000, we were party to two collaboration agreements with Novartis to research, develop and commercialize xenotransplantation products. During the collaboration, we received an aggregate of \$33.5 million in research funding and \$16.5 million in license fees and milestone payments from Novartis. In September 2000, we entered into an arrangement with Novartis to combine our respective expertise in the field of xenotransplantation into a newly formed, independently run Swiss company, Immerge BioTherapeutics AG, and terminated our prior collaborations in xenotransplantation.

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Novartis has committed to provide an aggregate of \$30.0 million in research funding over three years to the joint venture, \$20 million of which has been received to date by the joint venture to cover Novartis's funding obligations through 2002. Both we and Novartis have exclusively licensed to the joint venture patent rights and technology in the field of xenotransplantation. The joint venture has granted to Novartis an exclusive, worldwide, royalty-bearing license to develop and commercialize any xenotransplantation products resulting from its research. We will receive royalties from the sale of xenotransplantation products by Novartis, if any.

In December 2000, Immerge BioTherapeutics AG formed a wholly owned Delaware subsidiary, Immerge BioTherapeutics, Inc. The Delaware subsidiary entered into a contract research agreement with us, under which we have committed approximately 20 full-time employees to perform research for the joint venture and we have also agreed to provide administrative services for the joint venture, at a negotiated rate.

Novartis holds 67% of the shares of the joint venture and we hold the remaining 33%. All income, gain, profit or loss of the joint venture will be allocated to us and Novartis pro rata based on our respective equity ownership of the joint venture in effect in the period in which these items accrue. The board of directors of Immerge BioTherapeutics, Inc. consists of four directors: one selected by us, one selected by Novartis and two additional directors, one each designated by us and Novartis, who are experts in the field of xenotransplantation. Immerge BioTherapeutics AG has agreed not to undertake, or permit its subsidiaries to undertake, specified fundamental corporate actions without the consent of both shareholders. The joint venture began operations in January 2001.

### CHARLES RIVER LABORATORIES

According to the terms of a miniature swine transfer and maintenance agreement with Charles River Laboratories, we and Immerge BioTherapeutics will have exclusive rights to use miniature swine that Charles River Laboratories is developing for use in the allogeneic transplantation and xenotransplantation programs, respectively. We and Immerge BioTherapeutics will bear our proportionate costs of maintaining the miniature swine herd. The agreement expires in 2003, but the parties may agree to renew the agreement for an additional period.

### STEM CELL SCIENCES LTD.

We have made equity investments in Stem Cell Sciences Ltd. that currently represent approximately 25% of the outstanding shares of that company. Stem Cell Sciences has used substantially all of the consideration from our equity investment to fund the research and development of nuclear transfer technology and, in particular, the development of technology, products and processes useful for xenotransplantation in humans. According to the terms of a strategic

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alliance with Stem Cell Sciences, Immerge BioTherapeutics will have worldwide, exclusive rights, subject to the payment of a royalty, to technology, products and processes for the derivation and manipulation of porcine embryonic stem cells and nuclear transfer technology developed during the research term and useful in xenotransplantation in humans.

### ALBERTA RESEARCH COUNCIL

The Alberta Research Council has granted us a worldwide royalty-bearing license for specified patents and patent applications covering technology potentially useful for removal of natural antibodies against xenografts. We exclusively sublicense our rights under this agreement to Immerge BioTherapeutics. The license is exclusive except for one patent application directed to the removal of natural antibodies against xenografts, which is co-owned by one of the inventors and was assigned to a competitor. The Alberta Research Council has also granted us a non-exclusive, worldwide, royalty bearing license to use any of its information, data, formulas or processing information that pertain to

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the manufacture, development or use of any products resulting from the licensed patents in the field of xenotransplantation. We sublicense our rights under this agreement to Immerge BioTherapeutics.

The agreement imposes on us an obligation to indemnify Alberta Research Council against claims arising from our, or our sublicensee's, development, manufacture or sale of any products that are developed through the use of the patented technology licensed from Alberta Research Council. In addition, during any time when we or our sublicensees are selling products based upon the licensed technology, we are required to maintain general liability insurance. Finally, the agreement imposes on us an obligation to use reasonable efforts and diligence to research, develop and commercialize products based upon the licensed technology. If we fail to meet these obligations, Alberta Research Council may reduce the exclusive license to a non-exclusive one or terminate the agreement. Moreover, if we materially breach the agreement and fail to remedy our breach within 30 days, Alberta Research Council may terminate the agreement at any time on written notice to us. The license agreement expires when the last patent within the patent rights licensed to us by Alberta Research Council has expired.

### CATHOLIC UNIVERSITY OF LOUVAIN (BELGIUM)

We are funding research by Drs. Herve Bazin and Dominique Latinne at the Experimental Immunology Unit of the Catholic University of Louvain, Belgium, for the development of monoclonal antibodies. We have exclusive, worldwide royalty-bearing commercialization rights to discoveries, including the BTI-322 monoclonal antibody, made in laboratories under our sponsorship, subject to a royalty.

The agreement imposes on us an obligation to indemnify Catholic University of Louvain against claims arising from our, or our sublicensee's, development, manufacture or sale of any products that are developed through the use of the patented technology licensed from Catholic University of Louvain. The agreement also imposes on us an obligation to use reasonable efforts and diligence to research, develop and commercialize products based upon the licensed technology. If we fail to meet these obligations, Catholic University of Louvain may reduce the license to a non-exclusive one. Moreover, if we fail to meet our payment obligations and fail to remedy our breach within 30 days, Catholic University of Louvain may terminate the agreement at any time on written notice to us. The license agreement expires when the last patent within the patent rights licensed to us by Catholic University has expired.

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### MANUFACTURING AND SUPPLY

We currently have a manufacturing facility in Medford, Massachusetts, and manufacturing staff only for clinical and commercial production of the Eligix HDM Cell Separation Systems. We have no manufacturing facilities or staff for clinical or commercial production of any other products or systems under development. We plan to rely initially on third parties to manufacture our other product candidates for research, preclinical testing, clinical trials and commercialization, if any, with a long-term objective to develop internal manufacturing capability where appropriate.

MedImmune is manufacturing supplies of MEDI-507 required for our preclinical studies and clinical trials. We have the option to continue to use MedImmune as a supplier or to use an alternative manufacturer or supplier.

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Novartis has exclusive worldwide rights to manufacture any xenotransplantation products arising from the research program conducted by Immerge BioTherapeutics.

### SALES AND MARKETING

#### MEDI-507

MedImmune has exclusive worldwide marketing rights to the BTI-322 monoclonal antibody, MEDI-507 and future generations of these products, if any, other than the use of the BTI-322 monoclonal antibody and MEDI-507 for kits or systems for xenotransplantation and allogeneic transplantation.

#### ELIGIX HDM CELL SEPARATION SYSTEMS

In August 2001, we entered into an exclusive distribution agreement with Gambro BCT, a wholly owned subsidiary of Gambro AB, for the distribution of our Eligix HDM Cell Separation Systems. Under the agreement, as amended, we granted Gambro the exclusive right to distribute these products worldwide, with the exception of the United States and Japan, and the non-exclusive right to distribute these products in Canada. Gambro also has the option to negotiate the terms of an exclusive arrangement for Canada. If we are unable to negotiate an exclusive arrangement in Canada and subsequently reach an agreement with a third party, then Gambro's non-exclusive rights in Canada will terminate. Gambro has the exclusive option for a limited period of time to negotiate for the exclusive right to distribute products in the United States by making a one-time payment to us. Thereafter, Gambro has the option, without payment of a fee, to negotiate on a non-exclusive basis for United States distribution rights. Gambro also has a right of prior notice and first negotiation with respect to any third-party discussions we may seek to engage in with respect to distribution in Japan. The two companies will also share revenues based upon a specific formula. Under the terms of the agreement, we will be responsible for developing, manufacturing and seeking to obtain CE Mark approval for our Eligix HDM Cell Separation Systems. The first two of these products, the BCell-SC and CD8-DLI Cell Separation Systems, have received CE Mark approval, permitting their sale in the European Union. Gambro will be responsible for continued clinical market development and all other aspects of marketing, sales and distribution. In August and September 2001, we received an upfront licensing fee of \$4.0 million, plus milestone payments of \$2.0 million for obtaining CE Mark approval for our BCell-SC and CD8-DLI Cell Separation Systems. We will receive future milestone payments for other new products, if any, receiving CE Mark approval. We expect to receive CE Mark approval for our CD8-SC Cell Separation System by the end of 2002.

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We hired a vice president of marketing through the Eligix acquisition. This person will oversee our European commercialization initiatives and our market development efforts in other regions of the world. Additional marketing resources have been employed in Europe and in the U.S. to further support the market development of the Eligix HDM Cell Separation Systems platform.

### ALLOMUNE SYSTEMS

We currently hold all marketing rights to our AlloMune Systems, although we may seek a corporate partner to support the further development and commercialization of the AlloMune Systems. Pending regulatory approval in the United States, we intend to market our AlloMune System for Cancer and our AlloMune System for Transplantation to the approximately 250 transplant centers, which we believe will allow significant market coverage with relatively few sales personnel. To implement this marketing strategy, we expect to hire a limited number of sales and marketing personnel, although we may rely upon third parties that have established distribution systems and direct sales forces. In foreign markets, we expect to use local pharmaceutical companies to market our products and systems due to the complexities of foreign regulations and medical practices.

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### XENOTRANSPLANTATION

Novartis has exclusive worldwide rights to market and sell xenotransplantation products, if any, arising from the research program conducted by Immerge BioTherapeutics.

### RESEARCH AND DEVELOPMENT

Our total research and development expenses were approximately \$15.7 million, \$15.0 million and \$10.9 million for 1999, 2000 and 2001, respectively.

### PATENTS AND PROPRIETARY RIGHTS

As of February 15, 2002, we owned or had been licensed 56 issued United States patents and 31 allowed or pending United States patent applications, as well as applications for foreign patents. These patents, which expire at various times between 2005 and 2017, and patent applications are directed to, among other things, MEDI-507, our AlloMune Systems and our xenotransplantation technologies.

Our policy is to aggressively prosecute and enforce our patents and proprietary technology. We intend to continue to file United States and foreign patent applications to protect technology, inventions and improvements that are considered important to the development of our business. We also rely upon trade secrets, know how, continuing technological innovation and licensing opportunities to develop and maintain our competitive position.

A patent recently issued to a major pharmaceutical company directed towards recombinant production of monoclonal antibodies. We may require a license under this patent with respect to MEDI-507. There can be no assurance that such a license will be granted to us or that we can obtain a license on terms favorable to us. If a required license is not available, our ability to generate revenue would be adversely affected.

We have reviewed issued patents that include claims relating to humanized monoclonal antibodies. These patents are held by biotechnology companies and an academic institution. We, together with MedImmune, have obtained a license for MEDI-507 from Protein Design Laboratories Inc. under its humanized antibody



patents.

We are also aware of a granted United States patent directed to the production of transgenic animals by the use of a microinjection technique that is licensed to a competitor. This patent could have an adverse impact on our, or our licensees' and collaborators' ability to produce transgenic animals by microinjection. In addition, we are aware of a United States patent that is directed to embryonic stem cells. This patent may have an adverse impact on our, or our licensees' or collaborators', programs for producing transgenic swine by the use of embryonic stem cells.

Some of our know-how and technology is not patentable. To protect our rights, we require all of our employees, consultants, advisors and collaborators to enter into confidentiality agreements with us.

#### COMPETITION

We face intense competition from a wide range of pharmaceutical, biopharmaceutical and medical device companies, as well as academic and research institutions and government agencies. Our competitors include organizations that are pursuing the same or similar technologies as those that constitute our technology platform and organizations that are pursuing products that are competitive with our potential products. To the extent that these technologies or products address the problems associated with autoimmune disease, cancer or transplantation on which we have focused, they may represent significant competition.

Many of the organizations competing against us have financial and other resources substantially greater than our own. In addition, many of our competitors have significantly greater experience in

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testing pharmaceutical and other therapeutic products, obtaining FDA and other regulatory approvals, and commercializing and selling products for use in health care. Accordingly, our competitors may succeed more rapidly than we will in obtaining FDA approval or achieving market penetration for products. If we commence significant commercial sales of our products, we will also be competing with respect to manufacturing efficiency and marketing capabilities, areas in which we have limited or no experience.

Principal competitive factors for our products and product candidates include:

- efficacy;
- safety;
- reliability;
- price;
- availability of reimbursement; and
- intellectual property position.

We believe that the quality and breadth of our technology platform, the skill of our employees, our intellectual property platform and our capabilities for research and development are competitive strengths. However, many of our competitors have significantly larger technology and intellectual property platforms than we do and greater capabilities in research and development.

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MEDI-507. We are aware of several companies that are pursuing treatments for psoriasis, including Biogen, Inc., Immunex Corporation, Centocor, Inc. and Genentech, Inc.

ELIGIX HDM CELL SEPARATION SYSTEMS. There are two key device competitors to the Eligix HDM Cell Separation Systems platform: Baxter's Isolex 300I and Miltenyi Biotec's CliniMacs. Both of these technologies primarily focus on CD34+ selection to remove unwanted cell populations, either tumor cells or T cells. Several papers have recently been published which conclude that patients have an increased risk of infection and/or relapse when a stem cell product containing only CD34+ cells is given to the patient.

There are various pharmaceutical companies that compete for the treatment of patients suffering from B cell malignancies. IDEC Pharmaceuticals and Genentech Inc. co-market an antibody directed against CD20, a B cell surface antigen, and Corixa Incorporated has a similar product in late-stage clinical development. These products are indicated for use in patients suffering from relapse or refractory, low-grade NHL. Another monoclonal antibody, Campath-1H (alemtuzumab), was recently approved for the treatment of refractory chronic lymphocytic leukemia.

ALLOMUNE SYSTEMS. Various service providers are attempting to commercialize customized stem cell products for allogeneic transplantation, including Xcyte Pharmaceuticals and Chimeric Therapies, Inc. Chimeric has announced plans to develop mixed bone marrow chimerism to induce tolerance for allogeneic bone marrow transplants.

### GOVERNMENT REGULATION

#### OVERVIEW

The development and commercialization of our products will be subject to extensive regulation in the United States by a number of regulatory authorities, including the United States Food and Drug Administration, and by comparable regulatory authorities in foreign countries. These regulatory authorities and other federal, state and local entities will regulate, among other things, the preclinical

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and clinical testing, safety, effectiveness, approval, manufacturing, labeling, packaging, export, storage, recordkeeping, adverse event reporting, and promotion and advertising of our products.

We will require FDA approval of our products, including a review of the manufacturing processes and facilities used to produce our products, before we may market the products in the United States. Based upon initial discussions with the FDA, we believe that the BTI-322 monoclonal antibody and MEDI-507 will be classified as biological products by the FDA. Biological products are subject to dual regulation. Their approval for marketing, among other things, is regulated under the Public Health Service Act through a biologics license application, or BLA. However, biological products are also drugs and must meet drug standards under the Federal Food, Drug and Cosmetic Act, including good manufacturing practices regulations and regulations governing clinical trials. Our Eligix HDM Cell Separation Systems are currently undergoing clinical trials to gather safety and effectiveness data to support FDA approval for marketing in the United States. We believe that our Eligix HDM Cell Separation Systems will require approval of a premarket approval application, or PMA, before we can market them in the United States. Our AlloMune System may be treated as a combination product to the extent it combines devices, drugs, or biologics, E.G., use of our Eligix HDM Cell Separation Systems, a device, in combination with MEDI-507, a biologic. Combination products are regulated on the basis of

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product's primary mode of action, and can require approval and/or review by more than one regulatory center of FDA.

Xenotransplantation products are generally regulated as biologics, however, they also can be part of a combination product, I.E., a xenotransplantation product in combination with a drug or device. The Public Health Service and the FDA have published a number of draft and final guidances on xenotransplantation products. We cannot predict the content of future policy or regulations relating to xenotransplantation products, or the effect any future policy or regulation may have on our, or our licensees' or collaborators' ability to research, develop, manufacture and market xenotransplantation products.

### CLINICAL TRIAL PROCESS

Development of a therapeutic product for human use under applicable laws and regulations is a multi-step process. First, in vitro and/or animal testing must be conducted in a manner consistent with good laboratory practices to establish the potential safety and effectiveness of the experimental product in a given disease. Before human clinical trials may begin for new drugs and biologics, an investigational new drug application containing, among other things, the preclinical data, chemistry, manufacturing and control information, and an investigative plan, must be submitted to the FDA. Clinical trials of medical devices generally require the same sort of submission in the form of an application for an investigational device exemption. In addition, approval and oversight by an Institutional Review Board and adherence to requirements for proper informed consent from study subjects are required, unless a device sponsor is exempted from these requirements. Once a trial begins, changes to the investigational product or study protocol may require prior approval before they can be implemented. There can be no assurance that submission of an investigational new drug application or an investigational device exemption will result in the ability to commence clinical trials. In addition, the FDA may place a clinical trial on hold or terminate it at any phase if, among other reasons, it concludes that clinical subjects are being exposed to an unacceptable health risk.

Clinical trials of pharmaceuticals or biologics typically involve three phases, although those phases can overlap.

- Phase I is conducted to evaluate the safety and pharmacokinetics of the experimental product in humans, and if possible, to gain early indications of effectiveness and begin to evaluate various routes, dosages and schedules of product administration.

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- Phase I/II clinical trials are conducted to evaluate safety and initial efficacy indications in the patient population afflicted with a specific disease or condition for which the product is intended for use.
- Phase II clinical trials are conducted in groups of patients afflicted with a specific disease or condition for which the product is intended for use in order to further test safety, begin evaluating effectiveness, optimize dosage amounts and determine dose schedules and routes of administration.
- Phase III studies are usually randomized, double blind studies testing for product safety and effectiveness in an expanded patient population in order to evaluate the overall risk/benefit relationship of the product and to provide an adequate basis for product labeling. These studies also may compare the safety and effectiveness of the product with currently available products.

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### BIOLOGICS APPROVAL PROCESS

For products that are regulated through a BLA application, following completion of clinical investigations, the preclinical and clinical data that have been accumulated, together with chemistry and manufacturing and controls specifications and information, are submitted to the FDA in a BLA. The FDA may refuse to accept a BLA for filing if certain content criteria are not met and may require additional information, including clinical data, before approval. To approve a BLA, the agency must determine, among other things, that the product is safe, pure, and potent, and that any facility in which it is manufactured, processed, packed or held, meets standards designed to assure the product's continued safety, purity, and potency.

If the FDA approves a BLA, we will need to continue to be compliant with strict FDA requirements concerning good manufacturing practices, enforced by periodic inspections, and adverse event reporting, as well as with any special requirements imposed as a part of the biologics license application approval. With certain exceptions, changes to the labeling of approved biological products require approved supplemental applications. Also, changes in the product or manufacturing that have a substantial potential to adversely affect product safety or effectiveness likewise require supplemental applications. These supplemental applications may require the submission of clinical or comparability data and must be approved before the product may be marketed as modified. The approval process is lengthy, expensive and uncertain.

The Orphan Drug Act of 1983 generally provides incentives to manufacturers to undertake development and marketing of products to treat relatively rare diseases, those where fewer than 200,000 persons in the United States at the time of application for orphan drug designation would be likely to receive the treatment. A product that receives orphan drug designation by the FDA and is the first product to receive FDA marketing approval for its indication is entitled to a seven-year exclusive marketing period in the United States for that indication. We intend to pursue this designation with respect to any of our products intended for patient populations in the United States of less than 200,000. MEDI-507 has received orphan drug designation, both as a stand-alone product, and as a component of our AlloMune Systems. Orphan drug exclusivity can be terminated for a number of reasons, including that the manufacturer cannot provide an adequate supply of the drug.

### MEDICAL DEVICE APPROVAL PROCESS

Medical devices are regulated by FDA according to their classification. FDA classifies a medical device into one of three categories based on the device's risk and what is known about the device. The three categories are as follows:

Class I devices are generally lower risk products for which sufficient information exists establishing that general regulatory controls provide reasonable assurance of safety and effectiveness. Most class I

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devices are exempt from the requirement for premarket notification under section 510(k) of the Federal Food, Drug, and Cosmetic Act. FDA clearance of a premarket notification is necessary prior to marketing a non-exempt class I device in the United States.

Class II devices are devices for which general regulatory controls are insufficient to provide a reasonable assurance of safety and effectiveness and for which there is sufficient information to establish special controls, such as guidance documents or performance standards, to provide a reasonable assurance of safety and effectiveness. A 510(k) clearance is necessary prior to marketing a non-exempt class II device in the United States.

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Class III devices are devices for which there is insufficient information demonstrating that general and special controls will provide a reasonable assurance of safety and effectiveness and which are life-sustaining, life-supporting or implantable devices, or devices posing substantial risk. Unless a device is a preamendments device that is not subject to a regulation requiring a PMA, FDA generally must approve a PMA prior to the marketing of a class III device in the United States.

The PMA process is expensive and uncertain. A PMA must be supported by valid scientific evidence, which typically includes extensive data, including pre-clinical data and clinical data from well-controlled or partially controlled clinical trials, to demonstrate the safety and effectiveness of the device. Product and manufacturing and controls specifications and information must also be provided. As with BLAs, FDA may refuse to accept a PMA for filing and often will require additional clinical trial data or other information before approval. Obtaining approval can take several years and approval may be conditioned on, among other things, the conduct of postmarket clinical studies. Any subsequent change to an approved PMA that affects the safety or effectiveness of the device will require approval of a supplemental PMA. We cannot be sure that approval of a PMA or PMA supplement will be granted on a timely basis, if at all, or that FDA's approval process will not involve costs and delays that will adversely affect our ability to commercialize our products.

Whether or not a product is required to be approved before marketing, we must comply with strict FDA requirements applicable to devices, including quality system requirements pertaining to all aspects of our product design and manufacturing process, such as requirements for packaging, labeling, record keeping, including complaint files, and corrective and preventive action related to product or process deficiencies. The FDA enforces its quality system requirements through periodic inspections of medical device manufacturing facilities. In addition, Medical Device Reports must be submitted to FDA to report device-related deaths or serious injuries, and malfunctions the recurrence of which would likely cause serious injury or death. Medical device reports can result in agency action such as inspection, recalls, and patient/physician notifications, and are often the basis for agency enforcement actions. Because the reports are publicly available, they can also become the basis for private tort suits, including class actions.

### LABELING AND ADVERTISING

The nature of marketing claims that the FDA will permit us to make in the labeling and advertising of our biologics and medical devices will be limited to those specified in an FDA approval, and claims exceeding those that are approved will constitute a violation of the Federal Food, Drug, and Cosmetics Act. Violations of the Federal Food, Drug, and Cosmetics Act, Public Health Service Act, or regulatory requirements at any time during the product development process, approval process, or after approval may result in agency enforcement actions, including voluntary or mandatory recall, license suspension or revocation, premarket approval withdrawal, seizure of products, fines, injunctions and/or civil or criminal penalties. Any agency enforcement action could have a material adverse effect on us.

The advertising of our products will also be subject to regulation by the Federal Trade Commission, under the FTC Act. The FTC Act prohibits unfair methods of competition and unfair or deceptive acts in or affecting commerce. Violations of the FTC Act, such as failure to have

substantiation for product claims, would subject us to a variety of enforcement actions, including compulsory process, cease and desist orders, and injunctions.

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FTC enforcement can result in orders requiring, among other things, limits on advertising, corrective advertising, consumer redress, and restitution. Violations of FTC enforcement orders can result in substantial fines or other penalties.

### EUROPEAN REGULATION

Our BCell-SC and CD8-DLI Eligix Cell Separation Systems received CE Mark approval in 2001. The CE Mark denotes conformity with European standards for safety and allows certified devices to be placed on the market in all European Union countries. As of June 1998, medical devices may not be sold in European Union countries unless they display the CE Mark. We are subject to surveillance audits to ensure we remain in compliance with applicable European standards for quality assurance and manufacturing process control.

We also face several regulatory obstacles in the European Union for our biologic products. Although there are minor orphan drug provisions in some European countries, there is, as yet, no overall process equivalent to that followed in the United States. The results of all preclinical, development/manufacturing and Phase I, II and III clinical study data generated in Europe or the United States may also be submitted to the European Medicines Evaluation Agency, the counterpart of the FDA, for approval as a Marketing Approval Application, or MAA, which is the equivalent of a biologics license application. Approval of the MAA permits product marketing within all countries of the European Union. This MAA procedure can take a year or more to complete. Approval procedures for marketing of products in countries that are not European Union member states vary from country to country and the time required for approval may be longer or shorter than that required for FDA approval. In addition, for products exported from the United States to any foreign country or territory, applicable FDA export requirements must be met.

Federal, state and foreign laws and regulations regarding the manufacture and sale of medical devices and biologics are subject to change. We cannot predict what effect, if any, these changes may have on our business, and we cannot assure you that these changes will not have a material adverse effect.

### EMPLOYEES

As of December 31, 2001, we had 105 full-time employees, 89 of whom were engaged in research, development, manufacturing, clinical, regulatory affairs and quality assurance/quality control activities. Of our full time employees, 20 devote substantially all of their time to research for the joint venture with Novartis under a research agreement with Immerge BioTherapeutics, Inc. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We believe our relationship with our employees is good.

We were incorporated in the State of Delaware in 1990. Our corporate headquarters are located at Building 75, 3rd Avenue, Charlestown Navy Yard, Charlestown, MA 02129 and our telephone number is (617) 241-5200.

### CAUTIONARY STATEMENT CONCERNING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements. For this purpose, any statements contained in this Report that are not statements of historical fact may be deemed to be forward-looking statements. We use words such as "believes," "anticipates," "plans," "expects," "intends," and similar expressions to identify forward-looking statements. There are a number of important factors that could cause our actual results to differ materially from those indicated by such forward-looking statements. These factors include, without limitation, those set forth below and

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elsewhere in this Annual Report on Form 10-K. We caution investors that we may not update any or all of the forward-looking statements we have provided in this Annual Report on Form 10-K.

### FACTORS THAT MAY AFFECT RESULTS

WE HAVE A HISTORY OF OPERATING LOSSES AND OUR FUTURE PROFITABILITY IS UNCERTAIN.

We were incorporated in 1990 and have experienced significant operating losses in each year since that date. As of December 31, 2001, our accumulated deficit was \$111.5 million. Our net loss for the fiscal years ended December 31, 2001, 2000 and 1999 was \$42.6 million, \$11.7 million and \$8.7 million, respectively. We expect to continue to incur significant losses for the foreseeable future. We only began selling our BCell-SC and CD8-DLI Cell Separation Systems in Europe in late 2001. To date, our revenue has been generated principally from license fee and milestone payments from our collaborative partners. We may never achieve significant revenues from product sales, and we may not achieve profitable operations.

WE WILL REQUIRE SUBSTANTIAL ADDITIONAL FINANCING, WHICH MAY BE DIFFICULT TO OBTAIN AND MAY DILUTE YOUR OWNERSHIP INTEREST IN US.

We anticipate that our existing funds will be sufficient to fund our operating and capital requirements as currently planned into the first quarter of 2003. We expect to use rather than generate funds from operations for the foreseeable future. The actual amount of funds we will require will be determined by a number of factors, many of which are beyond our control. In particular, we will require substantial funds to conduct research and development, including preclinical testing and clinical trials of our AlloMune Systems and Eligix HDM Cell Separation Systems and to manufacture products that are approved for commercial sale, such as our BCell-SC and CD8-DLI Cell Separation Systems, which we began selling through a distributor in Europe in late 2001. If we cannot raise more funds, we could be required to reduce our capital expenditures, scale back or abandon our research and product development activities, reduce our workforce and license to others products or technologies we would otherwise seek to commercialize ourselves.

We will seek additional funding through collaborative arrangements, by borrowing money or by selling additional equity securities. Any sales of additional equity securities are likely to result in further dilution to our then existing stockholders. Further, if we issue additional equity securities, the new equity securities may have rights, preferences or privileges senior to those of existing holders of our common stock. We may also borrow money from conventional lenders, possibly at high interest rates and on other terms that are unfavorable to us, which will increase the risk of your holdings. Despite our efforts, additional funding may not be available to us at all or only on terms that are unacceptable to us. We also could be required to seek funds through arrangements with collaborative partners or others that may require us to relinquish rights to our technologies, product candidates or products which we would otherwise pursue on our own.

WE WILL DEPEND ON OUR BCELL-SC AND CD8-DLI CELL SEPARATION SYSTEMS FOR SUBSTANTIALLY ALL OF OUR NEAR-TERM PRODUCT REVENUE, AND IF THESE PRODUCTS DO NOT GAIN WIDESPREAD MARKET ACCEPTANCE, THEN OUR NEAR-TERM PRODUCT REVENUE WILL NOT GROW.

Our future growth depends upon our ability to successfully commercialize and sell our products. We expect to derive most of our near-term product revenues from sales of our BCell-SC and CD8-DLI Cell Separation Systems. We began distributing these products through a distribution agreement with Gambro in late 2001 and, to date, we have sold relatively few devices. Because we currently

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depend on our BCell-SC and CD8-DLI Cell Separation Systems to generate substantially all of our near-term product revenue, if we fail to achieve widespread market acceptance of these products or if Gambro

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BCT fails to effectively market these products, we will not be able to grow our near-term product revenue.

IF WE DO NOT DEVELOP AND MARKET NEW PRODUCTS, OUR ABILITY TO ACHIEVE PROFITABILITY WILL BE HARMED.

Our ability to achieve profitability depends on our ability to develop, obtain regulatory approval for, manufacture, introduce and successfully market new products and product candidates, either directly or with our partners. Our product candidates will require extensive development and testing, as well as regulatory approval, before they can be successfully marketed and sold to the public. The MEDI-507 antibody product under development, the Eligix HDM Cell Separation Systems technology and the prototype AlloMune Systems have been tested in relatively few patients and we may not be able to demonstrate the clinical benefits of these products in a larger patient population. Furthermore, the technology that we have exclusively licensed to our joint venture with Novartis Pharma AG is based upon the transplantation of organs from swine into humans. To our knowledge, transplantation of swine organs has never been tested in humans. As a consequence, we are not sure whether any of our products under development or the products under development by our collaborators will be effective in treating any of the disorders we have targeted. In addition, any products under development may prove to have undesirable or unintended side effects, toxicities or other characteristics that may prevent or limit their commercial use. If our technological approach is not successful or the medical community and/or third-party payors do not accept our products as clinically useful, cost-effective and safe, then neither we nor our collaborators will be able to develop or commercialize these products, which will substantially impair our ability to achieve profitable operations.

IF CLINICAL TRIALS OF OUR PRODUCTS UNDER DEVELOPMENT ARE NOT SUCCESSFUL OR ARE NOT COMPLETED ON A TIMELY BASIS, WE WILL NOT BE ABLE TO DEVELOP AND COMMERCIALIZE THESE PRODUCTS AND, THEREFORE, WE MAY NOT ACHIEVE PROFITABILITY.

To obtain regulatory approvals for the commercial sale of our products under development, we and our collaborative partners will need to complete extensive clinical trials in humans to demonstrate the safety and efficacy of these products. We have had limited experience in conducting clinical trials.

Prior to commencing new clinical trials, we must submit investigational new drug and/or investigational device exemption applications to the Food and Drug Administration. Even if we receive authorization from the FDA to commence clinical trials, we or our collaborative partners may not be able to successfully complete these trials within an acceptable timeframe, if at all. How quickly we and our collaborative partners complete clinical trials is dependent in part upon the rate of enrollment of patients. Patient enrollment is a function of many factors, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the study and the existence of competitive clinical trials. In particular, the patient population for a number of our potential products is small. If we experience delays in patient enrollment, we may incur additional costs and delay our research and development programs.

Furthermore, we, our collaborative partners or the FDA may suspend our clinical trials at any time on various grounds, including a finding that the patients in the trials are being exposed to unacceptable health risks. Finally, our clinical trials, if completed, may not show the potential product to be safe



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or effective, thereby preventing regulatory approval.

WE ARE DEPENDENT ON OUR COLLABORATIVE PARTNERS TO CONDUCT CLINICAL TRIALS ON OUR MEDI-507 AND XENOTRANSPLANTATION PRODUCTS AND, THEREFORE, WE ARE NOT IN CONTROL OF THE TIMING OF THESE CLINICAL TRIALS.

We are dependent upon MedImmune to conduct clinical trials with respect to MEDI-507 and will be dependent upon Novartis to conduct clinical trials for the development of xenotransplantation products, if any, that arise out of our joint venture's research program. We may become dependent

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upon other third parties to conduct future clinical trials of our AlloMune Systems and Eligix HDM Cell Separation Systems. As a result, we will have less control over these clinical trials than if we were conducting the trials directly. Consequently, these trials may not begin or be completed on a schedule that is acceptable to us, which could lead to delays or uncertainties in the regulatory approval process or in the commercial introduction of these products, either of which could substantially harm our business and ability to achieve profitability.

THE APPROVAL PROCESS IS COSTLY AND LENGTHY AND WE MAY NOT OBTAIN AND MAINTAIN THE REGULATORY APPROVALS REQUIRED TO SUCCESSFULLY MARKET AND SELL OUR PRODUCTS.

We must obtain regulatory approval for our ongoing research and development activities and before marketing or selling any of our products. For example, although our BCell-SC and CD8-DLI Cell Separation Systems have received CE Mark approval in Europe, we will need to conduct extensive clinical trials and receive FDA approval before we can market these products in the U.S. We may not receive regulatory approvals to conduct clinical trials of our products or to manufacture or market our products. In addition, regulatory agencies may not grant such approvals on a timely basis or may revoke previously granted approvals or impose fines, suspensions, product recalls and other sanctions if we fail to comply with applicable regulatory requirements. If our products do not receive regulatory approvals, or if we do not otherwise comply with government regulations, our business would be harmed.

The process of obtaining FDA and other required regulatory approvals is expensive and typically takes a number of years, depending on the complexity and novelty of the product. Moreover, for our approved products, the marketing, distribution and manufacture of these products remain subject to extensive regulatory requirements. For example, any regulatory approval for a product may limit the indications or markets in which the product can be used or require additional post-approval studies. Any regulatory body can have a product removed from the market if a previously unknown problem with the product is discovered. Any delay in obtaining or failure to obtain or maintain required clearance or approval of a product by the appropriate regulatory authorities, would materially adversely affect our ability to generate revenues from the affected product. We have limited experience in filing and prosecuting the applications required to gain and maintain regulatory approval.

There is limited regulatory precedent for the approval of products based upon the technologies that we are employing to develop products. MEDI-507, our AlloMune Systems and our Eligix HDM Cell Separation Systems are based on new technologies and/or new therapeutic approaches that have not been extensively tested in humans. Accordingly, the regulatory requirements governing these products under development may be more rigorous than for conventional products. In addition, the FDA has not yet established final or comprehensive guidelines for xenotransplantation. As a result, we may experience a longer regulatory process in connection with any products that we or our collaborators seek to develop based on these new technologies and/or new therapeutic approaches.

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We also are subject to numerous foreign regulatory requirements governing the design and conduct of the clinical trials and the manufacturing and marketing of our future products. The approval procedure varies among countries. The time required to obtain foreign approvals often differs from that required to obtain FDA approvals. Moreover, even if we receive FDA approval, we may not receive necessary approvals by regulatory authorities in other countries.

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All of these regulatory risks also are applicable to development, manufacturing and marketing undertaken by our key collaborators and any other future collaborators who may seek to develop, market and sell products based upon our technologies.

WE ARE DEPENDENT ON COLLABORATIVE RELATIONSHIPS TO DEVELOP, MANUFACTURE AND SELL SOME PRODUCTS, AND IF THESE PARTIES ARE NOT SUCCESSFUL, THEN WE WILL NOT ACHIEVE SIGNIFICANT REVENUES.

We have several strategic relationships for the development, manufacture and distribution of our products and products based upon our technologies. We have a collaborative agreement with MedImmune under which we have provided MedImmune with the exclusive worldwide right to develop and commercialize products derived from the BTI-322 and MEDI-507 antibodies. We have also entered into a multi-year exclusive distribution agreement with Gambro for the distribution of our Eligix HDM Cell Separation Systems, and other cell separation systems we may in the future develop. Gambro has been granted the exclusive right to distribute these products worldwide, with the exception of the United States, Canada and Japan. In addition, our joint venture with Novartis, Immerge BioTherapeutics, has exclusively licensed to Novartis the right to develop and commercialize any products derived from Immerge's research program in xenotransplantation, which refers to the transplantation of cells, tissues and organs from one species to another.

Under each of these collaborative agreements, we have the right to receive royalties or a share of revenue on product sales, if any. Our ability to achieve revenue under these arrangements will be heavily dependent on a number of factors, including the efforts and activities of our collaborative partners. Our arrangements with our collaborative partners allow them significant discretion in determining the efforts and resources that they will apply to the development, commercialization and sale of products based upon our technologies. If any of these collaborative partners do not perform successfully, such failure may delay or prevent regulatory approval, product launch, impair our ability to deliver products on a timely basis, impair our competitive position or otherwise reduce or eliminate any sales revenues that we may receive.

WE HAVE ONLY LIMITED SALES AND MARKETING EXPERIENCE AND MAY DEPEND SIGNIFICANTLY ON THIRD PARTIES WHO MAY NOT SUCCESSFULLY COMMERCIALIZE OUR PRODUCTS.

We have only limited sales, marketing and product distribution experience, and our current sales and marketing operations, which we only recently began to develop, is not sufficient to achieve the market presence and sales we need to expand our business. We plan to rely significantly on sales, marketing and distribution arrangements with third parties, including our collaborative partners. For example, we have granted Gambro exclusive worldwide distribution rights, exclusive of the United States, Canada and Japan, for our Eligix HDM Cell Separation Systems, and other cell separation products which we may in the future develop. Either we or Gambro may terminate the agreement if the other party breaches a material covenant, agreement or obligation under the agreement. If Gambro terminates the distribution agreement, we currently do not have the sales and marketing operations to commence selling these products independently. We have also granted MedImmune exclusive worldwide marketing rights to the

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MEDI-507 product under development, and our joint venture with Novartis, Immerge BioTherapeutics, has granted to Novartis the exclusive worldwide rights to develop and market products based upon our xenotransplantation technologies. We may have to enter into additional marketing arrangements in the future and we may not be able to enter into these additional arrangements on terms which are favorable to us, if at all. In addition, we may have limited or no control over the sales, marketing and distribution activities of these third parties and sales through these third parties could be less profitable to us than direct sales. These third parties could sell competing products and may devote insufficient sales efforts to our products. Our future revenues will be materially dependent upon the success of the efforts of these third parties.

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We may seek to independently market products that are not already subject to marketing agreements with other parties. If we determine to perform sales, marketing and distribution functions ourselves, we could face a number of additional risks, including:

- we may not be able to attract and build a significant and skilled marketing staff or sales force;
- the cost of establishing a marketing staff or sales force may not be justifiable in light of the revenues generated by any particular product; and
- our direct sales and marketing efforts may not be successful.

IF WE EXPERIENCE DELAYS OR INTERRUPTIONS IN MANUFACTURING OF OUR ELIGIX HDM CELL SEPARATION SYSTEMS, WE MAY EXPERIENCE CUSTOMER DISSATISFACTION AND OUR REPUTATION COULD SUFFER.

If we fail to produce enough products at our own manufacturing facility or at a third-party manufacturing facility, we may be unable to deliver products to our customers on a timely basis, which could lead to customer dissatisfaction and could harm our reputation and ability to compete. We currently produce key components of our BCell-SC and CD8-DLI Cell Separation Systems in one manufacturing facility. We would likely experience significant delays or cessation in producing our BCell-SC and CD8-DLI Cell Separation Systems at this facility if a labor strike, natural disaster or other supply disruption were to occur. If we are unable to manufacture our Eligix HDM Cell Separation Systems at our own facility, we may be required to enter into arrangements with one or more contract manufacturing companies. We could encounter delays or difficulties establishing relationships with contract manufacturers or in establishing agreements on terms that are favorable to us. In addition, if we are required to depend on third-party manufacturers, our profit margins may be lower, which will make it more difficult for us to achieve profitability.

WE WILL DEPEND ON THIRD-PARTY MANUFACTURERS TO PRODUCE SOME OF OUR PRODUCTS UNDER DEVELOPMENT, AND IF THESE THIRD PARTIES DO NOT SUCCESSFULLY MANUFACTURE OUR PRODUCTS OUR BUSINESS WILL BE HARMED.

We currently rely upon MedImmune to produce material for preclinical and clinical testing of MEDI-507 and expect to continue to do so in the future. In addition, if we receive the necessary regulatory approvals for other products under development, we also expect to rely upon third parties, including our collaborative partners, to produce materials required for commercial production. We may not be able to enter into commercial-scale manufacturing contracts on a timely or commercially reasonable basis, if at all. To the extent that we enter into manufacturing arrangements with third parties, we will be dependent upon these third parties to perform their obligations in a timely and effective manner. If third-party manufacturers with whom we contract fail to perform their

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obligations, our competitive position and ability to generate revenue may be adversely affected in a number of ways, including:

- we may not be able to initiate or continue clinical trials of products that are under development;
- we may be delayed in submitting applications for regulatory approvals for our products; and
- we may not be able to meet commercial demands for any approved products.

IF WE OR OUR THIRD-PARTY MANUFACTURERS FAIL TO COMPLY WITH REGULATORY REQUIREMENTS, WE COULD EXPERIENCE DISRUPTIONS IN THE MANUFACTURE AND SALE OF OUR PRODUCTS.

Manufacturers, including us, must adhere to the FDA's current good manufacturing practices regulations, which are enforced by the FDA through its facilities inspection program. We and any of our third-party manufacturers may not be able to comply or maintain compliance with good manufacturing practices regulations. If we or our manufacturers fail to comply with these regulations, our receipt of premarket approval and/or our ability to continue manufacturing our products could be

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significantly delayed, or we or the third-party manufacturer could be subject to FDA enforcement action. For a premarket approval device, if we change our manufacturing facility or switch to a third-party manufacturer we will be required to submit a premarket approval application supplement before the change is implemented. If we experience any regulatory-related manufacturing delays or difficulties, our ability to deliver products to our distributors or customers would be impaired, which could reduce our revenues and harm our business.

BECAUSE WE RELY ON A LIMITED NUMBER OF SUPPLIERS, WE MAY EXPERIENCE DIFFICULTY IN MEETING OUR CUSTOMERS' DEMANDS FOR OUR ELIGIX HDM CELL SEPARATION SYSTEMS IN A TIMELY MANNER OR WITHIN BUDGET.

We currently purchase key components of our Eligix HDM Cell Separation Systems from a variety of outside sources. Some of these components may only be available to us through a few sources. We generally do not have long-term agreements with any of our suppliers.

Our reliance on our suppliers exposes us to risks, including:

- the possibility that one or more of our suppliers could terminate their services at any time without penalty;
- the potential inability of our suppliers to obtain required components;
- the potential delays and expenses of seeking alternative sources of supply;
- reduced control over pricing, quality and timely delivery due to the difficulties in switching to alternative suppliers; and
- the possibility that one or more of our suppliers could fail to satisfy any of the FDA's required current good manufacturing practices regulations.

Consequently, in the event that our suppliers delay or interrupt the supply of components for any reason, our ability to produce and supply our products to our distributor could be impaired, which could lead to customer dissatisfaction.

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IF WE ARE NOT ABLE TO OBTAIN PATENT PROTECTION FOR OUR DISCOVERIES OR WE INFRINGE PATENT RIGHTS OF THIRD PARTIES, THEN OUR ABILITY TO MARKET OUR PRODUCTS WILL BE SUBSTANTIALLY HARMED.

Our success depends in significant part on our ability to:

- obtain patents;
- protect trade secrets;
- operate without infringing upon the proprietary rights of others; and
- prevent others from infringing on our proprietary rights.

The validity and permissible scope of claims covered in patents relating to our technology involve important unresolved legal principles. Furthermore, there is substantial uncertainty as to whether human clinical data will be required for issuance of patents for human therapeutics. If human clinical data are required, our ability to obtain patent protection could be delayed or otherwise adversely affected.

Patents may not issue from any patent applications that we own or license. If patents do issue, the claims allowed may not be sufficiently broad to protect our technology. In addition, issued patents that we own or license may be challenged, invalidated or circumvented. Our patents also may not afford us protection against competitors with similar technology. Because patent applications in the United States are maintained in secrecy until patents issue, third parties may have filed or maintained patent

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applications for technology used by us or covered by our pending patent applications without our being aware of these applications.

A patent recently issued to a major pharmaceutical company directed towards recombinant production of monoclonal antibodies. We may require a license under this patent with respect to MEDI-507. There can be no assurance that such a license will be granted to us or that we can obtain a license on terms favorable to us. If a required license is not available, our ability to generate revenue would be adversely affected.

We may not hold proprietary rights to all of the patents related to our proposed products or services. These patents may be owned or controlled by third parties. As a result, we or our collaborative partners may be required to obtain licenses under third-party patents to market our proposed products or services. If licenses are not available on acceptable terms, we or our collaborative partners will not be able to market these products or services.

We also rely on trade secrets and proprietary know-how that we seek to protect, in part, by confidentiality agreements with our employees and consultants. We cannot guarantee these agreements will not be breached, that we would have adequate remedies for any such breach or that our trade secrets will not otherwise become known or independently developed by competitors.

IF WE LOSE IMPORTANT LICENSE RIGHTS, WE MAY BE UNABLE TO SUCCESSFULLY DEVELOP AND COMMERCIALIZE OUR PRODUCTS AND ACHIEVE PROFITABILITY.

We are a party to technology in-licenses with the Catholic University of Louvain, the Alberta Research Council and the Coulter Corporation. We expect to enter into additional licenses in the future. These in-licenses relate to important technologies that may be necessary for the development and

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commercialization of our products. These licenses impose various commercialization, indemnification, royalty, insurance and other obligations on us. Although we currently meet the requirements imposed by the licenses, if we fail to comply with these requirements in the future, the licensors will have the right to terminate these licenses or make the licenses non-exclusive, which could affect our ability to exploit important technologies that are required for successful development of our products.

WE FACE SUBSTANTIAL COMPETITION, WHICH COULD ADVERSELY AFFECT OUR REVENUES AND RESULTS OF OPERATIONS.

The products we develop and market compete with existing and new products being created by pharmaceutical, biopharmaceutical, biotechnology and medical device companies and universities. Many of these entities have significantly greater research and development capabilities, as well as substantial marketing, manufacturing, financial and managerial resources and represent significant competition. With respect to our currently marketed BCell-SC and CD8-DLI Cell Separation Systems, we are competing against large companies that have significantly greater financial resources and established marketing and distribution channels for competing products.

The pharmaceutical industry is intensely price competitive and we expect we will face this and other forms of competition. Development by others may render our products or technologies obsolete or noncompetitive, and we may not be able to keep pace with technological developments to maintain a competitive position in the market. Many of our competitors have developed or are in the process of developing technologies that are, or in the future may be, the basis for products that compete with our own. Some of these products may have an entirely different approach or means of accomplishing the desired therapeutic effect than our products and may be more effective and less costly. In addition, many of these competitors have significantly greater experience than we do in undertaking preclinical testing and human clinical trials and obtaining regulatory approvals of such products. Accordingly, our competitors may succeed in commercializing products more rapidly than we can.

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IF WE ARE UNABLE TO MEET THE OPERATIONAL, LEGAL AND FINANCIAL CHALLENGES THAT WE WILL ENCOUNTER IN OUR INTERNATIONAL OPERATIONS, WE MAY NOT BE ABLE TO GROW OUR BUSINESS.

We currently expect to derive substantially all of our near-term product revenue from the sale through a third-party distributor of our BCell-SC and CD8-DLI Cell Separation Systems in the European Union. We are subject to a number of challenges which specifically relate to our international business activities. Our international operations may not be successful if we are unable to meet and overcome these challenges, which would limit the growth of our business. These challenges include:

- failure of local laws to provide the same degree of protection against infringement of our intellectual property;
- protectionist laws and business practices that favor local competitors, which could slow our growth in international markets; and
- potentially longer sales cycles to sell products, which could slow product orders and, accordingly, our revenue growth from international sales.

OUR BUSINESS EXPOSES US TO THE RISK OF PRODUCT LIABILITY CLAIMS FOR WHICH WE MAY NOT BE ADEQUATELY INSURED.

We face an inherent business risk of exposure to product liability claims in

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the event that the use of our products results in adverse effects during research, clinical development or commercial use. We cannot guarantee we will avoid significant product liability exposure. Our product liability insurance coverage is currently limited to \$10.0 million, which may not be adequate to cover potential liability exposures. Moreover, adequate insurance coverage may not be available at an acceptable cost, if at all. Any product liability claim would distract management's attention, impair market acceptance of our products and our reputation and harm our ability to achieve revenue from sales of the product.

OUR INABILITY TO ATTRACT OR RETAIN KEY PERSONNEL COULD HARM OUR BUSINESS.

Our ability to develop our business depends in part upon our attracting and retaining qualified management and scientific personnel. The number of qualified personnel is limited and competition for such personnel is intense. We may not be able to continue to attract or retain qualified people. The loss of our key personnel or the failure to recruit additional key personnel could significantly impede attainment of our objectives and harm our financial condition and results of operations.

THE UNCERTAINTY OF PHARMACEUTICAL PRICING AND REIMBURSEMENT MAY NEGATIVELY IMPACT OUR RESULTS OF OPERATIONS.

Our ability to successfully commercialize our products may depend in part on the extent to which reimbursement for the cost of such products and related treatment will be available from government health administration authorities, private health coverage insurers and other organizations. The pricing, availability of distribution channels and reimbursement status of newly approved healthcare products is highly uncertain and we cannot assure you that adequate third-party coverage will be available for us to maintain price levels sufficient for realization of an appropriate return on our investment in product development. In certain foreign markets, pricing or profitability of healthcare products is subject to government control. In the U.S., there have been, and we expect that there will continue to be, a number of federal and state proposals to implement similar governmental control. In addition, an increasing emphasis on managed care in the U.S. has and will continue to increase the pressure on pharmaceutical pricing. While we cannot predict whether any such legislative or regulatory proposals will be adopted or the effect such proposals or managed care efforts may have on our business, the announcement of such proposals or efforts could harm our ability to raise capital, and the adoption of

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such proposals or efforts could harm our results of operations. Further, to the extent that such proposals or efforts harm other pharmaceutical companies that are prospective corporate partners, our ability to establish corporate collaborations may be adversely affected. In addition, third-party payors are increasingly challenging the prices charged for medical products and services. We do not know whether our products and product candidates, if approved, will be considered cost effective or that reimbursement to the consumer will be available or will be sufficient to allow us to sell our products on a competitive basis.

OUR STOCK PRICE IS HIGHLY VOLATILE, AND THE MARKET PRICE OF OUR COMMON STOCK MAY DROP BELOW THE PRICE YOU PAID.

The market price of our common stock is highly volatile. For example, during the past three years, our stock price fluctuated from a low sale price of \$1.87 in the quarter ended March 31, 1999 to a high sale price of \$23.00 in the quarter ended March 31, 2000. Prices for our common stock will be determined in the market place and may be influenced by many factors, including fluctuations in our financial results and investors' perceptions of us, as well as their

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perceptions of general economic, industry and market conditions, and the daily trading volumes of our common stock. Market fluctuations may adversely affect the market price of our common stock and may cause a rapid and substantial decline in the value of your investment in our common stock. In particular, factors that may cause such volatility include our ability to complete clinical trials of our product candidates, the results of such trials, our ability to expand sales of our products and our ability to meet the expectations of investors and securities analysts.

In the past, companies that have experienced volatility in the market price of their stock have been subject to class action litigation. If we were to become involved in this type of litigation, even if it was found that the claim had no merit, we could incur substantial costs and diversion of management's attention, which could harm our business, financial condition and operating results.

THE GENERAL BUSINESS CLIMATE IS UNCERTAIN AND WE DO NOT KNOW HOW THIS WILL IMPACT OUR BUSINESS OR OUR STOCK PRICE.

Over the past 18 months, there have been dramatic changes in economic conditions and the general business climate has been negatively impacted. Indices of the U.S. stock markets have fallen significantly and consumer confidence has waned. Accordingly, it is generally accepted that the United States is in a recession. Compounding the general unease about the current business climate are the still unknown economic and political impacts of the September 11, 2001 terrorist attacks and hostilities in Afghanistan and elsewhere. We are unable to predict how any of these factors may affect our business or stock price.

PROVISIONS OF DELAWARE LAW AND OUR CHARTER AND BY-LAWS MAY MAKE A TAKEOVER MORE DIFFICULT.

Provisions in our certificate of incorporation and by-laws and in the Delaware corporate law may make it difficult and expensive for a third party to pursue a tender offer, change in control or takeover attempt which is opposed by our management and board of directors. Public stockholders who might desire to participate in such a transaction may not have an opportunity to do so. These anti-takeover provisions could substantially impede the ability of public stockholders to change our management and board of directors, which may reduce the market price of our common stock.

### ITEM 2. PROPERTIES

We lease a facility which contains approximately 34,000 square feet of laboratory and administrative space in Charlestown, Massachusetts. The lease has a 15-year term ending in 2009 with an option to extend for an additional five years. In addition, we lease approximately 33,000 square feet of manufacturing and development space in Medford, Massachusetts. The lease has a five-year term ending in 2003 with two options to extend for an additional ten years in total. We believe that our current facilities will be sufficient to meet our needs for the foreseeable future.

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### ITEM 3. LEGAL PROCEEDINGS

We are not a party to any material legal proceeding.

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

No matters were submitted to a vote of our security holders, through solicitation of proxies or otherwise, during the quarter ended December 31,



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2001.

### PART II

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

##### MARKET PRICE INFORMATION

BioTransplant common stock has traded on the Nasdaq National Market under the symbol "BTRN" since May 8, 1996.

The table below sets forth, for the periods indicated, the reported high and low sale prices of BioTransplant common stock on the Nasdaq National Market.

	BIOTRANSPLANT COMMON STOCK	
	HIGH	LOW
<b>CALENDAR 2001</b>		
Quarter ended March 31, 2001.....	\$ 9.22	\$2.97
Quarter ended June 30, 2001.....	8.75	3.25
Quarter ended September 30, 2001.....	8.00	4.05
Quarter ended December 31, 2001.....	9.14	4.55
<b>CALENDAR 2000</b>		
Quarter ended March 31, 2000.....	\$23.00	\$6.25
Quarter ended June 30, 2000.....	10.56	4.44
Quarter ended September 30, 2000.....	18.31	8.38
Quarter ended December 31, 2000.....	18.50	6.19

On March 11, 2002, the last reported sale price of BioTransplant common stock on the Nasdaq National Market was \$6.00 per share and we had 246 stockholders of record.

##### DIVIDEND INFORMATION

We have never declared or paid any dividends on our common stock. We do not expect to pay cash dividends in the foreseeable future. In addition, we are party to a loan agreement that prohibits us from paying dividends without the written consent of the lending institution. See "Management's Discussion and Analysis of Financial Condition and Results of Operations" and note 4 to our consolidated financial statements.

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#### ITEM 6. SELECTED FINANCIAL DATA

The annual financial information set forth below has been derived from the audited consolidated financial statements of BioTransplant. The information should be read in connection with, and is qualified in its entirety by reference to, BioTransplant's consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

YEARS ENDED DECEMBER 31,  
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	1997	1998	1999	2000
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	(IN THOUSANDS, EXCEPT PER SHARE DATA)			
CONSOLIDATED STATEMENT OF OPERATIONS DATA:				
Revenues:				
License fees.....	\$ 5,000	\$ 1,000	\$ 3,500	\$ --
Product.....	--	--	--	--
Research and development.....	7,125	5,688	5,189	4,563
	-----	-----	-----	-----
Total revenues.....	12,125	6,688	8,689	4,563
	-----	-----	-----	-----
Operating expenses:				
Cost of revenues.....	--	--	--	--
Research and development.....	13,988	14,730	15,680	14,974
General and administrative.....	2,963	2,477	2,446	2,543
Amortization of intangible assets and goodwill...	--	--	--	--
Stock-based compensation.....	--	--	--	--
In-process research and development.....	--	--	--	--
	-----	-----	-----	-----
Total operating expenses.....	16,951	17,207	18,126	17,517
	-----	-----	-----	-----
Operating loss.....	(4,826)	(10,519)	(9,437)	(12,954)
Interest income.....	1,731	1,318	782	1,335
Interest expense.....	(58)	(10)	(18)	(60)
	-----	-----	-----	-----
Net loss.....	\$ (3,153)	\$ (9,211)	\$ (8,673)	\$ (11,679)
	=====	=====	=====	=====
Basic and diluted net loss per common share.....	\$ (0.37)	\$ (1.07)	\$ (1.01)	\$ (1.01)
	=====	=====	=====	=====
Basic and diluted weighted average common shares				
outstanding.....	8,569	8,579	8,598	11,547
	=====	=====	=====	=====
CONSOLIDATED BALANCE SHEET DATA (AT PERIOD END):				
Cash and cash equivalents.....	\$ 9,784	\$ 13,168	\$ 17,649	\$ 11,481
Short-term investments.....	19,863	6,843	3,718	3,391
Working capital.....	24,111	15,499	14,629	13,315
Long-term investments.....	1,015	--	--	105
Intangible assets and goodwill, net.....	--	--	--	--
Total assets.....	32,939	22,683	23,419	17,158
Long-term debt, net of current portion.....	10	--	467	335
Stockholders' equity.....	26,154	16,958	15,645	14,422

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

OVERVIEW

Since commencement of our operations in 1990, we have been engaged primarily in the discovery, development and commercialization of therapeutics, therapeutic devices and therapeutic regimens designed to suppress undesired immune responses and enhance the body's ability to accept donor cells, tissues and organs. The major sources of our working capital have been the proceeds from sales of

equity securities, sponsored research funding and license fees, capital lease financings and borrowings under term loans. Although we commenced initial sales of our Eligix HDM Cell Separation Systems in Europe during the fourth quarter of 2001 through a distribution partner, we have not generated substantial product revenues from our sales of products to date. We will be required to conduct

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significant additional research, development, testing and regulatory compliance activities that, together with general and administrative expenses, are expected to result in significant and increasing operating losses for at least the next several years.

In addition to conducting research, development and manufacturing on our own, we are a party to a number of collaborations and strategic relationships. Since 1995, we have had a collaborative agreement with MedImmune, Inc. Currently, the main focus of this relationship is the development of Siplizumab, which we refer to as MEDI-507, a humanized monoclonal antibody we exclusively licensed to MedImmune for stand-alone indications. MedImmune is currently conducting multiple Phase II trials of Siplizumab for the treatment of psoriasis. We will be entitled to receive royalties on any sales of Siplizumab and future generation products. In 2001, we entered into a distribution agreement with Gambro BCT for the distribution of our Eligix HDM Cell Separation Systems, two versions of which are now being marketed in Europe. Since 1993, we have been involved in collaborations with Novartis to research, develop and commercialize xenotransplantation products. In 2001, Immerge BioTherapeutics AG, the joint venture we formed with Novartis to research xenotransplantation products, began operations as an independently run company. Novartis will fund the joint venture through 2003.

### MEDIMMUNE

Under our collaborative agreement with MedImmune, MedImmune paid us a \$2.0 million license fee at the time of execution of the agreement, and agreed to fund and assume responsibility for clinical testing and commercialization of the BTI-322 monoclonal antibody and other related products developed by us, including Siplizumab, which is the name given by MedImmune to MEDI-507, the humanized version of BTI-322. MedImmune has provided \$2.0 million of non-refundable research support and has agreed to make milestone payments which could total up to an additional \$11.0 million. All milestone payments which are received are repayable from royalties on the BTI-322 monoclonal antibody and other related products.

### ELIGIX ACQUISITION

On May 15, 2001, we completed our acquisition of Eligix, Inc. Upon consummation of the merger, Eligix became our wholly owned subsidiary. Under the terms of the merger, we issued 4,939,200 shares of common stock in exchange for the outstanding common stock of Eligix and 990,000 shares of common stock to certain former employees of Eligix. The shares issued to Eligix employees are subject to a repurchase option which lapses over a one-year period.

We accounted for the acquisition as a purchase. In accordance with the requirements of accounting principles generally accepted in the United States, we allocated the purchase price for the acquisition to the assets acquired, including intangible assets consisting of in-process research and development, acquired technology and goodwill. The allocations among the intangible assets were based upon an independent third-party valuation of the intangible assets acquired. Synergies, such as the value expected to be derived from the planned use of our Eligix-TM- HDM Cell Separation Systems technology in our AlloMune Systems, are excluded from the valuation pursuant to applicable accounting standards and SEC guidelines. As a result of a preliminary valuation, performed in December 2000, we allocated \$20.0 million to in-process research and development, or IPR&D, and \$25.0 million to acquired technology. The excess of the purchase price over the fair value of identified intangible and tangible assets of \$5.7 million was allocated to goodwill. During 2001, the intangible assets, including acquired technology and goodwill, were amortized over their estimated useful lives of seven years. The fair value

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of the IPR&D was recorded as an expense as of the acquisition date. In connection with our year-end audit, the third-party valuation firm finalized its valuation as of May 15, 2001 based upon revised estimates of expected cash flows from the developed portion of the technology acquired from Eligix and other variables. As a result of the final valuation report, we reallocated \$14.0 million from acquired technology to goodwill. As a result, we continued to allocate \$20.0 million to IPR&D, and allocated \$11.0 million to acquired technology and \$19.7 million to goodwill. Finally, we performed a review of our intangible assets as of December 31, 2001 and determined that no impairment exists. The reallocation had no impact on our statement of operations for the year ended December 31, 2001.

### GAMBRO DISTRIBUTION--ELIGIX HDM CELL SEPARATION SYSTEMS

In August 2001, we entered into an exclusive distribution agreement with Gambro BCT, a wholly owned subsidiary of Gambro AB, for the distribution of our Eligix HDM Cell Separation Systems. Under this agreement, as amended, we have granted Gambro the right to distribute these products worldwide, with the exception of the United States and Japan, and the non-exclusive right to distribute these products in Canada. Gambro also has the option to negotiate the terms of an exclusive arrangement for Canada. If we are unable to negotiate an exclusive arrangement in Canada and subsequently reach an agreement with a third party, then Gambro's non-exclusive rights in Canada will terminate. Gambro has the exclusive option for a limited period of time to negotiate for the exclusive right to distribute products in the United States by making a one-time payment to us. Thereafter, Gambro has the option, without payment of a fee, to negotiate on a non-exclusive basis for United States distribution rights. Gambro also has a right of prior notice and first negotiation with respect to any third-party discussions we may seek to engage in with respect to distribution in Japan.

We and Gambro will share revenues under the Gambro agreement based upon a specific formula. Under the terms of the agreement, we will be responsible for developing, manufacturing and seeking to obtain CE Mark approval for our Eligix HDM Cell Separation Systems. The first two of these products, the BCell-SC and CD8-DLI Cell Separation Systems, have received CE Mark approval, permitting their sale in the European Union. Gambro will be responsible for continued clinical market development and all other aspects of marketing, sales and distribution. In August and September 2001, we received an upfront licensing fee of \$4.0 million, plus milestone payments of \$2.0 million for obtaining CE Mark approval for our BCell-SC and CD8-DLI Cell Separation Systems. We are recognizing these amounts as revenue over the seven-year term of the distribution agreement. We are entitled to receive future milestone payments for other new products, if any, receiving CE Mark approval. We expect to receive CE Mark approval for our CD8-SC Cell Separation System in late 2002.

### NOVARTIS/IMMERGE BIOTHERAPEUTICS

From 1993 through October 2000, we were a party to two collaboration agreements with Novartis to research, develop and commercialize xenotransplantation products. During these collaborations, we received and recognized as revenue an aggregate of \$33.5 million in research funding and \$16.5 million in license fees and milestone payments from Novartis. In September 2000, we entered into an arrangement with Novartis to terminate the prior collaborations and combine our respective expertise in the field of xenotransplantation into a newly formed, independently run Swiss company, Immerge BioTherapeutics AG, which began operations in January 2001.

Novartis has committed to provide an aggregate of \$30.0 million in research funding over three years to the joint venture, \$20.0 million of which has been received to date by Immerge BioTherapeutics, Inc., a Delaware subsidiary of Immerge BioTherapeutics AG, to cover Novartis's funding obligation through 2002.

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Both we and Novartis have exclusively licensed to the joint venture patent rights and technology in the field of xenotransplantation. The joint venture has granted to Novartis an exclusive, worldwide, royalty-bearing license to develop and commercialize any

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xenotransplantation products resulting from the joint venture's research. We will receive royalties from the sale of xenotransplantation products by Novartis, if any.

We entered into a contract research agreement with Immerge BioTherapeutics, Inc. under which we have committed approximately 20 full-time employees to perform research and are providing administrative services at rates specified in the agreement. We are recognizing the expense reimbursement received from Immerge BioTherapeutics, Inc. as an offset to the expenses we incur. For the year ended December 31, 2001, we recorded approximately \$7.8 million in research and development services and support reimbursements and approximately \$1.0 million in general and administrative services and support reimbursements.

Novartis holds 67% of the shares of Immerge BioTherapeutics AG and we hold the remaining 33%. All income, gain, profit or loss of the joint venture will be allocated to us and Novartis pro rata based upon our respective equity ownership of the joint venture in effect in the period in which these items accrue. We will accrue losses up to the amount of our investment balance in Immerge BioTherapeutics AG. Because we have not invested any amount, or committed to invest any amounts, in the joint venture, our investment balance is zero. Accordingly, we have not recognized any losses related to the joint venture during 2001. Initially, the board of directors of Immerge BioTherapeutics, Inc. will consist of four directors: one selected by us, one selected by Novartis and two additional directors, one each designated by us and Novartis, who are experts in the field of xenotransplantation. Immerge BioTherapeutics AG has agreed not to undertake, or permit its subsidiaries to undertake, specified fundamental corporate actions without the consent of both shareholders.

### RESULTS OF OPERATIONS

#### YEARS ENDED DECEMBER 31, 2001 AND 2000

Revenues decreased to \$690,000 in 2001 from \$4.6 million in 2000. This decrease was primarily due to the fact that during 2000 all of our revenues were derived from sponsored research payments under the Novartis agreement. In late 2000, we formed a joint venture with Novartis in xenotransplantation and terminated the prior collaborations as part of this new relationship. Revenues in 2001 represent product sales of \$356,000 and \$334,000 in Gambro milestone payments and up-front license fees, which are being recognized ratably over the remaining life of our distribution agreement. Product sales consist of product sales to Gambro as well as domestic cost recovery sales to research institutions.

Cost of revenues of \$225,000 in 2001 consists of material, labor and overhead costs relating to our BCell-SC and CD8-DLI Cell Separation Systems.

Research and development expenses primarily consist of salaries and related expenses for personnel, sponsored research, consulting, clinical development costs, facilities related costs and depreciation. Research and development expenses decreased to \$10.9 million in 2001 from \$15.0 million in 2000. This decrease was due in part to \$7.8 million of reimbursements from Immerge for approximately 20 full-time research personnel and their related operating expenses, in accordance with the terms of our agreement with Immerge. We recorded these reimbursements as offsets to the appropriate expense accounts.

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The decrease was also due in part to decreased levels of external research support in 2001. This decrease was partially offset by approximately \$2.5 million of expenses related to the consolidation of Eligix operations, which are included in operations beginning May 15, 2001.

General and administrative expenses primarily consist of salaries and related expenses for personnel, facilities related costs, depreciation and professional fees. General and administrative expenses increased to \$4.9 million in 2001 from \$2.5 million in 2000. This increase was primarily due to

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the inclusion of expenses related to the consolidation of Eligix operations. This increase was offset by a \$1.0 million reimbursement from Immerge for support services.

Other, non-cash operating expenses in 2001 related to the acquisition of Eligix, including \$20.0 million of in-process research and development expense, approximately \$2.6 million in amortization of intangible assets and goodwill and approximately \$5.1 million in stock-based compensation. In accordance with Statement of Financial Accounting Standard No. 142, GOODWILL AND OTHER INTANGIBLE ASSETS, effective January 1, 2002, we will no longer amortize goodwill. Rather, we will review annually the carrying amount of goodwill for impairment. By not amortizing goodwill, our quarterly amortization expense will decrease by \$708,000 when compared to our quarterly amortization charge during the later half of 2001. The stock-based compensation charge represents the amortization of the deferred stock-based compensation relating to the Amended and Restated Eligix Management Equity Incentive Plan and the intrinsic value of the unvested options assumed by us in the Eligix acquisition. If we had allocated stock-based compensation to research and development and general and administrative expenses, these expenses would have increased by \$2.3 million and \$2.8 million, respectively, during 2001.

Interest income decreased to \$530,000 in 2001 from \$1.3 million in 2000. This decrease was primarily due to lower cash balances available for investment purposes as well as declining interest rates.

Interest expense increased to \$143,000 in 2001 from \$60,000 in 2000. This increase was primarily due to increased obligations under capital leases as a result of the acquisition of Eligix.

As a result of the above factors, we generated a net loss for the year ended December 31, 2001 of \$42.6 million, or \$2.60 per share, compared to a loss of \$11.7 million, or \$1.01 per share, for the year ended December 31, 2000.

### YEARS ENDED DECEMBER 31, 2000 AND 1999

Revenues decreased to \$4.6 million in 2000 from \$8.7 million in 1999. This decrease was primarily due to the fact that during 2000 we recognized \$4.6 million in sponsored research payments under the Novartis agreement, compared to \$8.7 million in sponsored research payments, milestone payments and license revenue received under the Novartis agreement during 1999.

Research and development expenses decreased to \$15.0 million in 2000 from \$15.7 million in 1999. This decrease was primarily due to decreased levels of external research support.

General and administrative expenses increased to \$2.5 million in 2000 from \$2.4 million in 1999. This increase was primarily due to increases in our general corporate expenditures in 2000 compared to 1999.

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Interest income increased to \$1.3 million in 2000 from \$782,000 in 1999. This increase was due primarily to higher cash balances available for investment purposes as well as rising interest rates.

Interest expense increased to \$60,000 in 2000 from \$18,000 in 1999. This increase was primarily due to increased obligations under a term note with a bank, in connection with the financing of capital equipment.

As a result of the above factors, we generated a net loss in 2000 of \$11.7 million, or \$1.01 per share, compared to a net loss of \$8.7 million, or \$1.01 per share, in 1999.

### QUARTERLY RESULTS OF OPERATIONS

The following table sets forth unaudited selected operating results for each of the eight fiscal quarters in the two years ended December 31, 2001. We believe that the following selected quarterly

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information includes all adjustments, consisting only of normal, recurring adjustments, that we consider necessary to present this information fairly. You should read this financial information in conjunction with the financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. Our results of operations have fluctuated in the past and are likely to continue to fluctuate greatly from quarter to quarter in the future. Therefore, results of operations for any previous periods are not necessarily indicative of results of operations to be recorded in the future.

	QUARTER ENDED					
	MARCH 31, 2000	JUNE 30, 2000	SEPT.30, 2000	DEC. 31, 2000	MARCH 31, 2001	JUNE 30, 2001
	(IN THOUSANDS, EXCEPT PER SHARE AMOUNTS)					
Revenue.....	\$ 1,488	\$ 1,488	\$ 1,476	\$ 106	\$ --	\$ --
Operating expenses.....	4,302	4,251	4,310	4,654	2,467	25,641
Net loss.....	(2,499)	(2,408)	(2,501)	(4,271)	(2,312)	(25,557)
Basic and diluted net loss per common share.....	\$ (0.23)	\$ (0.21)	\$ (0.21)	\$ (0.36)	\$ (0.20)	\$ (1.76)

Revenue during each quarter of 2000 relates to sponsored research payments we received from Novartis. We terminated our sponsored research agreement with Novartis in October 2000, concurrent with the formation of Immerge BioTherapeutics, our joint venture with Novartis. During the third quarter of 2001, we commenced initial sales of our Eligix HDM Cell Separation Systems in Europe. In addition, we began to recognize license and milestone revenue under our agreement with Gambro BCT.

The decrease in operating expenses during the quarter ended March 31, 2001 related primarily to the expense reimbursements we received from Immerge. The increases in expenses during the quarters ended June 30, 2001, September 30, 2001 and December 31, 2001 related principally to our acquisition of Eligix on May 15, 2001. Operating expenses for the quarter ended June 30, 2001 included a \$20.0 million charge for the IPR&D acquired in the Eligix acquisition.

### LIQUIDITY AND CAPITAL RESOURCES

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Since our inception, our operations have been funded principally through the net proceeds of an aggregate of \$99.8 million from sales of equity securities. We have also received \$50.0 million from research and development and collaboration agreements with Novartis, \$4.0 million from an alliance agreement with MedImmune, \$6.0 million in up-front licensing fees and milestone payments from our distribution agreement with Gambro and \$2.9 million in equipment financing. The proceeds of the sales of equity securities, equipment financing and cash generated from the corporate collaborations with Novartis, MedImmune and our distribution agreement with Gambro have been used to fund operating losses of approximately \$111.5 million and the investment of approximately \$9.3 million in equipment and leasehold improvements through December 31, 2001.

During the years ended December 31, 2001, 2000 and 1999, we used cash in operating activities of \$13.1 million, \$16.4 million and \$6.3 million, respectively. The cash used in operations resulted primarily from our operating loss adjusted for non-cash expenses and changes in our working capital.

During 2001, we used \$9.8 million of cash in investing activities, consisting primarily of \$1.1 million of property and equipment additions, a net increase in short-term investments of \$5.2 million and \$3.5 million of cash paid for transaction costs in connection with the acquisition of Eligix. During the years ended December 31, 2000 and 1999, we generated cash from investing activities of \$40,000 and \$2.7 million, respectively. The net proceeds from investing activities consisted of maturities of short-term investments offset by the purchase of property and equipment.

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During the years ended December 31, 2001, 2000 and 1999, we generated cash of \$17.5 million, \$10.2 million and \$8.0 million from financing activities. Our financing activities consisted principally of issuances of our common stock and long-term debt offset by payments on long-term debt.

During 1999, we extended the term of, and increased our borrowings under, our term note with a bank from \$500,000 to \$1.0 million for certain equipment and fixtures borrowing. As of December 31, 2001, there was approximately \$233,000 in borrowings outstanding. We are required to maintain certain financial covenants under the agreement. As of December 31, 2001, we were in compliance with these covenants. In connection with the acquisition of Eligix, we assumed the obligations under two outstanding loans to which Eligix was a party at the time of the acquisition. As of December 31, 2001, the aggregate amount outstanding under these two loans was approximately \$1.3 million.

On June 8, 2001, we issued and sold to a group of investors an aggregate of 3,022,000 shares of our common stock, at a purchase price of \$6.30 per share, for net proceeds of approximately \$17.8 million.

We have entered into sponsored research and consulting agreements with certain hospitals, academic institutions and consultants, requiring periodic payments by us. Our aggregate minimum funding obligations under these agreements, each of which allows us to cancel without penalty, given sufficient notice, total approximately \$5.4 million, which includes approximately \$2.9 million payable in 2002. We lease our facilities under operating leases that expire between 2003 and 2009. The aggregate minimum annual rental payments under these leases is \$9.7 million, of which \$1.8 million is payable in 2002. For additional information relating to our commercial and contractual commitments, please see notes 4, 9 and 11 to our consolidated financial statements included herein.

We had cash, cash equivalents and short-term investments of \$14.7 million as of December 31, 2001 as compared to \$14.9 million as of December 31, 2000.



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We anticipate that our existing cash, cash equivalents and short-term investments will be sufficient to fund our operating and capital requirements as currently planned into the first quarter of 2003. To continue operations beyond the first quarter of 2003, we will need to raise additional funds, and may seek to raise these funds through additional financings, including public or private equity offerings, collaborative arrangements with corporate partners or a combination of any of the foregoing. There can be no assurance that funds will be available on terms acceptable to us, if at all. If adequate funds are not available, we may be required to delay, scale back or eliminate some or all of our product development programs or to license to others the right to commercialize products or technologies that we would otherwise seek to develop and commercialize ourselves, any of which would have a material and adverse effect on us.

Even if we are able to raise the substantial additional funds required to finance our operations, our cash requirements may vary materially from those now planned. Factors that may affect this variability include, without limitation:

- the progress of our research and development programs;
- the scope and results of preclinical and clinical testing;
- changes in existing and potential relationships with corporate collaborators;
- the time and cost in obtaining regulatory approvals;
- the costs involved in obtaining and enforcing patents, proprietary rights and any necessary licenses;
- our ability to establish development and commercialization capacities or relationships; and
- the costs of manufacturing.

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### CRITICAL ACCOUNTING POLICIES

Our significant accounting policies are summarized in note 2 to our consolidated financial statements. However, certain of our accounting policies require the application of significant judgment by our management, and such judgments are reflected in the amounts reported in our financial statements. In applying these policies, our management uses its judgment to determine the appropriate assumptions to be used in the determination of estimates. Those estimates are based on our historical experience, terms of existing contracts, our observance of trends in the industry, information provided by our strategic partners and information available from other outside sources, as appropriate. Actual results may differ significantly from the estimates contained in our financial statements. Our significant accounting policies include:

**IMPAIRMENT OF LONG-LIVED ASSETS.** Our long-lived assets include intangible assets and goodwill. At December 31, 2001, we had \$28.1 million of intangible assets and goodwill, net, which accounted for approximately 56.5% of our total assets. In assessing the recoverability of our intangible assets and goodwill, we must make assumptions in determining the fair value of the asset by estimating future cash flows and considering other factors, including significant changes in the manner or use of the assets, or negative industry or economic trends. If these estimates or their related assumptions change in the future, we may be required to record impairment charges for these assets. We adopted the provisions of Statement of Financial Accounting Standards, or SFAS, No. 142, GOODWILL AND OTHER INTANGIBLE ASSETS, as of January 1, 2002, and will

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be required to test our intangible assets for impairment during the first six months of fiscal 2002, and then on a periodic basis thereafter. We performed a review of the realizability of our intangible assets as of December 31, 2001 and determined that no impairment exists. However, future events could cause us to conclude that impairment indicators exist and that goodwill or other intangible assets are impaired. Any resulting impairment loss could have a material adverse impact on our financial condition and results of operations.

**REVENUE RECOGNITION.** Our revenue recognition policy is significant because our revenue is a key component of our results of operations. In addition, our revenue recognition determines the timing of certain expenses. We follow specific and detailed guidelines in measuring revenue; however, certain judgments affect the application of our revenue policy. Revenue results are difficult to predict, and any shortfall in revenue or delay in recognizing revenue could cause our operating results to vary significantly from quarter to quarter and could result in future operating losses. For a description of our revenue recognition policy, see note 2(f) to our consolidated financial statements.

**INVENTORIES.** Inventories are stated at the lower of cost or market, cost being determined on the first-in, first-out method. Reserves for slow moving and obsolete inventories are provided based on historical experience and product demand. We have only recently begun the commercialization of our products and have limited experience in assessing obsolescence. We evaluate the adequacy of these reserves periodically.

### RECENT ACCOUNTING PRONOUNCEMENTS

In July 2001, the FASB issued SFAS No. 141, BUSINESS COMBINATIONS. SFAS No. 141 requires that all business combinations initiated after June 30, 2001 be accounted for under the purchase method of accounting, thereby eliminating the use of the pooling-of-interests method. Management does not believe the adoption of this statement will have a material impact on our financial statements.

We are required to adopt the provisions of SFAS No. 142, GOODWILL AND OTHER INTANGIBLE ASSETS on January 1, 2002. This statement affects our treatment of goodwill and other intangible assets. The statement requires that goodwill existing at the date of adoption be reviewed for possible impairment and that impairment tests be periodically repeated, with impaired assets written down to fair value. Additionally, existing goodwill and intangible assets must be assessed and classified within the

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statement's criteria. Intangible assets with finite useful lives will continue to be amortized over those periods. Amortization of goodwill and intangible assets with indeterminable lives will cease.

We have until June 30, 2002 to complete the first step of the transitional goodwill impairment test. However, the amounts used in the transitional goodwill impairment test are measured as of the beginning of the year of initial application. If the carrying amount of the net assets of a reporting unit, including goodwill, exceeds the fair value of that reporting unit, the second step of the transitional goodwill impairment test will be completed by us as soon as possible, but no later than December 31, 2002.

An impairment loss recognized as a result of a transitional goodwill impairment test, if any, would be recognized by us as the effect of a change in accounting principle. Although a transitional impairment loss for goodwill may be measured by us in other than the first interim reporting period of fiscal year 2002, we are required to report the loss, if any, in the first interim period of fiscal year 2002, irrespective of the period in which it is measured,

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consistent with paragraph 10 of SFAS No. 3, REPORTING ACCOUNTING CHANGES IN INTERIM FINANCIAL STATEMENTS. Accordingly, if we determine that as a result of adopting SFAS No. 142, we have incurred a transitional impairment loss relating to our goodwill after we have reported our first quarter results for 2002, we will restate our reported fiscal year 2002 interim periods to effect the change in accounting.

In August 2001, the Financial Accounting Standards Board issued SFAS No. 144, ACCOUNTING FOR THE IMPAIRMENT OR DISPOSAL OF LONG-LIVED ASSETS, which supersedes SFAS No. 121, ACCOUNTING FOR THE IMPAIRMENT OF LONG-LIVED ASSETS TO BE DISPOSED OF, and the accounting and reporting provisions of APB No. 30. SFAS No. 144 addresses financial accounting and reporting for the impairment or disposal of long-lived assets and is effective for fiscal years beginning after December 15, 2001, and interim periods within those fiscal years. Management does not believe the adoption will have a material impact on our financial statements.

### ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISKS

We own financial instruments that are sensitive to market risks as part of our investment portfolio. The primary objective of the investment portfolio is to preserve our capital until we are required to fund operations, including our research and development activities. All of these market-risk sensitive instruments are classified as held-to-maturity and are not held for trading purposes. We do not own derivative financial instruments in our investment portfolio. Our investment portfolio includes investment-grade debt instruments. These bonds are subject to interest rate risk, and could decline in value if interest rates fluctuate. Due to the short duration and conservative nature of these instruments, we do not believe that we have a material exposure to interest rate risk. We do not anticipate any near-term changes in the nature of our market risk exposure or management's objectives and strategies with respect to managing such exposures.

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### ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

#### REPORT OF INDEPENDENT PUBLIC ACCOUNTANTS

To BioTransplant Incorporated:

We have audited the accompanying consolidated balance sheets of BioTransplant Incorporated and subsidiaries as of December 31, 2001 and 2000, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2001. 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 in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of BioTransplant Incorporated and subsidiaries as of December 31, 2001 and 2000, and the results of their

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operations and their cash flows for each of the three years in the period ended December 31, 2001, in conformity with accounting principles generally accepted in the United States.

/S/ ARTHUR ANDERSEN LLP

Boston, Massachusetts  
February 22, 2002

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### BIOTRANSPLANT INCORPORATED AND SUBSIDIARIES CONSOLIDATED BALANCE SHEETS

	DECEMBER 31,	
	2001	2000
<b>ASSETS</b>		
<b>Current assets:</b>		
Cash and cash equivalents.....	\$ 6,110,079	\$ 11,481,297
Short-term investments.....	8,546,726	3,391,568
Accounts receivable, trade.....	242,045	--
Accounts receivable from Immerge.....	662,783	--
Inventory.....	646,713	--
Prepaid expenses and other current assets.....	983,588	842,894
	17,191,934	15,715,759
<b>Property and equipment, at cost:</b>		
Equipment under capital leases.....	119,772	119,772
Laboratory equipment.....	4,674,010	3,726,821
Leasehold improvements.....	2,963,119	795,017
Office equipment.....	1,595,251	932,706
	9,352,152	5,574,316
Less--Accumulated depreciation.....	5,011,145	4,237,110
	4,341,007	1,337,206
Investment in Stem Cell Sciences Ltd.....	--	105,000
Other long-term assets.....	128,000	--
Intangible assets and goodwill, net.....	28,078,044	--
	\$ 49,738,985	\$ 17,157,965
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current liabilities:</b>		
Current portion of long-term debt.....	\$ 1,257,256	\$ 233,333
Current obligation under capital leases.....	45,215	37,486
Accounts payable.....	1,270,787	408,115
Accrued expenses.....	2,326,520	1,721,745
Current portion of deferred revenue.....	858,864	--
	5,758,642	2,400,679
Long-term debt, net of current portion.....	261,640	252,778

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Long-term obligation under capital leases, net of current portion.....	32,746	82,285
Deferred revenue, net of current portion.....	4,807,373	--
Commitments (Notes 9 and 11)		
Stockholders' equity:		
Preferred stock, \$.01 par value--		
Authorized--2,000,000 shares		
Issued and outstanding--no shares.....	--	--
Common stock, \$.01 par value--		
Authorized--50,000,000 shares		
Issued and outstanding--21,272,672 and 11,796,120 shares at December 31, 2001 and 2000, respectively.....	212,728	117,962
Additional paid-in capital.....	152,088,879	83,129,855
Deferred compensation.....	(1,951,838)	--
Accumulated deficit.....	(111,471,185)	(68,825,594)
Total stockholders' equity.....	38,878,584	14,422,223
	\$ 49,738,985	\$ 17,157,965
	=====	=====

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

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BIOTRANSPLANT INCORPORATED AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF OPERATIONS

	FOR THE YEARS ENDED DECEMBER 31,		
	2001	2000	1999
	-----	-----	-----
Revenues:			
License fees.....	\$ 333,763	\$ --	\$ 3,500,000
Product.....	356,010	--	--
Research and development.....	--	4,563,475	5,188,475
Total revenues.....	689,773	4,563,475	8,688,475
Operating Expenses:			
Cost of revenues.....	224,648	--	--
Research and development.....	10,947,730	14,973,719	15,680,281
General and administrative.....	4,853,665	2,543,624	2,445,912
Amortization of intangible assets and goodwill (Note 3).....	2,615,319	--	--
Stock-based compensation(1) (Note 3).....	5,081,680	--	--
In-process research and development (Note 3).....	20,000,000	--	--
Total expenses.....	43,723,042	17,517,343	18,126,193
Operating loss.....	(43,033,269)	(12,953,868)	(9,437,718)
Interest income.....	530,478	1,334,486	782,182
Interest expense.....	(142,800)	(59,981)	(17,914)
Net loss.....	\$ (42,645,591)	\$ (11,679,363)	\$ (8,673,450)

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Net loss per common share:			
Basic and diluted.....	\$ (2.60)	\$ (1.01)	\$ (1.01)
Weighted average common shares outstanding:			
Basic and diluted.....	16,413,038	11,547,262	8,598,085

(1) The following summarizes the departmental allocation of the stock-based compensation charge:

Research and development.....	\$ 2,312,567	\$ --	\$ --
General and administrative.....	2,769,113	--	--
Total stock-based compensation.....	\$ 5,081,680	\$ --	\$ --

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

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BIOTRANSPLANT INCORPORATED AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	COMMON STOCK		ADDITIONAL PAID-IN CAPITAL	DEFERRED COMPENSATION	ACCUMULATED DEFICIT
	NUMBER OF SHARES	\$.01 PAR VALUE			
Balance, December 31, 1998....	8,581,463	\$ 85,815	\$ 65,345,228	\$ --	\$ (48,472,
Exercise of stock options...	11,265	113	24,803	--	
Restricted stock sold to directors.....	1,875	19	4,433	--	
Issuance of common stock in private placement, net of issuance costs of \$517,215.....	1,706,287	17,063	7,313,571	--	
Net loss.....	--	--	--	--	(8,673,
Balance, December 31, 1999....	10,300,890	103,010	72,688,036	--	(57,146,
Exercise of stock options...	221,514	2,215	902,307	--	
Exercise of warrants.....	58,716	587	392,512	--	
Net gain on investment in Stem Cell Sciences Ltd....	--	--	160,000	--	
Issuance of common stock in private placement, net of issuance costs of \$720,150.....	1,215,000	12,150	8,987,000	--	
Net loss.....	--	--	--	--	(11,679,
Balance, December 31, 2000....	11,796,120	117,962	83,129,855	--	(68,825,
Exercise of stock options...	362,809	3,628	435,519	--	

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Exercise of warrants.....	162,087	1,621	65,490	--	
Shares issued in connection with acquisition of Eligix, Inc.....	4,939,200	49,392	43,633,622	--	
Issuance of management incentive shares in connection with Eligix acquisition.....	990,000	9,900	6,529,069	(6,538,969)	
Value of unvested options acquired in connection with Eligix acquisition...	--	--	483,348	(483,348)	
Stock-based compensation....	--	--	125,559	--	
Amortization of deferred compensation.....	--	--	--	4,956,121	
Reversal of deferred compensation.....	--	--	(114,358)	114,358	
Issuance of common stock in private placement, net of issuance costs of \$1,211,000.....	3,022,456	30,225	17,800,775	--	
Net loss.....	--	--	--	--	(42,645,591)
	-----	-----	-----	-----	-----
Balance, December 31, 2001....	21,272,672	\$212,728	\$152,088,879	\$ (1,951,838)	\$ (111,471,121)
	=====	=====	=====	=====	=====

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

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BIOTRANSPLANT INCORPORATED AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF CASH FLOWS

	FOR THE YEARS ENDED DECEMBER 31		
	2001	2000	1999
	-----	-----	-----
Cash flows from operating activities:			
Net loss.....	\$ (42,645,591)	\$ (11,679,363)	\$ (8,645,591)
Adjustments to reconcile net loss to net cash used in operating activities--			
Depreciation and amortization.....	774,035	430,970	300,000
Provision for excess inventory.....	438,758	--	--
Amortization of intangible assets.....	2,615,319	--	--
Stock-based compensation.....	5,081,680	--	--
In-process research and development.....	20,000,000	--	--
Decrease in investment in Stem Cell Sciences Ltd.....	105,000	55,000	--
Changes in current assets and liabilities, net of Eligix acquisition--			
Accounts receivable, trade.....	(205,666)	381,505	(4,000,000)
Accounts receivable from Immerge.....	(662,783)	--	--
Inventory.....	(1,085,471)	--	--
Prepaid expenses and other current assets.....	435,263	(654,166)	1,000,000
Accounts payable.....	(1,067,631)	(24,952)	2,000,000
Accrued expenses.....	(2,564,755)	(794,428)	4,000,000
Deferred revenue.....	5,666,237	(4,125,000)	7,000,000
	-----	-----	-----
Net cash used in operating activities.....	(13,115,605)	(16,410,434)	(6,245,591)

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Cash flows from investing activities:			
Purchases of property and equipment.....	(1,137,350)	(299,114)	(4,000,000)
Disposal of property and equipment, net.....	--	12,940	(4,000,000)
Purchases of investments.....	(8,550,158)	(6,508,538)	(4,000,000)
Proceeds from sale of investments.....	3,395,000	6,835,000	7,200,000
Cash paid for transaction costs, net of cash received in acquisition of Eligix, Inc.....	(3,488,715)	--	--
Net cash provided by (used in) investing activities.....	(9,781,223)	40,288	2,700,000
Cash flows from financing activities:			
Payments of obligations under capital leases.....	(41,810)	--	(4,000,000)
Payments on long-term debt.....	(769,838)	(213,889)	(4,000,000)
Proceeds from equipment leases.....	--	119,771	7,200,000
Proceeds from long-term debt.....	--	--	7,200,000
Net proceeds from sale of common stock.....	18,337,258	10,296,772	7,300,000
Net cash provided by financing activities.....	17,525,610	10,202,654	8,000,000
Net increase (decrease) in cash and cash equivalents.....	(5,371,218)	(6,167,492)	4,400,000
Cash and cash equivalents, beginning of period.....	11,481,297	17,648,789	13,100,000
Cash and cash equivalents, end of period.....	\$ 6,110,079	\$ 11,481,297	\$17,600,000
Supplemental disclosure of noncash investing and financing transactions:			
Net gain related to investment in Stem Cell Sciences Ltd.....	\$ --	\$ 160,000	\$ --
In connection with the acquisition of Eligix, Inc. (Note 3), the following noncash transactions occurred:			
Fair value of assets acquired.....	\$ 54,460,000	\$ --	\$ --
Deferred compensation related to acquisition of Eligix unvested options and warrants.....	483,000	--	--
Liabilities assumed.....	(6,902,000)	--	--
Cash paid for acquisition and acquisition costs.....	(3,875,000)	--	--
Value of common stock and common stock options and warrants issued.....	\$ 44,166,000	\$ --	\$ --
Deferred compensation related to Eligix, Inc. Management Incentive Plan.....	\$ 6,538,969	\$ --	\$ --
Supplemental disclosure of cash flow information:			
Interest paid during the period.....	\$ 143,845	\$ 54,922	\$ --

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

BIOTRANSPLANT INCORPORATED AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(1) OPERATIONS

BioTransplant Incorporated ("BioTransplant" or the "Company") was



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incorporated on March 20, 1990 in the state of Delaware. The Company discovers, develops and commercializes therapeutics, therapeutic devices and therapeutic regimens designed to suppress undesired immune responses and enhance the body's ability to accept donor cells, tissues and organs. The Company believes that its patented therapeutic regimens, either alone, in combination or with modified conventional therapies, will address significant unmet medical needs in autoimmune diseases, cancer and transplantation.

During the third quarter of 2001, the Company emerged from the development stage with sales of the Eligix-TM- HDM cell separation systems which received CE mark approval in Europe. However, the Company is still devoting extensive efforts toward product research and development and raising capital. The Company is subject to a number of risks similar to those of other emerging biotechnology companies, including risks related to: its dependence on key individuals and collaborative research partners, competition from substitute products and larger companies, its ability to develop and market commercially usable products and obtain regulatory approval for its products under development, and its ability to obtain the substantial additional financing necessary to adequately fund the development, commercialization and marketing of its products.

The Company incurred net losses of approximately \$42.6 million, \$11.7 million and \$8.7 million for the years ended December 31, 2001, 2000 and 1999, respectively, and had an accumulated deficit of approximately \$111.5 million as of December 31, 2001. The Company has funded these losses principally through equity financings. In June 2001, the Company received approximately \$17.8 million in net proceeds from the sale of common stock. Management believes that these proceeds, along with existing resources, will be adequate to fund operations into the first quarter of 2003.

### (2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The accompanying consolidated financial statements reflect the application of certain accounting policies described below and elsewhere in the notes to consolidated financial statements.

#### (A) PRINCIPLES OF CONSOLIDATION

The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All material intercompany accounts and transactions have been eliminated in consolidation.

#### (B) USE OF ESTIMATES IN THE PREPARATION OF FINANCIAL STATEMENTS

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

#### (C) CASH AND CASH EQUIVALENTS AND INVESTMENTS

Cash and cash equivalents include short-term, highly liquid investments with original maturities of ninety days or less from the date of purchase. Short-term investments consist primarily of corporate notes with maturities of less than one year and original maturities of greater than ninety days. In

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### (2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

accordance with Statement of Financial Accounting Standards (SFAS) No. 115, ACCOUNTING FOR CERTAIN INVESTMENTS IN DEBT AND EQUITY SECURITIES, the Company's investments are classified as held-to-maturity and are stated at amortized cost, which approximates fair market value.

The Company held the following cash equivalents and investments at December 31, 2001 and 2000:

	2001	2000
	-----	-----
Cash and cash equivalents including restricted cash of \$411,000.....	\$ 6,110,079	\$11,481,297
	-----	-----
Short-term investments:		
Corporate Bonds (average maturity of 2 months at December 31, 2000).....	--	1,897,640
Commercial Paper (average maturity of 2 months and 1 month at December 31, 2001 and 2000, respectively).....	8,546,726	1,493,928
	-----	-----
	8,546,726	3,391,568
	-----	-----
Total cash, cash equivalents and short-term investments.....	\$14,656,805	\$14,872,865
	=====	=====

There were no realized gains or losses in the years ended December 31, 2000 and 2001. As a condition to its consent to the Eligix acquisition (see Note 3), a bank has required the Company to secure the outstanding balance on certain loan and security agreements (see Note 4) with cash funds until the date the loan is paid off. The Company transferred \$540,000 into a restricted cash account during April 2001. As of December 31, 2001, \$411,000 of this amount is still restricted.

#### (D) INVENTORY

Inventory is stated at the lower of cost (determined on a first-in, first-out basis) or market, and is made up of raw materials and finished goods of \$273,000 and \$374,000, respectively, at December 31, 2001.

#### (E) DEPRECIATION AND AMORTIZATION

The Company provides for depreciation using the straight-line method by charges to operations in amounts estimated to allocate the cost of these assets over estimated useful lives which range from three to ten years. Amortization of equipment under capital lease and leasehold improvements is computed using the straight-line method over the shorter of the estimated useful life of the asset or the lease term.

#### (F) REVENUE RECOGNITION

Substantially all of the Company's license and research and development revenues have been derived from three collaborative research arrangements (see Note 9). Annual research and development payments are recognized on a straight-line basis over the period of the contract, which approximates when work is performed and costs are incurred. License fee revenue represents

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technology transfer fees received for rights to certain technology of the Company. Prior to the adoption

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### BIOTRANSPLANT INCORPORATED AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

of SEC Staff Accounting Bulletin (SAB) No. 101 (SAB 101), REVENUE RECOGNITION, during 2000, the Company recorded license fees as revenue when all obligations as defined in the individual arrangements are fulfilled by the Company and there is no risk of refund. Research and development expenses in the accompanying consolidated statements of operations include funded and unfunded expenses.

Beginning in the third quarter of 2001, the Company generated product revenues in connection with the development and sale of the Company's Eligix HDM cell separation systems. Product revenues are recognized upon shipment, provided there is persuasive evidence of an arrangement, the fee is fixed or determinable, and collectibility of the related receivable is assured. The Company also received license fees and milestone payments in connection with the Gambro BCT distribution agreement (see Note 9(b)). The Company recognizes these payments as revenue on a straight-line basis over the term of the distribution agreement. During the year ended December 31, 2001, the Company received \$6.0 million in license fees and milestone payments, of which \$334,000 was recognized as revenues in the year ended December 31, 2001 and \$5.7 million is included as deferred revenue at December 31, 2001.

SAB 101 requires companies to recognize upfront non-refundable license fees over the life of the related alliance when such fees are received in conjunction with alliances which have multiple elements, such as the two collaborative research and distribution agreements described in Note 9. The Company was required to adopt this new accounting principle through a cumulative charge to the statement of operations, in accordance with Accounting Principles Board (APB) Opinion No. 20, ACCOUNTING CHANGES, no later than the fourth quarter of 2000, effective January 1, 2000. The adoption of this statement did not have a material impact on the Company's financial statements for the year ended December 31, 2000.

(G) NET LOSS PER COMMON SHARE

The Company applies SFAS No. 128, EARNINGS PER SHARE (SFAS 128). SFAS 128 establishes standards for computing and presenting earnings per share and applies to entities with publicly held common stock or potential common stock. Diluted weighted average shares is the same as basic weighted average shares since the inclusion of shares issuable pursuant to the exercise of stock options and warrants would have been antidilutive.

Calculations of basic and diluted net loss per common share are as follows:

	2001	2000	1999
	-----	-----	-----
Net loss.....	\$ (42,645,591)	\$ (11,679,363)	\$ (8,673,450)
	=====	=====	=====
Weighted average common shares outstanding--			
basic and diluted.....	16,413,038	11,547,262	8,598,085
	=====	=====	=====
Basic and diluted net loss per common			
share.....	\$ (2.60)	\$ (1.01)	\$ (1.01)

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	=====	=====	=====
Antidilutive securities not included--weighted common stock options....	449,088	853,297	296,396
Weighted common stock warrants.....	59,147	282,471	151,998

BIOTRANSPLANT INCORPORATED AND SUBSIDIARIES  
 NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)  
 (H) COMPREHENSIVE INCOME (LOSS)

SFAS No. 130, REPORTING COMPREHENSIVE INCOME, requires disclosure of all components of comprehensive income (loss). Comprehensive income (loss) is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from nonowner sources. The Company does not have any items of comprehensive loss other than its reported net loss.

(I) SEGMENT REPORTING

The Company applies SFAS No. 131, DISCLOSURES ABOUT SEGMENTS OF AN ENTERPRISE AND RELATED INFORMATION (SFAS 131), which establishes standards for the way that public business enterprises report information about operating segments in annual financial statements and requires that enterprises report selected information about operating segments in interim financial reports issued to stockholders. In accordance with SFAS 131, the Company has concluded that it operates in one operating segment.

(J) CONCENTRATION OF CREDIT RISK

Financial instruments that subject the Company to significant concentrations of credit risk consist of cash equivalents, short-term investments, accounts receivable, trade, accounts receivable due from Immerge, accounts payable, long-term debt and obligations under capital leases. The Company maintains its cash equivalents and investments with well capitalized financial institutions.

For the year ended December 31, 2001, one customer accounted for approximately 88% of total revenues. The same customer accounted for 77% of total accounts receivable, trade, as of December 31, 2001. Additionally, another customer accounted for 23% of accounts receivable, trade, as of December 31, 2001.

(K) ACCOUNTING FOR THE IMPAIRMENT OF LONG-LIVED ASSETS

In accordance with SFAS No. 121, ACCOUNTING FOR THE IMPAIRMENT OF LONG-LIVED ASSETS AND FOR LONG-LIVED ASSETS TO BE DISPOSED OF (SFAS 121), the Company assesses the realizability of intangible assets. Under SFAS 121, the Company is required to assess the valuation of its long-lived assets including intangible assets based on the estimated cash flow to be generated by such assets. Based on its most recent analysis, the Company believes that no impairment exists as of December 31, 2001.

(L) FAIR VALUE OF FINANCIAL INSTRUMENTS

Financial instruments consist primarily of cash equivalents, short-term investments, accounts receivable, trade, accounts receivable from Immerge, accounts payable and long-term debt. As of December 31, 2001 and 2000, the

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carrying amount of these instruments approximates their fair value.

### (M) RECLASSIFICATIONS

Certain prior period amounts have been reclassified to be consistent with the current year's period presentation.

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### BIOTRANSPLANT INCORPORATED AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

#### (2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

##### (N) RECENT ACCOUNTING PRONOUNCEMENTS

In July 2001, the Financial Accounting Standards Board (FASB) issued SFAS No. 141, BUSINESS COMBINATIONS (SFAS 141). SFAS 141 requires that all business combinations initiated after June 30, 2001 be accounted for under the purchase method of accounting, thereby eliminating the use of the pooling-of-interests method. Management does not believe the adoption of this statement will have a material impact on the Company's financial statements.

The Company is required to adopt the provisions of SFAS No. 142, GOODWILL AND OTHER INTANGIBLE ASSETS (SFAS 142), on January 1, 2002. This statement affects the Company's treatment of goodwill and other intangible assets. This statement requires that goodwill existing at the date of adoption be reviewed for possible impairment and that impairment tests be periodically repeated, with impaired assets written down to fair value. Additionally, existing goodwill and intangible assets must be assessed and classified within the statement's criteria. Intangible assets with finite useful lives will continue to be amortized over those periods. Amortization of goodwill and intangible assets with indeterminable lives will cease.

The Company has until June 30, 2002 to complete the first step of the transitional goodwill impairment test. However, the amounts used in the transitional goodwill impairment test are measured as of the beginning of the year of initial application. If the carrying amount of the net assets of a reporting unit (including goodwill) exceeds the fair value of that reporting unit, the second step of the transitional goodwill impairment test will be completed by the Company as soon as possible, but no later than December 31, 2002.

An impairment loss recognized as a result of a transitional goodwill impairment test, if any, would be recognized by the Company as the effect of a change in accounting principle. Although a transitional impairment loss for goodwill may be measured by the Company in other than the first interim reporting period of fiscal year 2002, the Company is required to report the loss, if any, in the first interim period of fiscal year 2002, irrespective of the period in which it is measured, consistent with paragraph 10 of SFAS No. 3, REPORTING ACCOUNTING CHANGES IN INTERIM FINANCIAL STATEMENTS. Accordingly, if the Company determines that as a result of adopting SFAS 142, it has incurred a transitional impairment loss relating to its goodwill, the Company will restate its reported fiscal year 2002 interim periods to effect the change in accounting.

In August 2001, the FASB issued SFAS No. 144, ACCOUNTING FOR THE IMPAIRMENT OR DISPOSAL OF LONG-LIVED ASSETS (SFAS 144), which supersedes SFAS No. 121 and the accounting and reporting provisions of APB Opinion No. 30. SFAS No. 144 addresses financial accounting and reporting for the impairment or disposal of long-lived assets and is effective for fiscal years beginning after December 15, 2001, and interim periods within those fiscal years. Management does not believe the adoption will have a material impact on the Company's

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financial statements.

### (3) ELIGIX ACQUISITION

On May 15, 2001, the Company completed its acquisition of Eligix, Inc. Under the terms of the merger agreement, a wholly owned subsidiary of BioTransplant, BT/EL Acquisition Co., merged with and into Eligix, and upon such merger Eligix became a wholly owned subsidiary of the Company. The security holders of Eligix are entitled to receive an aggregate of up to 5,610,000 shares of BioTransplant common stock, either in the merger or upon exercise or conversion of Eligix options, warrants and

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### BIOTRANSPLANT INCORPORATED AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

#### (3) ELIGIX ACQUISITION (CONTINUED)

notes assumed by BioTransplant in the merger. Of these shares, 493,327 shares issued to Eligix shareholders were deposited in an escrow account to satisfy any indemnification claims made by the Company within 15 months after the closing of the merger. Any indemnification escrow shares that have not been used to satisfy indemnification claims made by BioTransplant and that are not subject to any unresolved claims for indemnification by BioTransplant, will be distributed to Eligix stockholders 15 months following the completion of the merger. In addition, 493,327 shares of BioTransplant common stock issued to Eligix stockholders were deposited into an escrow account to secure achievement by Eligix, on or before December 31, 2001, of CE mark approval from the European Union with respect to Eligix' TCell-HDM product. On September 26, 2001, CE mark approval for Eligix' TCell-HDM product, CD8-DLI, was received and the corresponding escrow shares were distributed to Eligix stockholders.

In accordance with APB Opinion No. 16, BUSINESS COMBINATIONS, the purchase price for the acquisition of Eligix has been allocated to the assets and liabilities of Eligix based upon their respective fair values. The aggregate purchase price is based upon the fair market value of Eligix common stock of \$48.0 million, including the value of the vested outstanding options and warrants to purchase the Company's common stock and the transaction costs related to the merger, as well as the value of the 493,327 shares released from escrow related to the Company's CE mark approval in September 2001.

In accordance with the requirements of accounting principles generally accepted in the United States, the Company allocated the purchase price for the acquisition to the assets acquired, including intangible assets consisting of in-process research and development, acquired technology and goodwill. The allocations among the intangible assets were based upon an independent third-party valuation of the intangible assets acquired. Synergies, such as the value expected to be derived from the planned use of the Eligix-TM- HDM Cell Separation Systems technology as part of the Company's AlloMune Systems, were excluded from the valuation pursuant to applicable accounting standards and SEC guidance. As a result of a preliminary valuation, performed in December 2000, the Company allocated \$20.0 million to in-process research and development, or IPR&D, and \$25.0 million to acquired technology. The excess of the purchase price over the fair value of identified intangible and tangible assets of \$5.7 million was allocated to goodwill. During 2001, the intangible assets, including acquired technology and goodwill, were amortized over their estimated useful lives of seven years. The fair value of the IPR&D was recorded as an expense as of the acquisition date. In connection with the Company's year-end audit, the third-party valuation firm finalized its valuation as of May 15, 2001 based upon revised estimates of expected cash flows from the developed portion of the technology acquired from Eligix and other variables. As a result of the final valuation report, the Company reallocated \$14.0 million from acquired

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technology to goodwill. As a result, the Company continued to allocate \$20.0 million to IPR&D, and allocated \$11.0 million to acquired technology and \$19.7 million to goodwill. Finally, the Company performed a review of its intangible assets as of December 31, 2001 and determined that no impairment exists.

The Company adjusted its purchase accounting during the fourth quarter for this presentation as of December 31, 2001, upon determination of the values based on the final appraisal. The final purchase price resulted in a reclassification of \$14.0 million from acquired technology to goodwill in the accompanying consolidated balance sheets. The final allocation did not have an effect on the statement of operations, as all intangibles and goodwill were being amortized over the same period.

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The fair value of the IPR&D relating to current in-process research and development projects was recorded as an expense as of the merger date. Intangible assets and goodwill are being amortized over their estimated useful lives of seven years. Beginning on January 1, 2002, the Company will no longer amortize goodwill and will perform an impairment test in accordance with the provisions of SFAS 142 (see Note 2(m)).

The aggregate purchase price of \$48.0 million, including acquisition costs, was allocated as follows (in thousands):

Current assets.....	\$	998
Property and equipment.....		2,640
Other assets.....		128
In-process research and development.....		20,000
Acquired intangible assets.....		11,000
Goodwill.....		19,694
Liabilities assumed.....		(6,902)
Deferred compensation.....		483
		-----
		\$48,041
		=====

As of December 30, 2001, intangible assets and goodwill, net, relates entirely to the Eligix merger and consist of the following (in thousands):

Acquired intangibles.....	\$11,000
Goodwill.....	19,694
	-----
	30,694
Less accumulated amortization.....	2,615
	-----
	\$28,079
	=====

For the year ended December 31, 2001, the Company recorded \$982,000 and \$1,633,000 in amortization expense related to acquired intangibles and goodwill, respectively. Additionally, for the year ended December 31, 2001, the Company recorded approximately \$153,000 in stock-based compensation related to the vesting of stock options held by employees and consultants of Eligix. During the year ended December 31, 2001, the Company also reversed deferred compensation of

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\$101,000, related to options forfeited by terminated employees.

In connection with the transaction, certain employees of Eligix received an aggregate of 990,000 shares of BioTransplant common stock under the Eligix management equity incentive plan. These shares vest over a 365-day period following the closing of the merger, with 33 1/3% of the shares vesting 90 days after closing of the merger, an additional 33 1/3% of the shares vesting 180 days after the closing of the merger, an additional 23 1/3% of the shares vesting 270 days after the closing of the merger and the remaining 10% of the shares vesting 365 days after the closing of the merger. If, within 365 days after the closing of the merger, BioTransplant terminates a former Eligix employee other than for cause, or an employee terminates his or her employment for good reason, that employee's shares will vest immediately in full upon termination. Otherwise, BioTransplant will have the right to repurchase a terminated employee's unvested shares for \$.01 per share. Of the shares issued under the Eligix management equity incentive plan, 99,000 are being held in escrow for 15 months following the completion of the merger to satisfy any claims of indemnification made by BioTransplant under the merger agreement. An additional 99,000 shares were held in escrow until September 26, 2001 to secure achievement of CE mark approval by the European Union of the Eligix TCell-HDM product. The value of the 990,000 shares, less the 99,000 shares held in escrow to secure achievement of CE mark approval, is being treated as deferred compensation and is being expensed over the 365-day vesting

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period of the shares. The per share price used to determine the value of these shares, excluding the 99,000 shares held in escrow to secure CE mark approval, was \$6.84, the fair market value of BioTransplant common stock on the closing date of the merger. Accordingly, at the merger date, \$6,094,000 was recorded as deferred compensation. Upon release of the CE mark approval shares from escrow, the Company recorded additional deferred compensation of \$445,000, based on the fair market value of the Company's common stock on September 25, 2001 of \$4.50. These management equity incentive plan shares are being expensed over the one-year vesting period of the shares.

During the year ended December 31, 2001, the Company amortized approximately \$4,812,000 of deferred compensation, including approximately \$2,050,000 related to the termination of three Eligix employees, as the vesting of the shares held by the terminated employees was accelerated in full on their termination dates. This entire amount is included as stock-based compensation in the accompanying statement of operations for the year ended December 31, 2001. Additionally, during the year ended December 31, 2001, the Company reversed deferred compensation of \$13,000 related to the shares forfeited by terminated employees.

Unaudited pro forma operating results for the Company, assuming the merger occurred at the beginning of the periods presented are as follows:

	YEAR ENDED DECEMBER 31,	
	2001	2000
Revenues.....	\$ 690,000	\$ 4,563,000
Net loss.....	\$ (24,378,000)	\$36,070,024
Net loss per share.....	\$ (1.25)	\$ (2.18)

For purposes of these pro forma operating results, the IPR&D was assumed to have been written off prior to the pro forma periods, so that operating results



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presented only include recurring costs.

(4) DEBT

In September 1997, the Company entered into a term note with a bank, whereby the Company may borrow up to \$500,000 for certain equipment and fixtures during a specified drawdown period, after which time the outstanding balance will become payable in 36 equal monthly principal installments plus interest. During 1999, the Company extended the drawdown period and increased its availability to \$1.0 million under the same conditions as this term note. Borrowings under the term note bear annual floating interest at the bank's Prime Rate (5.0% at December 31, 2001) during the drawdown period, with an option to convert during the repayment period to an annual fixed rate at the three-month London Interbank Offered Rate ("LIBOR") (1.93% at December 31, 2001) plus 2.25%. Borrowings under the term note are secured by equipment and fixtures purchased using the proceeds of the note. There was \$233,333 in borrowings outstanding under this term note at December 31, 2001. The Company is required to maintain certain financial covenants under the agreement. As of December 31, 2001, the Company was in compliance with these covenants.

In connection with the acquisition of Eligix, Inc. (Note 3), the Company has become a co-borrower on two loan and security agreements. The first loan and security agreement was entered into in September 1997 and allows the Company to borrow up to \$750,000. The minimum funding amount is \$100,000 with a maximum of five loans. Loans under the agreement bear interest at a fixed rate equal to the yield to maturity for the U.S. Treasury note having a term equivalent with the loan's term on the date of funding plus 300 basis points. The loans are collateralized by certain equipment. There were \$221,000 in borrowings outstanding under this term note at December 31, 2001. The second loan and security agreement was entered into in June 1999 and allows the Company to borrow up to \$2,700,000. The minimum funding amount under each loan is \$35,000. Each note will have a fixed term of 42 months. Loans under the agreement bear interest at a fixed rate equal to the prime rate on the date of

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(4) DEBT (CONTINUED)

commencement plus the average interest rate of a similar term U.S. Treasury note for the week preceding the date of commencement. The loans are collateralized by certain equipment. There were \$1,065,000 in borrowings outstanding under this term note at December 31, 2001. The weighted average interest rate on these Eligix loan and security agreements outstanding was 13.22% at December 31, 2001.

Future minimum payments of long-term loans as of December 31, 2001 are as follows:

2002.....	\$1,375,745
2003.....	267,347
	-----
Total minimum payments.....	1,643,092
	-----
Less: amount representing interest.....	124,196
	-----
Loans Payable.....	\$1,518,896
	=====

(5) ACCRUED EXPENSES

Accrued expenses consist of the following at December 31, 2001 and 2000:

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	2001	2000
	-----	-----
Consulting and contract research.....	\$1,088,723	\$ 748,342
Payroll and payroll related.....	132,413	2,076
Professional fees.....	144,489	587,587
Other.....	960,895	383,740
	-----	-----
	\$2,326,520	\$1,721,745
	=====	=====

(6) COMMON STOCK

In June 2001, the Company completed a private placement of 3,022,456 shares of its common stock at \$6.30 per share for net proceeds of approximately \$17.8 million.

In May 2001, the Company completed the acquisition of Eligix, Inc. in a stock-for-stock transaction, accounted for as a purchase (see Note 3).

In February 2000, the Company completed a private placement of 1,215,000 shares of its common stock at \$8.00 per share for net proceeds of approximately \$9.0 million.

In December 1999, the Company completed a private placement of 1,706,287 shares of its common stock at \$4.50 per share for net proceeds of approximately \$7.3 million.

As of December 31, 2001 and 2000, the Company has reserved the following shares of common stock for issuance:

	2001	2000
	-----	-----
1991 Stock Option Plan.....	467,602	552,382
1994 Directors' Equity Plan.....	93,250	52,064
1997 Stock Option Plan.....	3,365,845	1,417,350
Outstanding warrants.....	233,011	463,179
	-----	-----
	4,159,708	2,484,975
	=====	=====

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(7) OPTIONS AND WARRANTS

(A) COMMON STOCK PLANS

In May 1997, the Company's stockholders approved the 1997 Stock Incentive Plan (the "1997 Plan"), which was intended to replace the Company's Amended 1991 Stock Incentive Plan (the "1991 Plan"), under which it may grant incentive stock options, nonqualified stock options and stock appreciation rights. In July 2001, the stockholders approved an amendment to increase the number of shares of common stock reserved for issuance under the 1997 Plan to 3,500,000 from 1,500,000. These options generally vest ratably over a four-to-five-year

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period. As of December 31, 2001, 1,482,487 shares were available for future grant.

In May 1997, the stockholders approved an amendment to the Company's 1994 Directors' Equity Plan (the "Directors' Plan"). The amendment increased from 50,000 to 100,000 the number of shares of common stock reserved for issuance under the Directors' Plan. The Director's Plan was terminated on June 27, 2000. New grants to the board of directors are being made under the 1997 Plan. Currently, the board of directors grants each director, upon his or her initial election to the board of directors, an option to purchase 15,000 shares of BioTransplant common stock at an exercise price equal to the then fair market value. In addition, each director is eligible to receive an option to purchase 6,000 shares of BioTransplant common stock, at an exercise price equal to the then fair market value, upon his or her reelection to the board of directors at each annual meeting of stockholders. As of December 31, 2001, 40,686 shares were available for future grant.

The following table summarizes the employee and director stock option activity under the plans discussed above:

	NUMBER OF OPTIONS	WEIGHTED AVERAGE EXERCISE PRICE
	-----	-----
Outstanding, December 31, 1998.....	1,372,454	\$4.51
Granted.....	329,745	4.46
Exercised.....	(11,265)	2.21
Canceled.....	(69,326)	4.61
	-----	-----
Outstanding, December 31, 1999.....	1,621,608	4.53
Granted.....	321,889	9.91
Exercised.....	(221,514)	4.10
Canceled.....	(44,270)	4.57
	-----	-----
Outstanding, December 31, 2000.....	1,677,713	5.59
Granted.....	1,556,825	4.49
Exercised.....	(362,809)	1.21
Canceled.....	(142,800)	5.02
	-----	-----
Outstanding, December 31, 2001.....	2,728,929	\$5.57
	=====	=====
Exercisable, December 31, 1999.....	747,266	\$4.70
	=====	=====
Exercisable, December 31, 2000.....	862,733	\$4.92
	=====	=====
Exercisable, December 31, 2001.....	1,326,588	\$4.44
	=====	=====

(7) OPTIONS AND WARRANTS (CONTINUED)

The following tables summarize certain information about options outstanding at December 31, 2001:

RANGE OF	OPTIONS	WEIGHTED AVERAGE REMAINING CONTRACTUAL	WEIGHTED AVERAGE
----------	---------	--	------------------

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EXERCISE PRICES	OUTSTANDING	LIFE IN YEARS	EXERCISE PRICE
\$ 0.04 - \$ 1.60	339,905	7.59	\$ 1.05
1.63 - 3.00	365,399	5.43	2.37
3.13 - 4.50	277,354	5.68	3.73
4.72 - 6.30	299,945	7.43	5.66
6.38 - 6.75	405,964	5.86	6.62
6.84 - 7.38	131,767	8.11	7.01
7.44 - 7.50	634,750	9.96	7.50
7.56 - 17.00	265,845	8.59	10.33
17.81 - 17.81	7,300	8.15	17.81
18.63 - 18.63	700	8.18	18.63
	-----		
0.04 - 18.63	2,728,929	7.51	5.57
	=====		

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The following tables summarize certain information about options exercisable at December 31, 2001:

RANGE OF EXERCISE PRICES	OPTIONS EXERCISABLE	WEIGHTED AVERAGE EXERCISE PRICE
\$ 0.04 - \$ 1.60	248,345	\$ 0.88
1.63 - 3.00	265,678	2.45
3.13 - 4.50	195,299	3.72
4.72 - 6.30	150,547	5.86
6.38 - 6.75	347,690	6.61
6.84 - 7.38	46,850	7.07
7.44 - 7.50	175	7.44
7.56 - 17.00	70,004	10.57
17.81 - 17.81	1,825	17.81
18.63 - 18.63	175	18.63
	-----	
0.04 - 18.63	1,326,588	4.44
	=====	

SFAS No. 123, ACCOUNTING FOR STOCK-BASED COMPENSATION (SFAS 123), requires the measurement of the fair value of stock options or warrants granted to employees be included in the statement of operations or disclosed in the notes to financial statements. The Company accounts for stock-based compensation for employees under APB Opinion No. 25 and follows the pro forma disclosure-only alternative under SFAS 123. The Company has computed the pro forma disclosures required under SFAS 123 for options granted using the Black-Scholes option pricing model prescribed by SFAS 123. The assumptions used for the years ended December 31, 2001, 2000 and 1999 are as follows: risk-free interest rates of 4.63%, 4.93% and 6.72%; expected common stock volatility factors of 93%, 92% and 87%; and a weighted average expected life of the stock options of seven years. The Company does not currently pay any dividends, and it does not expect to pay cash dividends in the foreseeable future; therefore, dividend yields for 2001, 2000 and 1999 are assumed to be 0%. The weighted average fair value of options granted in 2001, 2000 and 1999 was \$6.05, \$8.14 and \$3.57, respectively.

The Black-Scholes option pricing model was developed for use in estimating the fair value of traded options that have no vesting restrictions and are fully

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transferable. In addition, option pricing models require the input of highly subjective assumptions, including expected stock price volatility. Because the Company's employee stock options have characteristics significantly different from those of traded options, and because changes in the subjective input assumptions can materially affect the fair value estimate, in management's opinion, the existing models do not necessarily provide a reliable single measure of the fair value of its employee stock options.

The total fair value of the options granted during the years ended December 31, 2001, 2000 and 1999 was computed as approximately \$9,419,000, \$2,619,000 and \$1,177,000, respectively. These amounts are assumed to be amortized over the related vesting periods. The resulting pro forma compensation expense may not be representative of the amount to be expected in future years, as pro forma compensation expense may vary, based upon the number of options granted and the assumptions used in valuing these options.

The pro forma net loss and pro forma net loss per common share presented below have been computed assuming no tax benefit. The effect of a tax benefit has not been considered since a substantial portion of the stock options granted are incentive stock options and the Company does not

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anticipate a future deduction associated with the exercise of these stock options. The pro forma effect of SFAS 123 for the years ended December 31, 2001, 2000 and 1999 is as follows:

	2001 -----	2000 -----	1999 -----
Net loss			
As reported.....	\$ (42,645,591)	\$ (11,679,363)	\$ (8,673,450)
	=====	=====	=====
Pro forma.....	\$ (47,309,848)	\$ (13,032,181)	\$ (9,769,704)
	=====	=====	=====
Basic and diluted net loss per common share			
As reported.....	\$ (2.60)	\$ (1.01)	\$ (1.01)
	=====	=====	=====
Pro forma.....	\$ (2.88)	\$ (1.13)	\$ (1.14)
	=====	=====	=====

### (B) WARRANTS

In connection with certain financing and facility leasing transactions that occurred from 1991 through 1995, the Company issued warrants to purchase 373,569 shares of common stock at prices ranging from \$0.04 to \$49.80. In December 1999, the Company issued warrants to purchase 71,391 shares of common stock at a price of \$5.63 per share in connection with a private placement of the Company's common stock. In February 2000, the Company issued warrants to purchase 97,200 shares of common stock at a price of \$10.00 per share in connection with a private placement of the Company's common stock. In connection with the Eligix transaction (see Note 3), the Company issued warrants to purchase 11,594 shares of the Company's common stock at prices ranging from \$1.60 to \$16.00 per share. These warrants were valued in connection with the transaction. As of December 31, 2001, warrants to purchase 99,940 shares of common stock had expired or been cancelled. During 2000 and 2001, warrants to purchase 58,716 and 162,087 shares, respectively of common stock were exercised for net proceeds of approximately \$393,000 and \$67,000, respectively. As of December 31, 2001, all outstanding warrants were fully vested.

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The following table summarizes certain information about warrants outstanding at December 31, 2001:

RANGE OF EXERCISE PRICES	WARRANTS OUTSTANDING	WEIGHTED AVERAGE REMAINING CONTRACTUAL LIFE IN YEARS	WEIGHTED AVERAGE EXERCISE PRICE
\$0.04 - \$10.00	233,011	2.82	\$5.80

(8) IMMERGE BIOTHERAPEUTICS, INC.

In April 1993, as amended and restated in September 1995, the Company entered into a five-year collaboration agreement with Novartis to develop and commercialize xenotransplantation technology utilizing gene transduction. Pursuant to this agreement, all committed research funding of \$20.0 million and all committed license fees of \$10.0 million had been received as of December 31, 1997. In October 1997, the Company and Novartis expanded their relationship in xenotransplantation by entering into a collaboration and license agreement for the development and commercialization of xenotransplantation products utilizing the Company's proprietary mixed bone marrow chimerism technology. Under this agreement, Novartis committed up to \$36.0 million in research funding, license fees and milestone payments, assuming the agreement continued to its full term. As of December 31, 2000, \$13.5 million of research funding, \$4.0 million of license fees and \$2.5 million of milestone payments had been received. All agreements between the Company and Novartis were terminated in the fourth quarter of 2000.

(8) IMMERGE BIOTHERAPEUTICS, INC. (CONTINUED)

In addition to these agreements, Novartis purchased \$5.0 million of the Company's Series B convertible preferred stock in 1992, which converted into 532,125 shares of common stock upon the Company's initial public offering in 1996. The Company believes all transactions with Novartis were at arm's length.

In September 2000, the Company and Novartis entered into an agreement to combine their respective expertise in the field of xenotransplantation into a newly formed, independently run company named Immerge BioTherapeutics AG ("Immerge"). Immerge began operations in January 2001. In return for contributing its technology and an aggregate of \$30 million in funding over three years beginning January 1, 2001, Novartis obtained a 67% ownership share of Immerge and the exclusive, worldwide, royalty-bearing rights to the development and commercialization of any xenotransplantation products resulting from Immerge's research. In return for contributing its technology, the Company obtained a 33% share of Immerge and will receive royalty payments from Novartis sales of xenotransplantation products, if any.

In December 2000, Immerge formed a wholly owned Delaware operating subsidiary, Immerge BioTherapeutics, Inc. Effective January 1, 2001, the Company entered into a contract research agreement with the Delaware subsidiary under which the Company has committed approximately 20 full-time employees to perform specified research activities exclusively for Immerge and has agreed to provide administrative services and support at agreed upon rates. Amounts due to the Company under this agreement are being recorded as offsets to the relevant Company expenses incurred. For the year ended December 31, 2001, the Company has

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recorded offsets of its expenses of approximately \$7.8 million for research and development services and support and approximately \$1.0 million for general and administrative services and support provided under the agreement. Of these amounts, approximately \$663,000 is included as accounts receivable from Immerge at December 31, 2001.

The Company will accrue losses up to the amount of its investment balance in Immerge. Because, to date, they have not invested any amounts, or committed means to investing any amounts in the joint venture, the Company's investment balance is zero. Accordingly, the Company has not recognized any losses related to the joint venture during the year ended December 31, 2001.

### (9) COLLABORATIVE RESEARCH AND DISTRIBUTION AGREEMENTS

#### (A) MEDIMMUNE, INC.

In October 1995, the Company and MedImmune, Inc. ("MedImmune") formed a collaborative agreement for the development and commercialization of products to treat and prevent organ transplant rejection. The collaboration is based upon the development of products derived from BTI-322, MEDI-500 and future generations of products derived from these two molecules (including MEDI-507, the humanized version of BTI-322). Pursuant to the collaboration, the Company granted MedImmune an exclusive worldwide license to develop and commercialize BTI-322 and any products based on BTI-322, other than the use of BTI-322 in kits or systems for xenotransplantation or allogeneic transplantation. MedImmune paid the Company a \$2.0 million license fee at the time of formation of the collaboration, and agreed to fund and assume responsibility for clinical testing and commercialization of any resulting products. This payment is nonrefundable. Additionally, MedImmune had provided \$2.0 million in non-refundable research support in the year ended December 31, 1997. MedImmune has also agreed to make milestone payments that could total up to an additional \$11.0 million, all of which is repayable from royalties on BTI-322/MEDI-507 or MEDI-500, as well as pay royalties on any sales of BTI-322/MEDI-507, MEDI-500 and future generations of products, if any. The Company has not received any milestone payments to date. The Company will defer recognition of revenue upon receipt of a milestone payment and recognize the related royalty revenue as it is earned.

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### (9) COLLABORATIVE RESEARCH AND DISTRIBUTION AGREEMENTS (CONTINUED)

#### (B) GAMBRO BCT

In August 2001, BioTransplant entered into an exclusive distribution agreement with Gambro BCT, a wholly owned subsidiary of Gambro AB, for the distribution of its Eligix HDM Cell Separation Systems. BioTransplant granted Gambro the exclusive right to distribute these products worldwide, with the exception of the United States and Japan, and the non-exclusive right to distribute these products in Canada. Gambro also has the option to negotiate the terms of an exclusive arrangement for Canada. If BioTransplant is unable to negotiate an exclusive arrangement in Canada and subsequently reaches an agreement with a third party, then Gambro's non-exclusive rights in Canada will terminate. Gambro has the exclusive option for a limited period of time to negotiate for the exclusive right to distribute products in the United States by making a one-time payment to the Company. Thereafter, Gambro has the option, without payment of a fee, to negotiate on a non-exclusive basis for United States distribution rights. Gambro also has a right of prior notice and first negotiation with respect to any third-party discussions BioTransplant may seek to engage in with respect to distribution in Japan.

Under the terms of the agreement, BioTransplant is responsible for developing, manufacturing and seeking to obtain CE mark approval for the Company's Eligix HDM Cell Separation Systems. The first two of these products,

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the Eligix BCell-SC and CD8-DLI Cell Separation Systems, have received CE mark approval, permitting their sale in the European Union. Gambro will be responsible for continued clinical market development and all other aspects of marketing, sales and distribution. In August and September 2001, the Company received an upfront licensing fee of \$4.0 million, plus milestone payments of \$2.0 million for obtaining CE mark approval for the Company's Eligix BCell-SC and CD8-DLI Cell Separation Systems. The Company is recognizing these amounts as revenue over the seven-year term of the distribution agreement. During the year ended December 31, 2001, the Company recognized \$334,000 as license fee revenues, all of which were shipped to Gambro's location in the United States, and of December 31, 2001, \$5.7 million is included as deferred revenue in the accompanying consolidated balance sheets. BioTransplant may receive future milestone payment for other new products, if any, receiving CE mark approval.

### (10) INCOME TAXES

The Company accounts for income taxes in accordance with SFAS No. 109, ACCOUNTING FOR INCOME TAXES. At December 31, 2001, the Company had net operating loss carryforwards for income tax purposes of approximately \$107,973,000. The Company also has available tax credit carryforwards of \$2,400,000 at December 31, 2001 to reduce future federal income taxes, if any. The net operating loss carryforwards and tax credit carryforwards expire through 2021, and are subject to review and possible adjustment by the Internal Revenue Service. Net operating loss carryforwards and tax credit carryforwards may be limited in the event of certain changes in the ownership interests of significant stockholders.

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The components of the net deferred tax asset as of December 31, 2001 and 2000 are approximately as follows:

	2001	2000
	-----	-----
Net operating loss carryforwards.....	\$43,466,000	\$25,999,000
Tax credit carryforwards.....	2,400,000	2,200,000
Other temporary differences.....	(2,443,000)	607,000
	-----	-----
Less--Valuation allowance.....	43,423,000	28,806,000
	-----	-----
Net deferred tax assets.....	\$ --	\$ --
	=====	=====

Because of the history of operating losses, a valuation allowance has been provided for the entire deferred tax asset since it is uncertain if the Company will realize the benefit of the deferred tax asset.

### (11) COMMITMENTS

#### (A) RESEARCH AND LICENSE AGREEMENTS

The Company has entered into several research and license agreements with a hospital whereby the Company obtained the rights to the hospital's research pertaining to the transplantation of organs and tissues and other related technologies. The Company also obtained an exclusive license to commercially develop, manufacture, use and distribute worldwide any products developed pursuant to the agreements, in exchange for research funding and royalties on



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any future sales. These agreements have initial terms of one to ten years; however, either party may terminate the agreements at various times, as defined, with written notice.

The Company has entered into research and license agreements with universities whereby the Company funds research and development. The Company also obtained exclusive worldwide licenses for certain patents, patent rights and research information and rights to develop, manufacture, use and sell any product developed pursuant to the licensed technology in exchange for royalties on any future sales, as defined.

The Company has entered into a miniature swine transfer and maintenance agreement with a breeding laboratory and was granted exclusive, worldwide rights to the miniature swine. Pursuant to this agreement, the Company has agreed to pay specified maintenance costs, as defined in the agreement.

Commitments as of December 31, 2001, pursuant to these research and license agreements are as follows:

	TOTAL
	-----
Year Ending December 31,	
2002.....	\$2,932,000
2003.....	775,000
2004.....	775,000
2005.....	775,000
2006.....	150,000
	-----
	\$5,407,000
	=====

During the years ended December 31, 2001, 2000 and 1999, the Company expensed \$2,594,000, \$4,865,000 and \$6,725,000, respectively, as research and development expense related to these research and license agreements.

(11) COMMITMENTS (CONTINUED)  
(B) OPERATING LEASE COMMITMENTS

The Company leases its facilities under operating leases that expires between years 2003 and 2009. In addition, the Company is responsible for the real estate taxes and operating expenses related to these facilities. Minimum annual rental payments, excluding taxes and operating costs, under these lease agreements are as follows:

2002.....	\$1,826,477
2003.....	1,631,981
2004.....	1,037,759
2005.....	1,035,000
2006.....	1,035,000
Thereafter.....	3,105,000
	-----
	\$9,671,217
	=====

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Rental expense, which includes facility lease, ground lease and real estate tax costs, for the years ended December 31, 2001, 2000 and 1999 was approximately \$1,133,000, \$1,188,000 and \$1,192,000, respectively.

The Company leases a portion of its Medford, Massachusetts office facility to a third party. The third party does not have a formal sublease agreement with the Company and pays rent on a monthly basis at approximately \$18,500 per month. The Company recorded approximately \$154,000 of sublease income for the year ended December 31, 2001 as a reduction of rent expense.

(C) CAPITAL LEASE COMMITMENTS

The Company has capital lease commitments related to certain property and equipment.

Future minimum payments under these capital lease agreements as of December 31, 2001 are as follows:

YEAR ENDING DECEMBER 31, -----	AMOUNT -----
2002.....	\$50,141
2003.....	34,124
	-----
Total minimum payments.....	84,265
Less--Amount representing interest.....	6,304
	-----
Present value of minimum lease payments.....	77,961
Less--Current obligation under capital leases.....	45,215
	-----
	\$32,746
	=====

Equipment under capital leases collateralize these lease obligations.

(12) INVESTMENT IN STEM CELL SCIENCES LTD.

In April 1994, the Company entered into a shareholders' agreement and a research and license agreement (the "Agreements") with Stem Cell Sciences Ltd. ("Stem Cell"). Under the Agreements, the Company paid \$1.0 million for: 30% of the outstanding common stock of Stem Cell, an exclusive license to certain technology and other intellectual property and also supported an option to maintain its pro rata equity ownership at 30% through December 31, 1998.

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(12) INVESTMENT IN STEM CELL SCIENCES LTD. (CONTINUED)

Subsequent to the initial \$1.0 million investment, the Company made additional capital contributions totaling \$3,125,000 through 1999 to support all of the activities at Stem Cell under the research and license agreement. The Company is accounting for its investment in Stem Cell under the equity method of accounting. Because the Company provided substantially all of the capital to fund the activities of Stem Cell through 1999, the Company has recorded the losses of Stem Cell as research and development expenses in its statements of operations. The amount of research and development expense relating to Stem Cell losses for 1999 was \$825,000.

During 2000, Stem Cell received approximately \$1.8 million from the issuance

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of convertible notes to parties other than the Company. Certain noteholders of Stem Cell converted their interest into common stock during the year. This conversion diluted the Company's ownership interest in Stem Cell to 25.5%. Additionally, in connection with the note conversion the Company recognized a gain in stockholders' equity of \$160,000 on its investment in accordance with SAB No. 51, ACCOUNTING FOR SALES OF STOCK BY A SUBSIDIARY. The Company also recorded its equity in the loss of Stem Cell of \$55,000 for the year ended December 31, 2000 based on its ownership interest. This loss is included in research and development expense in the accompanying consolidated statement of operations.

There were no changes in the capital structure of Stem Cell during the year ended December 31, 2001. During the year ended December 31, 2001, the Company recorded its equity in the loss of Stem Cell of \$105,000 based on its ownership interest and limited to its investment balance. This loss is included in research and development expense in the accompanying consolidated statement of operations.

### (13) EMPLOYMENT RETIREMENT/SAVINGS PLAN

The Company maintains an employee retirement/savings plan (the "Plan") which permits participants to make tax deferred contributions by salary reduction pursuant to section 401(k) of the Internal Revenue Code. All active employees, 21 years of age or older, who have completed a calendar quarter of service are eligible to participate in the Plan. The Company pays all administrative costs of the Plan. During 2000, the Company began making matching contributions into the Plan and contributed a total of approximately \$62,000 and \$82,000 for the years ended December 31, 2001 and 2000, respectively.

### (14) RELATED PARTY TRANSACTIONS

In March 1991, the Company entered into a supply agreement with Charles River Laboratories (CRL), which was amended in 1998. Under the terms of the amended agreement, CRL provides the Company with miniature swine and miniature swine organs for research and development purposes in exchange for payment of the costs of maintaining the miniature swine herd. Upon commencement of commercial sales of miniature swine organs, the Company and CRL may enter into a definitive supply agreement for the ongoing supply of miniature swine. In the years ended December 31, 2001 and 2000, the Company paid CRL approximately \$770,000 and \$988,000, respectively, under this agreement. Beginning in 2001, Immerge BioTherapeutics is reimbursing BioTransplant for a portion of the CRL costs, in accordance with an agreement between the two companies. James C. Foster, President and Chief Executive Officer of CRL, is a director of the Company.

Additionally, the Company has entered into a number of transactions with Immerge and Novartis. (See Note 8)

The Company believes that all related party transactions are at arm's length.

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### (15) QUARTERLY RESULTS OF OPERATIONS (UNAUDITED)

The following tables present a condensed summary of quarterly results of operations for the years ended December 31, 2001 and 2000 (in thousands, except per share data).

YEAR ENDED DECEMBER 31, 2001

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	FIRST QUARTER	SECOND QUARTER	THIRD QUARTER	FOURTH QUARTER
Total revenues.....	\$ --	\$ --	\$ 212	\$ 8
Net loss.....	\$(2,312)	\$(25,557) (1)	\$(6,766)	\$(8,200)
Basic and diluted net loss per share.....	\$ (0.20)	\$ (1.76)	\$ (0.35)	\$ (0.40)

(1) Includes one-time write-off of in process research and development of \$20.0 million.

	YEAR ENDED DECEMBER 31, 2000			
	FIRST QUARTER	SECOND QUARTER	THIRD QUARTER	FOURTH QUARTER
Total revenues.....	\$ 1,488	\$ 1,488	\$ 1,476	\$ 1,488
Net loss.....	\$(2,499)	\$(2,408)	\$(2,501)	\$(4,200)
Basic and diluted net loss per share.....	\$ (0.23)	\$ (0.21)	\$ (0.21)	\$ (0.28)

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

During our two most recent fiscal years, there have been no disagreements with our independent accountants on accounting and financial disclosure matters.

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

The following table sets forth the names, ages and positions of each of our directors and executive officers as of February 28, 2002.

NAME	AGE	POSITION
Elliot Lebowitz, Ph.D.....	61	President, Chief Executive Officer and Director
James Hope, Ph.D.....	50	Chief Technology Officer
Barbara Wallner, Ph.D.....	59	Chief Scientific Officer
James Embree.....	52	Senior Vice President, Manufacturing and Development
Richard V. Capasso, C.P.A.....	40	Vice President, Finance and Treasurer
Tara Clark.....	40	Vice President, Marketing
Ian Fier.....	35	Vice President, Clinical Operations
Constance Garrison.....	41	Vice President, Regulatory Affairs
Judith Snow.....	44	Vice President, Quality Assurance
James C. Foster, J.D.....	50	Director
Daniel O. Hauser, Ph.D.....	63	Director
Arnold L. Oronsky, Ph.D.....	61	Director
Michael S. Perry, D.V.M., Ph.D.....	42	Director
Susan M. Racher.....	48	Director

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### EXECUTIVE OFFICERS

ELLIOT LEBOWITZ, PH.D. has served as President and Chief Executive Officer and as a member of the Board of Directors of BioTransplant since April 1991. From 1985 to 1991, he served as Vice President for Research and Development at C.R. Bard, Inc., a medical device company, directing internal and collaborative research and development programs for Bard's Vascular Systems, Cardiosurgery and Cardiopulmonary Divisions. From 1981 until 1985, Dr. Lebowitz served as Director of Long Range Research and Development at DuPont Corporation, a diversified health care company, developing immunopharmaceuticals. From 1977 until 1981, he served as Division Manager of the Medical Products Division of New England Nuclear Corporation, which developed, manufactured and sold radiopharmaceuticals for in vivo diagnosis. Earlier in his career, Dr. Lebowitz served at Brookhaven National Laboratories, a United States Department of Energy research facility, where he developed Thallium-201, a radiopharmaceutical for the diagnosis of coronary artery disease. Dr. Lebowitz was a founder of Diagnostic Isotopes, Inc., a radiopharmaceutical company which was subsequently acquired by Hoffmann-La Roche Inc., a pharmaceutical company. He was also a founder of Procept, Inc., a biopharmaceutical company which focused on rational drug design. He holds a B.A. from Columbia College and a Ph.D. from Columbia University.

JAMES HOPE, PH.D. has served as Chief Technology Officer of BioTransplant since May 2001. From December 1995 to May 2001, he served as Senior Vice President of Development. From August 1992 until December 1995, he served as Vice President of Development of BioTransplant. From 1990 until 1992, he served as Executive Director of Operations Technical Support of Serono Laboratories, Inc., a pharmaceutical company, where he directed the transfer, scale-up and validation of biopharmaceutical manufacturing processes and was responsible for product manufacturing. From 1986 until 1990, he

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served as the Director of Bioprocess Development and Production at Invitron Corp., a contract manufacturer for the development and scale-up of mammalian, cell-based biopharmaceutical manufacturing processes. Dr. Hope received a B.S. in microbiology and chemistry from the University of Reading (U.K.) and a Ph.D. in biochemistry from the University of London (U.K.).

BARBARA WALLNER, PH.D. has served as Senior Vice President, Research and Chief Scientific Officer of BioTransplant since January 2002. From 1996 to 2001, Dr. Wallner served as Senior Vice President of Research and Development, Chief Scientific Officer of Point Therapeutics, Inc., a biotechnology company focused on immune system modulation. From 1992 to 1996, Dr. Wallner served as Vice President of Research of Immulogic, Inc., a biotechnology company focused on allergies and autoimmune diseases. From 1982 to 1992, Dr. Wallner served as a Senior Scientist for Biogen, Inc., a biopharmaceutical company with products to treat autoimmune and other diseases. Dr. Wallner received a B.S. degree and a Ph.D. in biochemistry from the University of Illinois.

JAMES EMBREE has served as Senior Vice President, Manufacturing and Development of BioTransplant since September 2001. From May 2001 to September 2001, Mr. Embree served as Vice President, Manufacturing of BioTransplant. From January 1998 to May 2001, Mr. Embree served as Vice President, Manufacturing of Eligix, Inc., a medical device company acquired by BioTransplant in May 2001. From 1993 to 1998, Mr. Embree served as Director of Manufacturing for SyStemix, a Novartis cell therapy company. From 1991 to 1993, he held manufacturing and development positions with Cytotherapeutics, a biotechnology company developing cell therapy based-products. From 1988 to 1991, he held positions at Immunogen, a biopharmaceutical company developing

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parenteral oncology products. From 1985 to 1988, he held positions at Seragen, Inc., a developer of therapeutic protein products. From 1978 to 1985, he worked for New England Nuclear, a research, diagnostic and pharmaceutical company. Mr. Embree received a B.S. degree in microbiology from the University of Massachusetts and an M.A. degree in bacterial genetics and molecular biology from Northeastern University.

RICHARD V. CAPASSO, C.P.A. has served as Vice President, Finance and Treasurer of BioTransplant since May 1997. From December 1994 until May 1997, he served as Director of Finance of BioTransplant and from December 1991 until December 1994, he served as Controller of BioTransplant. From 1988 to 1991, Mr. Capasso served as Manager of Financial Reporting and Controller at Softbridge, Inc., a computer software development company. From 1984 to 1988, he served as a member of the professional staff of the Enterprise Group of Arthur Andersen LLP, an international public accounting firm. Mr. Capasso received his B.S. from Northeastern University with a major in accounting, his M.B.A. from Bentley College and received his C.P.A. in 1987.

TARA CLARK has served as Vice President, Marketing of BioTransplant since May 2001. From 1999 to May 2001, Ms. Clark served as Vice President, Marketing of Eligix. From 1988 to 1999, Ms. Clark held positions of increasing responsibility within the Fenwal and Scientific Products Divisions of Baxter Healthcare Corporation, a hospital supply and biotechnology company, most recently as Director of Marketing. Ms. Clark served in various quality assurance and microbiology research positions with Invitron, Corp., a biopharmaceutical company, from 1986 to 1988, and McDonnell Douglas, an aeronautical, engineering and manufacturing company, from 1984 to 1986. Ms. Clark received a B.S. degree in microbiology from the University of Missouri-Columbia.

IAN FIER has served as Vice President, Clinical Operations of BioTransplant since October 2001. From October 1997 to September 2001, he served as Senior Director, Product Development of The Medicines Company, a biopharmaceutical company. From November 1993 to September 1997, he served as Assistant Director, Strategic Planning, Finance and Tracking at Astra USA (now AstraZeneca), a pharmaceutical company. Prior to 1993, he held various positions in pharmacology and clinical research with Hoechst Roussel Pharmaceuticals Inc (now Aventis), a pharmaceutical company.

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Mr. Fier received his B.S. in Bio-Psychology from Tufts University, and his M.B.A. in Health Care Management from the Boston University Graduate School of Management.

CONSTANCE GARRISON has served as Vice President, Regulatory Affairs of BioTransplant since September 2001. From May 2001 to September 2001, Ms. Garrison served as Director, Regulatory Affairs of BioTransplant. From 2000 to May 2001, Ms. Garrison served as Director, Regulatory Affairs for Eligix. From 1997 to 2000, Ms. Garrison served as Director, Project Management for Eligix. From 1984 to 1997, Ms. Garrison held various positions at Coulter Corporation, a medical device company. Ms. Garrison received a B.S. degree in natural science from Doane College and an M.B.A. degree in Marketing from Barry University. Ms. Garrison is a Certified Medical Technologist.

JUDITH SNOW has served as Vice President, Quality Assurance of BioTransplant since May 2001. From 1998 to 2001, Ms. Snow served as Vice President, Quality Assurance of Eligix. From 1995 to 1998, Ms. Snow served as Vice President of Quality, Regulatory and Clinical Affairs at UroMed Corp., a urological medical device company. From 1990 to 1995, she held quality assurance positions at Haemonetics, Inc., a manufacturer of blood and stem cell collection and processing systems. From 1988 to 1989, she held quality assurance positions at Coulter Electronics, Inc., a manufacturer of diagnostic equipment. She held

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various positions at Cordis Corporation, a manufacturer of cardiac pacemakers and neurological shunts, from 1985 to 1988. Ms. Snow received a B.S. degree in medical technology from Wesley College.

### DIRECTORS

JAMES C. FOSTER, J.D. has served as a director of BioTransplant since February 1992. Since 1992, he has served as President and Chief Executive Officer of Charles River Laboratories, Inc., or CRL, a supplier of research animals and animal related products and services. Prior to 1992, he served in various other capacities at CRL. Mr. Foster received his B.S. in psychology from Lake Forest College, his J.D. from the Boston University School of Law and his M.A. in Science and Management from the Massachusetts Institute of Technology.

DANIEL O. HAUSER, PH.D. has served as a director of BioTransplant since January 1994. Dr. Hauser is currently retired. From 1997 to 1998, he served as a member of the Executive Committee of Novartis Pharmaceuticals Corporation, a pharmaceutical corporation. From May 1992 until December 1996, he served as President of Sandoz Research Institute and a member of the Executive Committee of Sandoz Pharmaceutical Corporation, a predecessor of Novartis. In 1993, Dr. Hauser served as Global Head of Research of Sandoz Pharma, Ltd. From 1965 to 1992, he served in various positions at the Pharma Division of Sandoz Pharma Ltd. (Switzerland), including Senior Vice President from 1985 to 1992. Dr. Hauser received his M.S. and Ph.D. in chemistry from the Swiss Federal Institute of Technology (Switzerland) in Zurich.

ARNOLD L. ORONSKY, PH.D. has served as a director of BioTransplant since May 2001. Dr. Oronsky has been affiliated with InterWest Partners, a venture capital firm, since 1989, where he became a General Partner in 1994. From 1977 to 1994, he served in positions of increasing responsibility at Lederle Laboratories division of American Cyanamid Company, a pharmaceutical company, most recently serving as Vice President for Discovery Research where he directed a \$90 million research budget and a staff of approximately 300 employees. Dr. Oronsky has also served as a Research Fellow and an Assistant Professor at Harvard Medical School and currently serves as a director of Corixa Corporation. Dr. Oronsky holds a B.S. degree from New York University and a Ph.D. from Columbia University's College of Physicians and Surgeons.

MICHAEL S. PERRY, D.V.M., PH.D. has served as a director of BioTransplant since January 1999. Since February 2002, he has served as President and Chief Executive Officer of Pharsight Corporation, a provider of drug development products and services to the pharmaceutical and biotechnology industry.

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From October 2000 to February 2002, he served as Vice President, Global Research and Development of Baxter Healthcare Corporation, a hospital supply and medical technology company. From 1998 until September 2000, he served as President and Chief Executive Officer of Genetic Therapy, Inc. and from 1997 until September 2000, he has served as President and Chief Executive Officer of SyStemix, Inc. Genetic Therapy and SyStemix are biopharmaceutical corporations which are wholly-owned by Novartis. From 1995 to 1996, he served as Vice President, Drug Registration and Regulatory Affairs (North America) for Sandoz Pharmaceutical Corporation, the predecessor of Novartis. From 1994 to 1995, he served as Vice President, Drug Registration and Regulatory Affairs (USA) for Sandoz. Dr. Perry received his Ph.D. in pharmacology (cardiopulmonary) and his D.V.M. from the Ontario Veterinary College, University of Guelph (Canada).

SUSAN M. RACHER has served as a director of BioTransplant since May 2001. Since 1998, Ms. Racher has served as the Chief Financial Officer of the Wallace H. Coulter Foundation, a charitable entity dedicated to furthering the improvement of healthcare through medical technology and research, and as a

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member of its executive committee. From 1978 to 1997, she served in positions of increasing responsibility with BankAmerica and its predecessor, Continental Bank. Most recently she served as Senior Vice President and Manager of BankAmerica's Florida Corporate Division, where she held responsibility for all commercial banking and investment banking relationships in Florida. Ms. Racher received her B.A. from Smith College and an M.B.A. in Finance and Accounting from the University of Chicago Graduate School of Business.

All of our directors serve for one-year terms and have been nominated and will be presented to the stockholders for re-election at the 2002 annual meeting of our stockholders. Dr. Oronsky and Ms. Racher were elected as directors on May 15, 2001 pursuant to the terms of the merger agreement among BioTransplant, BT/EL Acquisition Co. and Eligix. The merger agreement provides that our board of directors will continue to nominate each of Dr. Oronsky and Ms. Racher to our board until such person dies, resigns, refuses to stand for re-election or is otherwise removed from office.

### SECTION 16(a) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE

Section 16(a) of the Securities Exchange Act of 1934 requires our directors, executive officers and holders of more than 10% of our common stock to file with the SEC initial reports of ownership and reports of changes in ownership of our common stock and other equity securities. Except as set forth below, and based solely on our review of copies of reports filed by such reporting persons furnished to us, we believe that during 2001 such reporting persons complied with all Section 16(a) filing requirements. Dr. Perry filed a Form 5 on February 15, 2002 with the SEC to report his receipt, on August 1, 2001, of 1,000 shares of the Company's common stock and the grant of an option, on July 9, 2001, to purchase 6,000 shares of common stock.

### ITEM 11. EXECUTIVE COMPENSATION

**SUMMARY COMPENSATION TABLE.** The following table sets forth information with respect to the annual and long-term compensation for the last three fiscal years of BioTransplant's Chief Executive Officer and its five other most highly compensated executive officers whose total annual salary and bonus for 2001 exceeded \$100,000, referred to collectively as the "named executive officers." The dollar amount in the "Other Annual Compensation" column represents the aggregate dollar value of a grant of 1,000 shares of common stock made to Dr. Lebowitz by the board of directors on August 1, 2001. Dollar amounts in the "All Other Compensation" column consist of matching contributions under BioTransplant's 401(K) plan, except a severance payment in the amount of \$241,560 paid or payable to Mr. Ogier. Dr. White-Scharf resigned as Vice President of Research on December 31, 2001 and Mr. Ogier resigned as President and Chief Operating Officer on October 31, 2001. Each of Messrs. Capasso, Embree and Ogier became a named executive officer for the first time in the fiscal year ended December 31, 2001.

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#### SUMMARY COMPENSATION TABLE

NAME AND PRINCIPAL POSITION	YEAR	ANNUAL COMPENSATION			LONG-TERM
		SALARY (\$)	BONUS (\$)	OTHER ANNUAL COMPENSATION (\$)	COMPENSATION AWARD UNDERLYING OPTIONS
Elliot Lebowitz,	2001	\$282,000	\$70,200	\$6,520	81,200



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Ph.D. ....	2000	266,000	40,000	--	64,500
Chief Executive Officer	1999	252,956	--	--	67,098
James Hope, Ph.D. ...	2001	211,000	26,000	--	26,500
Chief Technology Officer	2000	206,000	20,000	--	22,000
	1999	195,038	5,000	--	23,000
Mary White-Scharf, Ph.D. .	2001	182,700	26,000	--	--
Vice President of Research	2000	168,000	20,000	--	26,000
	1999	155,424	--	--	27,000
Richard V. Capasso, C.P.A.	2001	160,577	26,000	--	34,900
Vice President of Finance and Treasurer					
James A. Embree	2001	104,397	36,000	--	18,200
Senior Vice President of Manufacturing and Development					
Walter C. Ogier .	2001	152,155	70,455	--	--
President and Chief Operating Officer					

OPTION GRANTS IN LAST FISCAL YEAR. The following table sets forth information regarding options to purchase common stock granted during the year ended December 31, 2001 by BioTransplant to our named executive officers. Options granted in 2001 become exercisable in four equal annual installments, commencing twelve months after the vesting commencement date, which is typically the date of grant. Amounts in the last two columns represent hypothetical gains that could be achieved for options if exercised at the end of the option term. These gains are based on assumed rates of stock price appreciation of 5% and 10% compounded annually from the date options were granted to their expiration date. Actual gains, if any, on stock option exercises will depend on the future performance of the common stock on the date on which options are exercised.

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OPTION GRANTS IN LAST FISCAL YEAR

NAME	INDIVIDUAL GRANTS				EXPIRATION DATE	POTENTIAL RATIO
	NUMBER OF UNDERLYING OPTIONS GRANTED (#)	PERCENT OF TOTAL OPTIONS GRANTED TO EMPLOYEES IN FISCAL YEAR (%)	EXERCISE OR BASE PRICE (\$/SH)			
Elliot Lebowitz, Ph.D.....	81,200	5.22%	\$7.500		12/18/11	\$38
James Hope, Ph.D.....	26,500	1.70	7.500		12/18/11	12

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Mary White-Scharf, Ph.D.....	--	--	--	--	--
Richard V. Capasso, C.P.A.....	34,900	2.24	7.500	12/18/11	16
James A. Embree.....	18,200	1.16	7.500	12/18/11	8
Walter C. Ogier.....	--	--	--	--	--

AGGREGATED OPTION EXERCISES AND YEAR-END OPTION TABLE. The following table sets forth information regarding options exercised by each named executive officer during 2001 and exercisable and unexercisable stock options held as of December 31, 2001 by each named executive officer. The value realized upon the exercise of options represents the difference between the option exercise price and the closing sale price of the common stock on the date of exercise. The value of the unexercised in-the-money options at year end has been calculated based on \$8.85, which was the closing sales price of the common stock on the Nasdaq National Market on December 31, 2001, the last trading day of BioTransplant's 2001 fiscal year, less the applicable option exercise price.

AGGREGATED OPTION EXERCISES IN LAST FISCAL YEAR AND FISCAL YEAR END OPTION VALUES

	SHARES ACQUIRED ON EXERCISE (#)	VALUE REALIZED (\$)	NUMBER OF SECURITIES UNDERLYING UNEXERCISED OPTIONS AT FISCAL YEAR- END (#)		VALUE OF THE-M FISC EXERCISA
			EXERCISABLE	UNEXERCISABLE	
Elliot Lebowitz, Ph.D.....	--	\$ --	355,887	187,371	\$1,424,4
James Hope, Ph.D.....	6,900	43,499	102,282	63,700	397,2
Mary White-Scharf, Ph.D.....	--	--	132,333	44,299	476,2
Richard V. Capasso, C.P.A.....	7,850	44,657	45,178	62,399	108,0
James A. Embree.....	--	--	40,247	23,163	332,4
Walter C. Ogier.....	112,560	899,918	--	--	

SEVERANCE AGREEMENTS WITH EXECUTIVE OFFICERS

We have entered into severance agreements with all of our vice presidents and our chief executive officer. Other than the severance agreements with Dr. Hope and Mr. Ogier, which agreements are described below, these severance agreements provide for a severance payment, in the event of an involuntary termination, in an amount equal to the base salary paid by BioTransplant until the earlier of six months following the termination date or the date on which the individual receives other employment. The following seven individuals are vice presidents: Richard Capasso, Tara Clark, James Embree, Ian Fier, Constance Garrison, Judith Snow and Barbara Wallner. Elliot Lebowitz is our chief executive officer.

Under the terms of an agreement with Dr. Hope, Senior Vice President of Development, in the event of involuntary termination of employment, he is eligible to receive a severance payment in an

amount equal to six months' base salary until the earlier of six months after termination or the date on which he receives other employment. Furthermore, if

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at the end of such six-month period Dr. Hope is unable to secure other employment, then we and Dr. Hope have agreed to negotiate an additional severance payment of up to six months.

On October 16, 2001, we entered into a separation agreement with Mr. Ogier in connection with his resignation as President and Chief Operating Officer. In connection with Mr. Ogier's termination, Mr. Ogier has received the following amounts:

- an aggregate of \$241,560 severance, which was paid in two equal lump sums on the tenth and 90th day following execution of the agreement and which represents an amount equal to two times Mr. Ogier's then base salary over a six-month period, and
- a lump sum cash bonus equal to \$70,455.

### COMPENSATION OF DIRECTORS

Our non-employee directors who are not affiliated with Novartis each receive \$1,500, plus reasonable travel and out-of-pocket expenses, for each meeting of the board of directors they attend.

Our board of directors intends to make awards of stock options to directors as compensation for service on the board of directors under our 1997 stock incentive plan. Currently, the board of directors grants each director, upon his or her initial election to the board of directors, an option to purchase 15,000 shares of our common stock at an exercise price equal to the then fair market value. Each director is also eligible to receive an option to purchase 6,000 shares of our common stock, at an exercise price equal to the then fair market value, upon his or her reelection to the board of directors at each annual meeting of stockholders. In addition, on August 1, 2001, the board of directors granted to each of Drs. Perry and Hauser and Mr. Foster an award of 1,000 shares of our common stock pursuant to our 1997 Stock Incentive Plan as compensation for service on the board of directors. Each share award had a market value of \$6,250 based upon the closing price of our common stock on August 1, 2001.

### COMPENSATION COMMITTEE INTERLOCKS AND INSIDER PARTICIPATION

The members of our Compensation Committee during 2001 were Mr. Foster and Dr. Perry. No member of our Compensation Committee was at any time during 2001, or formerly, an officer or employee of BioTransplant or any subsidiary of BioTransplant.

For a discussion of an arrangement between BioTransplant and Charles River Laboratories, an entity of which Mr. Foster is President and Chief Executive Officer, see "Item 13--Certain Relationships and Related Transactions."

None of our executive officers has served as a director or member of the Compensation Committee, or other committee serving an equivalent function, of any other entity, one of whose executive officers served as a director of or member of our Compensation Committee.

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### ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth information as to the number of shares of our common stock beneficially owned as of December 31, 2001 by:

- each person that beneficially owns more than 5% of the outstanding shares of our common stock;

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- each director of BioTransplant;
- BioTransplant's chief executive officer;
- the five other named executive officers of BioTransplant; and
- all BioTransplant executive officers and directors as a group.

Except as indicated by the notes to the following table, the holders listed below will have sole voting power and investment power over the shares beneficially held by them. Beneficial ownership is determined according to the rules of the Securities and Exchange Commission. The table below includes shares subject to options and warrants which will be exercisable within 60 days following December 31, 2001. All percentages assume that the options and warrants of the particular person or group in question, and no others, have been exercised.

NAME OF BENEFICIAL OWNER -----	BENEFICIAL OWNERSHIP	
	SHARES -----	PERCENT -----
5% BENEFICIAL OWNERS		
Entities affiliated with InterWest Partners V, L.P.(1)..... 300 Sand Hill Road Building 3, Suite 255 Menlo Park, CA 94025	1,218,772	5.7%
S-Squared Technology Corporation(2)..... 515 Madison Avenue New York, NY 10022	1,078,500	5.1
DIRECTORS AND NAMED EXECUTIVE OFFICERS		
Elliot Lebowitz, Ph.D.(3).....	443,086	2.0
James C. Foster, J.D.(4).....	28,481	*
Daniel O. Hauser(5).....	15,853	*
Arnold L. Oronsky, Ph.D.(6).....	1,214,881	5.8
Michael S. Perry, D.V.M., Ph.D.(7).....	13,750	*
Susan M. Racher(8).....	997,417	4.7
James Hope, Ph.D.(9).....	102,582	*
Mary White-Scharf, Ph.D.(10).....	127,784	*
Richard V. Capasso(11).....	49,178	*
James A. Embree(12).....	96,144	*
Walter C. Ogier(13).....	146,777	*
All directors and executive officers as a group (14 individuals)(14).....	3,408,568	15.4

\* Beneficial ownership does not exceed 1% of the outstanding shares of BioTransplant common stock.

(1) Represents shares held by InterWest Partners V, L.P., InterWest Investors V, InterWest Partners VI, L.P. and InterWest Investors VI, L.P.

(2) This information is based solely on information included in a Schedule 13G/A filed with the Securities and Exchange Commission on

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February 14, 2002.

- (3) Includes 368,012 shares of common stock which Dr. Lebowitz has the right to acquire within 60 days of December 31, 2001 upon the exercise of stock options.
- (4) Includes 2,856 shares of common stock owned by Charles River Laboratories, Inc. Mr. Foster, a director of BioTransplant, is the President and Chief Executive Officer of Charles River Laboratories and may be deemed to beneficially own the shares of Charles River Laboratories, although he disclaims beneficial ownership. Also includes 13,125 shares of common stock which Mr. Foster has the right to acquire within 60 days of December 31, 2001 upon the exercise of stock options.
- (5) Includes 14,853 shares of common stock which Dr. Hauser has the right to acquire within 60 days of December 31, 2001 upon the exercise of stock options.
- (6) Arnold L. Oronsky, a director of BioTransplant, is general partner of InterWest Management Partners V, L.P., the sole general partner of InterWest Partners V, L.P. Dr. Oronsky also serves as Managing Director of InterWest Management Partners VI, L.L.C., the sole general partner of InterWest Partners VI, L.P. and InterWest Investors VI, L.P. Dr. Oronsky, together with the other general partners of InterWest Partners V, L.P., InterWest Partners VI, L.P. and InterWest Investors VI, L.P., respectively, shares voting and investment control with respect to the shares owned by InterWest Partners V, L.P., InterWest Partners VI, L.P. and InterWest Investors VI, L.P. Dr. Oronsky disclaims beneficial ownership of the shares held by InterWest Partners V, L.P., InterWest Partners VI, L.P. and InterWest Investors VI, L.P. except to the extent of his pecuniary interest therein.
- (7) Consists of 12,750 shares of common stock which Dr. Perry has the right to acquire within 60 days of December 31, 2001 upon the exercise of stock options.
- (8) Susan Racher, a director of BioTransplant, is the Chief Financial Officer of the Wallace H. Coulter Foundation and may be deemed to exercise voting and investment control with respect to shares held by the Foundation. Ms. Racher disclaims beneficial ownership of these shares.
- (9) Includes 102,382 shares of common stock which Dr. Hope has the right to acquire within 60 days of December 31, 2001 upon the exercise of stock options. Includes 300 shares of common stock owned by Dr. Hope's minor children.
- (10) Dr. White-Scharf resigned effective December 31, 2001. Includes 116,033 shares of common stock which Dr. White-Scharf has the right to acquire within 60 days of December 31, 2001 upon the exercise of stock options. Also includes 300 shares of common stock owned by Dr. White-Scharf's minor children.
- (11) Consists of 49,178 shares of common stock which Mr. Capasso has the right to acquire within 60 days of December 31, 2001 upon the exercise of stock options.
- (12) Includes 55,351 shares of common stock which Mr. Embree has the right to acquire within 60 days of December 31, 2001 upon the exercise of stock options.
- (13) Mr. Ogier resigned effective October 31, 2001.
- (14) Includes 753,538 shares of common stock which all directors and executive

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officers as a group may acquire upon the exercise of outstanding stock options and warrants exercisable within 60 days of December 31, 2001.

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### ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

**CHARLES RIVER LABORATORIES.** In March 1991, we entered into a supply agreement with Charles River Laboratories. We amended the agreement in 1998. Under the terms of the agreement, as amended, CRL provides us with miniature swine and miniature swine organs for research and development purposes in exchange for payments under a research and supply agreement. We paid CRL \$770,000 under this agreement in 2001. James C. Foster, President and Chief Executive Officer of CRL, is a director of BioTransplant. We have assigned our rights in the field of xenotransplantation under this agreement to Immerge BioTherapeutics, our joint venture with Novartis.

**ELIGIX ACQUISITION.** On May 15, 2001, we completed our acquisition of Eligix, Inc. Under the terms of the merger agreement, Eligix stockholders have the right to receive up to 5,610,000 shares of our common stock either in the merger or upon exercise or conversion of outstanding Eligix options, warrants and notes assumed by us in the merger. Pursuant to the terms of the merger, Susan Racher and Arnold Oronsky were elected to our board of directors. Dr. Oronsky is the general partner of InterWest Management Partners V, L.P., the sole general partner of InterWest Partners, V, L.P. Dr. Oronsky also serves as a managing director of InterWest Management Partners, VI, L.L.C., the sole general partner of InterWest Partners VI, L.P. and InterWest Investors VI, L.P. Together, InterWest Partners V, L.P., InterWest Partners, VI, L.P. and InterWest Investors VI, L.P., former stockholders of Eligix, received 1,214,881 shares of our common stock in the merger. Ms. Racher serves as the Chief Financial Officer of the Wallace H. Coulter Foundation, a former Eligix stockholder, which received 997,417 shares of our common stock in the merger.

In addition, former employees of Eligix who became officers of BioTransplant received shares of our common stock pursuant to the Eligix management equity incentive plan as follows:

NAME	COMMON STOCK ISSUED
----	-----
James A. Embree.....	103,570
Connie Garrison.....	51,785
Judith Snow.....	103,570
Tara Clark.....	103,570
Walter C. Ogier.....	172,617

The shares of our common stock issued pursuant to the Eligix management equity incentive plan vest as follows:

- 33 1/3% vested 90 days after closing;
- 33 1/3% vested 180 days after closing;
- 23 1/3% vested 270 days after closing; and
- the remaining 10% will vest 365 days after the closing of the merger.

Walter Ogier resigned as President and Chief Operating Officer on October 31, 2001. In connection with his resignation, Mr. Ogier's shares vested

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in full on October 31, 2001. If any of Mesdames Garrison, Snow or Clark or Mr. Embree terminates his or her employment with us for good reason, or is terminated by us without cause, all of the remaining unvested shares will vest immediately in full. If, however, any of these officers is terminated for cause or leaves without good reason, then we have the right to repurchase any then unvested shares held by such officer at a repurchase price of \$0.01 per share.

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Under the merger agreement, we also assumed the Eligix 1997 equity incentive plan and all options granted under the plan. Accordingly, we assumed options held by former Eligix employees who became officers of BioTransplant as follows:

NAME -----	STOCK UNDERLYING ASSUMED OPTIONS -----	EXERCISE PRICE PER SHARE -----
James A. Embree.....	27,295 17,915	\$0.11 \$1.60
Connie Garrison.....	7,785 7,785	\$0.11 \$1.60
Judith Snow.....	22,512 22,512	\$0.11 \$1.60
Tara Clark.....	16,743 16,743	\$0.11 \$1.60
Walter C. Ogier.....	56,280 56,280	\$0.11 \$1.60

### PART IV

#### ITEM 14. EXHIBITS, FINANCIAL STATEMENT SCHEDULES, AND REPORTS ON FORM 8-K

(a) The following documents are included as part of this Annual Report on Form 10-K.

1. Financial Statements:

	PAGE -----
Report of Independent Public Accountants.....	39
Consolidated Balance Sheets as of December 31, 2000 and 2001.....	40
Consolidated Statements of Operations for the years ended December 31, 1999, 2000 and 2001.....	41
Consolidated Statements of Stockholders' Equity (Deficit) for the years ended December 31, 1999, 2000 and 2001.....	42
Consolidated Statements of Cash Flows for the years ended December 31, 1999, 2000 and 2001.....	43

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Notes to Consolidated Financial Statements..... 44

2. The Exhibits listed in the Exhibit Index immediately preceding the Exhibits are filed as part of this Annual Report on Form 10-K.
- (b) The following Current Reports on Form 8-K were filed by the Company during the last quarter covered by this report:
1. A Current Report on Form 8-K was filed on December 10, 2001 to file, pursuant to Item 5, the Amended and Restated By-Laws of the Company, which were approved by the Company's board of directors on December 5, 2001.

ELIGIX-TM-, BIOTRANSPLANT-REGISTERED TRADEMARK-, ALLOMUNE-REGISTERED TRADEMARK- AND BTI-322-REGISTERED TRADEMARK---ARE BIOTRANSPLANT'S TRADEMARKS. THIS ANNUAL REPORT ON FORM 10-K MAY ALSO CONTAIN TRADEMARKS AND TRADE NAMES OF OTHERS.

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### 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: March 14, 2002

BIOTRANSPLANT INCORPORATED

By: /s/ ELLIOT LEBOWITZ

-----  
Elliot Lebowitz, Ph.D.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

NAME -----	TITLE -----	DATE -----
/s/ ELLIOT LEBOWITZ ----- Elliot Lebowitz, Ph.D.	President, Chief Executive Officer and Director (Principal Executive Officer)	March 14,
/s/ RICHARD V. CAPASSO ----- Richard V. Capasso	Vice President, Finance and Treasurer (Principal Financing and Accounting Officer)	March 14,
/s/ JAMES C. FOSTER ----- James C. Foster	Director	March 14,
/s/ DANIEL O. HAUSER -----	Director	March 14,



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Daniel O. Hauser, Ph.D.

/s/ ARNOLD ORONSKY ----- Arnold Oronsky	Director	March 14,
/s/ MICHAEL S. PERRY ----- Michael S. Perry, D.V.M., Ph.D.	Director	March 14,
/s/ SUSAN M. RACHER ----- Susan M. Racher	Director	March 14,

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EXHIBIT INDEX

The following exhibits are filed as part of this Annual Report on Form 10-K.

EXHIBIT NO. -----	DESCRIPTION -----
2.1(1)	Agreement and Plan of Merger, dated as of December 8, 2000, by and among the Company, BT/EL Acquisition Co. and Eligix, Inc.
3.1(2)	Amended and Restated Certificate of Incorporation of the Company, as amended to date.
3.2(3)	Amended and Restated By-laws of the Company, as amended to date.
4.1(4)	Specimen certificate for shares of common stock, \$.01 par value per share, of the Company.
+10.1(4)	Research and License Agreement between the Company and The General Hospital Corporation, dated January 1, 1991 as amended by Agreements dated November 10, 1993, June 28, 1995 and January 31, 1996 (the "1991 MGH Agreement").
+10.2(4)	Research and License Agreement between the Company and The General Hospital Corporation dated December 8, 1992.
+10.3(4)	Research and License Agreement between the Company and The General Hospital Corporation dated August 1, 1994.
+10.4(4)	Alliance Agreement between the Company and MedImmune, Inc. dated October 2, 1995.
+10.5(5)	An extension to the Research and License Agreement between The General Hospital Corporation and the Company, having an effective date of January 1, 1991, as amended.
10.6(5)	Shareholders' Agreement by and among the Company, Castella Research, Secure Sciences and Stem Cell Sciences Pty. Ltd. dated April 5, 1994, as amended.

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- 10.7(5) Research and License Agreement between the Company and Stem Cell Sciences Pty. Ltd. dated April 5, 1994.
- 10.8(4) Form of Common Stock Warrant issued to certain investors in August 1994 and Schedule of Warrantholders.
- 10.9(4) Form of Common Stock Warrant issued to certain investors in October 1994 and Schedule of Warrantholders.
- 10.10(4) Form of Common Stock Warrant issued to certain investors in August 1995 and Schedule of Warrantholders.
- 10.11(4) Convertible Promissory Note and Warrant Purchase Agreement by and among the Company, HealthCare Ventures II, L.P. and Everest Trust dated December 20, 1991.
- 10.12(4) Convertible Promissory Note and Warrant Purchase Agreement by and among the Registrant and the parties signatory thereto dated October 31, 1994.
- 10.13(4) Third Amended and Restated Stockholders Agreement by and among the Company and the parties signatory thereto, as amended by a Consent, Waiver and Amendment dated January 23, 1996.
- 10.14(4) Form of Consent, Waiver and Amendment Agreement to the Third Amended and Restated Stockholders' Agreement by and among the Company and the parties signatory thereto.
- \*10.15(4) Amended 1991 Stock Option Plan.
- \*10.16(6) 1994 Directors' Equity Plan, as amended.
- \*10.17(5) 1997 Stock Incentive Plan, as amended

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EXHIBIT NO.	DESCRIPTION
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10.18(4)	Consulting Agreement between the Company and Dr. David H. Sachs dated January 1, 1991.
10.19(7)	Amendments to Consulting Agreement between the Company and Dr. David H. Sachs dated December 1, 1998, January 5, 2000 and January 8, 2001.
10.20(4)	Lease between the Company and BioLease, Inc. dated March 17, 1994.
10.21(8)	First Amendment to Lease between the Company and BioLease, Inc. dated November 17, 1998.
+10.22(9)	Development and Supply Agreement between the Company and Dendreon Corporation (formerly, Activated Cell Therapy), dated August 22, 1996.
10.23(5)	Agreement to further vary Shareholders' Agreement among the

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Company and Castella Research, Secure Sciences and Stem Cell Sciences Pty., Ltd., dated December 20, 1996.

- 10.24(5) Agreement to further vary Shareholders' Agreement among the Company and Castella Research, Secure Sciences and Stem Cell Sciences Pty., Ltd., dated March 16, 1997, as amended.
- 10.25(11) Letter Agreement, Security Agreement and Promissory Note between the Company and Fleet National Bank, dated August 10, 1999.
- +10.26(10) Miniature Swine Transfer and Maintenance Agreement dated January 1, 1998 by and between Charles River Laboratories, Inc., Wilmington Partners, L.P. and the Company.
- +10.27(12) Shareholder Agreement dated September 24, 2000 by and between the Company, Novartis AG and Immerge BioTherapeutics AG (formerly known as Loxo AG), together with exhibits.
- +10.28(13) Patent License Agreement (MEDI-507), dated July 17, 1997 by and between Protein Design Labs and MedImmune, Inc.
- 10.29(14) Promissory Note made by Eligix, Inc. in favor of the Company.
- +10.30(15) Services Agreement dated January 1, 2001 by and between the Company and Immerge BioTherapeutics, Inc., together with exhibits.
- 10.31(16) Commercial Lease by and between Cummings Properties Management, Inc., and Eligix, Inc. (f.k.a. Coulter Cellular Therapies, Inc.).
- 10.32(16) Master Loan and Security Agreement, dated as of July 28, 1999, by and between Eligix, Inc. and Transamerica Business Credit Corporation, including Form of Stock Subscription Warrant to Purchase Common Stock and Promissory Notes in favor of Transamerica Business Credit Corporation dated August 9, 1999, December 29, 1999 and January 31, 2000.
- 10.33(16) First Amendment to Master Loan and Security Agreement, dated as of May 15, 2001, by and among the Company, Eligix, Inc. and Transamerica Business Credit Corporation.
- +10.34(16) Agreement, dated as of June 2, 2000, by and between Eligix, Inc. and Coulter Pharmaceutical, Inc
- +10.35(16) License, Assignment and Supply Agreement, dated as of February 13, 1997, by and between Coulter Corporation, Coulter International Corporation and Eligix, Inc. (f.k.a. Coulter Cellular Therapies, Inc.)
- \*10.36(16) Assumed Eligix, Inc. Amended and Restated Management Equity Incentive Plan, as amended.
- \*10.37(16) Assumed Eligix, Inc. 1997 Equity Incentive Plan, as amended.

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EXHIBIT NO.	DESCRIPTION
*10.38(16)	Employment Offer Letter by and between the Company and Elliot Lebowitz dated April 4, 1991.
*10.39(16)	Employment Offer Letter by and between the Company and Richard Capasso dated November 13, 1991, as amended on March 31, 1996.
*10.40(16)	Employment Offer Letter by and between the Company and James Hope dated June 29, 1992.
*10.41(16)	Employment Offer Letter by and between the Company and Tara Clark dated May 15, 2001.
*10.42(16)	Employment Offer Letter by and between the Company and James Embree dated May 15, 2001.
*10.43(16)	Employment Offer Letter by and between the Company and Judith Sommer dated May 15, 2001.
+10.44(17)	Distribution Agreement between the Company and Gambro BCT, Inc. dated August 14, 2001.
*10.45	Separation Agreement dated October 16, 2001 by and between the Company and Walter Ogier.
*10.46(16)	Employment Offer Letter by and between the Company and Walter Ogier dated May 15, 2001.
*10.47(16)	Employment Offer Letter by and between the Company and Mary White-Scharf dated July 30, 1991, as amended on March 1, 1996.
21	Subsidiaries of the Registrant.
23.1	Consent of Arthur Andersen LLP.

+ Confidential treatment granted as to certain portions.

\* Management contract or compensatory plan or arrangement filed in response to Item 14(a)(3) of the instructions to Form 10-K.

- (1) Incorporated herein by reference from the Company's Form S-4 dated April 10, 2001 (File No. 333-53386).
- (2) Incorporated herein by reference from the Company's Form 8-K dated July 18, 2000.
- (3) Incorporated herein by reference to the Company's Form 8-K filed on December 10, 2001.
- (4) Incorporated herein by reference to the Company's Registration Statement on Form S-1, as amended (File No. 333-02144).
- (5) Incorporated herein by reference to the Company's Registration Statement on Form S-4, as amended (File No. 333-53386).

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- (6) Incorporated herein by reference to the Company's Definitive Proxy Statement for the 1999 Annual Meeting of Stockholders filed on Schedule 14A.
- (7) Incorporated herein by reference to the Company's Form 10-K for the year ended December 31, 2000.
- (8) Incorporated herein by reference to the Company's Form 10-K for the year ended December 31, 1999.

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- (9) Incorporated herein by reference to the Company's Form 10-Q for the quarter ended September 30, 1996.
- (10) Incorporated herein by reference to the Company's Form 10-Q for the quarter ended June 30, 1998.
- (11) Incorporated herein by reference to the Company's Form 10-Q for the quarter ended September 30, 1999.
- (12) Incorporated herein by reference to the Company's Form 10-Q for the quarter ended September 30, 2000.
- (13) Incorporated herein by reference to the exhibit filed with MedImmune, Inc.'s Quarterly Report on Form 10-Q for the quarter ended September 30, 1997.
- (14) Incorporated herein by reference to the Company's Current Report on Form 8-K dated March 9, 2001
- (15) Incorporated herein by reference to the Company's Form 10-Q for the quarter ended March 31, 2001.
- (16) Incorporated herein by reference to the Company's Form 10-Q for the quarter ended June 30, 2001.
- (17) Incorporated herein by reference to the Company's Current Report on Form 10-Q for the quarter ended September 30, 2001.

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