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BIOTRANSPLANT INC  
Form 10-K/A  
June 29, 2001

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SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549  
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FORM 10-K/A

AMENDMENT NO. 2 TO 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, 2000  
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

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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 \$44,937,925 based on the last reported sale price of the Common Stock on the Nasdaq consolidated transaction reporting system on March 21, 2001.

Number of shares of the registrant's class of Common Stock outstanding as of March 21, 2001: 11,795,120.

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This Amendment No. 2 on Form 10-K/A to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2000 is being filed to reflect the Registrant's June 2001 financing and to provide a report of the Registrant's independent public accountants for fiscal 2000 that, as a result of the June 2001 financing, is not subject to a going concern contingency.

In connection with the June 2001 financing, the Registrant was required to register for resale the shares of common stock that it sold in the financing. As a part of the registration process, the Registrant requested that its independent public accountants reissue its report for fiscal 2000. The Registrant's independent public accountants have, as a result of the June 2001 financing, issued a report for fiscal 2000 that is not subject to a going concern contingency and this report is filed with this Amendment No. 2 on Form 10-K/A. The Registrant is also amending the "Business" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of the Form 10-K to reflect the June 2001 financing.

Items 1, 7, 8 and 14 of the Registrant's Annual Report on Form 10-K are hereby amended and restated as follows:

ITEM 1. BUSINESS

COMPANY OVERVIEW

BioTransplant is developing pharmaceutical products and systems to enable the body's immune system to better tolerate the transplantation of foreign cells, tissues and organs. Our lead product, MEDI-507, is being developed in collaboration with MedImmune, Inc. We are also independently developing other proprietary technology, which we refer to as ImmunoCognance technology, which is based upon mixing elements of a donor's immune system with that of a patient in a manner that enables the patient to recognize the donor's tissues as if those foreign tissues belonged to the patient. We believe that our ImmunoCognance

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technology will have the following benefits when compared to current technologies:

- improve clinical outcomes in bone marrow transplantation for cancer and other diseases;
- reduce or eliminate the need for long-term administration of potentially debilitating immunosuppressive drugs to a patient after a transplantation procedure;
- minimize infections and health complications that may result from conventional therapies used in connection with the transplantation of foreign cells, tissues and organs;
- reduce the cost of treating end-stage organ disease; and
- increase the supply of cells, tissues and organs available for transplantation procedures.

Based upon our ImmunoCognance technology, we are developing a portfolio of products designed to improve therapies associated with organ and bone marrow transplantation as well as to improve the treatment of cancer, autoimmune diseases and blood disorders. Our AlloMune System for Cancer is currently in a multi-center Phase I/II clinical trial for therapy-resistant lymphoma, and we anticipate filing an investigational new drug application in 2001 for a Phase I clinical trial in patients with advanced melanoma and kidney cell tumors. We expect that Phase I clinical studies of our AlloMune System for Transplantation for human kidney transplantation will begin in 2001.

In September 2000, we and Novartis Pharma AG formed a new company, Immerge BioTherapeutics AG, to conduct further research in the area of xenotransplantation, which is the transplantation of cells, tissues and organs from one species to another. We and Novartis contributed our respective technology and intellectual property to Immerge. Novartis owns 67% of Immerge, and we own 33%. See "--Collaborations and Agreements--Novartis/BioTransplant Joint Venture."

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We are working with MedImmune in the development of MEDI-507. We have exclusively licensed MEDI-507 to MedImmune as a stand-alone agent, and we are entitled to royalties on the sale of the drug, as well as milestone payments for the achievement of specific product-related milestones. MEDI-507 is currently in Phase II clinical trials for the treatment of psoriasis. MedImmune has completed Phase I/II trials for graft-versus-host disease, an often fatal outcome of bone marrow transplantation procedures.

In addition to our corporate collaboration with MedImmune and our joint venture with Novartis, we are collaborating with a number of other organizations, including the Massachusetts General Hospital, in the field of cell, tissue and organ transplantation.

We believe that we have built a strong patent portfolio relating to our technology. As of February 28, 2001, we owned or had licensed 37 issued United States patents and 39 allowed or pending United States patent applications, as well as applications for foreign patents.

### RECENT DEVELOPMENT

On December 8, 2000, we entered into a definitive agreement to acquire Eligix, Inc. Upon consummation of the merger, Eligix will become a wholly-owned subsidiary. Under the terms of the merger, we will issue up to 5,610,000 shares

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of our common stock in exchange for the fully-diluted common stock of Eligix and 990,000 shares of our common stock to members of Eligix management. The merger is expected to close in the second quarter of 2001, subject to the satisfaction of closing conditions, including BioTransplant and Eligix stockholder approval. For a description of Eligix' business, see "--Information Concerning Eligix" on page 19.

We have entered into a promissory note with Eligix whereby Eligix will borrow up to \$2.0 million to fund operations through the closing date of the merger. The loan bears interest at the prime rate. Upon consummation of the merger, the loan will be forgiven, provided that if the merger does not close on or before June 30, 2001, the note will become immediately due and payable in full.

### INDUSTRY OVERVIEW

#### TRANSPLANTATION BIOLOGY

The immune system is one of the major biological defense mechanisms protecting an individual against disease and invasion by disease-carrying agents, referred to as pathogens. In the context of 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 clear and destroy the cells carrying the foreign, non-self 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 are different from those of the recipient. If, as in the case of identical twins, the antigens of the donor and the recipient are identical, no rejection response occurs. In all other cases, differences between antigens can provide sufficient stimulus to cause an immune response and, consequently, rejection of the cell, tissue or organ.

Throughout an individual's life, the immune system reacts to foreign antigens and develops white blood cells known as T cells that are capable of recognizing and responding to specific foreign antigens. T cells learn to distinguish self from non-self when they mature in a specialized organ called the thymus. This maturation step induces tolerance to the individual's own antigens. When mature antigen-specific T cells recognize antigens in transplanted tissue, they become activated and initiate a cascade of events, including the proliferation of T cells and another type of white blood cell, known as B cells.

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Certain activated T cells can kill cells bearing foreign antigens and B cells are capable of producing antigen-specific proteins called antibodies. Antibodies can bind to foreign cells or proteins and lead to their destruction or clearance from the body.

There are two primary types of immune response to transplanted foreign tissue--hyperacute and acute rejection. Hyperacute rejection occurs immediately upon transplantation and results from the reactivity of pre-existing antibodies with antigens presented by the donor tissue. In hyperacute rejection, the donor cell, tissue or organ is destroyed within hours and no treatment is currently available. Acute rejection occurs after transplantation of a cell, tissue or organ when T cells recognize the antigens of the donor as foreign, become activated and, over a period of days or weeks, initiate a rejection response

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that may lead to the ultimate loss of the cell, tissue or organ. Approximately 50% of organ transplant patients will experience an acute rejection episode in the first year after transplantation.

The current approach to preventing acute 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. Most importantly, despite the administration of various immunosuppressive medications, instances of rejection still occur frequently and may necessitate increased doses of immunosuppressive drugs or inclusion of other anti-rejection therapies, thus compounding unwanted side effects and complications. If the rejection cannot be controlled, the rejected cell, tissue or organ must be removed and another transplant will be required.

### BONE MARROW TRANSPLANTATION

Bone marrow contains cells, referred to as stem cells, which 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. Because it is often easier to collect the stem cells from blood rather than bone marrow, a donor can be treated with chemical agents that induce the stem cells to migrate from the bone marrow into the blood. Thus, the same effect can be achieved by transplanting either bone marrow or blood from pretreated individuals. For simplicity, we use the term bone marrow transplantation to refer to the transplantation of stem cells from either bone marrow or blood.

Bone marrow transplantation is used as a treatment for:

- a number of cancers, including:
  - kidney cell tumors,
  - breast tumors,
  - certain childhood cancers, such as Ewing's sarcoma, and
  - hematologic, or blood cell, cancers such as acute and chronic leukemia, lymphoma, and multiple myeloma;
- certain congenital immune system deficiencies; and
- bone marrow failure, referred to as aplastic anemia.

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Researchers are also investigating experimentally bone marrow transplantation for:

- the treatment of a number of metabolic diseases, such as Hurler's syndrome;
- genetic disorders, such as sickle cell anemia and thalassemia; and

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- severe autoimmune diseases, such as therapy-resistant psoriasis and rheumatoid arthritis.

There are two types of bone marrow transplantation that are currently performed: autologous bone marrow transplantation and allogeneic bone marrow transplantation.

**AUTOLOGOUS BONE MARROW TRANSPLANTATION.** In autologous transplantation, doctors treat the patient with high-dose chemotherapy to kill the tumor, and use the patient's own bone marrow cells, harvested prior to administration of the chemotherapy, to reconstitute the patient's bone marrow cells following the chemotherapy treatment. In autologous transplantation, the goal of administration of the bone marrow that had been harvested prior to the chemotherapy is to overcome the damage to the patient's bone marrow that occurs during the chemotherapy.

**ALLOGENEIC BONE MARROW TRANSPLANTATION.** In allogeneic transplantation, the patient receives transplanted bone marrow cells harvested from a healthy donor. In allogeneic transplantation for cancer, not only does the bone marrow transplantation overcome the damage that the chemotherapy causes to the bone marrow, but the transplanted donor immune cells also may be capable of eradicating the patient's tumor. In allogeneic transplantation for metabolic diseases and genetic disorders, the infusion of donor cells allows for the recovery of healthy, metabolically normal donor cells to replace the recipient's genetic defects. In autoimmune disease, the body's immune response becomes abnormal in that it mistakenly recognizes its own cells or tissues as non-self. For allogeneic transplantation for severe autoimmune disease, the goal is to ablate, or destroy, the patient's malfunctioning immune system and replace it with the donor immune system. We expect this treatment to result in the patient's reconstituted immune system ceasing to recognize its own cells or tissues as non-self and tolerating them.

In conventional autologous or allogeneic bone marrow transplantation, patients first undergo a pre-transplant process called ablation in which their diseased bone marrow is destroyed by either intense radiation or chemotherapy, essentially wiping out their immune system. More recently, milder conditioning regimens have been introduced to minimize the damage of the chemotherapy. The use of milder, non-ablative preparatory regimens has expanded the group of patients eligible for bone marrow transplantation.

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 from minor antigen differences between donor and recipient as well as from the side effects caused by the treatments used to overcome these differences. Graft-versus-host disease is a potentially fatal complication of allogeneic transplantation in which the donor cells, once transplanted in the patient, recognize the patient as non-self, and attack the patient's normal tissues, such as the skin, gastrointestinal track and liver. Moderately severe to life-threatening acute graft-versus-host disease occurs in 10 to 50% of patients given an allogeneic transplantation from a tissue-matched sibling donor. A significantly higher incidence and severity of the disease is reported in patients receiving transplants from partially matched family donors or unrelated volunteers. The treatment for graft-versus-host disease includes steroids and other immunosuppressive drugs. However, up to 50% of patients do not respond to steroids and other currently-available immunosuppressants, and a significant number of these patients will die as a result of the graft-versus-host disease.

To minimize the possibility of graft-versus-host disease, typically only patients who have closely genetically matched donors are considered suitable

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candidates for allogeneic bone marrow

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transplantation. The likelihood of having a perfectly matched donor is only approximately 1%, which is the approximate rate of identical twin births in the United States. Statistically, the likelihood of any sibling being a full tissue match is 25%, and there is approximately an additional 5% likelihood of finding a full tissue matched relative in the extended family. Thus, there is approximately a 30% chance of finding a suitably matched donor in the family, where suitability is defined as being an appropriate donor for a conventional transplant. Because of the difficulty in locating a fully tissue matched bone marrow donor, many patients are unable to undergo the bone marrow transplantation procedure.

### ORGAN TRANSPLANTATION

During the last two decades organ transplantation has become an established therapy for end-stage organ disease due in part to the significant progress that has been made since the introduction of cyclosporine by Novartis in 1983. In 1999, over 30,000 organ transplants were performed in patients suffering from end-stage kidney, liver, heart 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 organ transplantation. However, rejection of the transplanted organ by the recipient's immune system frequently limits the success of these procedures. To prevent rejection of the transplanted organ, recipients must maintain a lifelong regimen of immunosuppressive therapy. 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. Other treatments for end-stage organ disease, such as kidney dialysis, are even more expensive. While dialysis is an option for the treatment of kidney failure, many non-kidney transplant patients die while waiting for organs. Accordingly, we expect that improvements in transplantation technology that reduce the wait for suitable organs and minimize infections and other complications, including retransplantation and the toxicities associated with chronic use of immunosuppressive drugs, will lower the overall cost of treating end-stage organ disease.

There is a critical shortage of organs worldwide and waiting lists have been established for potential organ transplant recipients. Over 74,000 patients in the United States suffering from end-stage organ disease were on waiting lists for a lifesaving organ transplant in 2000, based on data provided by the United Network for Organ Sharing. This number has more than quadrupled since 1988, and the number of deaths on the waiting list has increased proportionately. 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 treating end-stage organ disease by using organ transplantation to replace disease-damaged organs instead of using artificial devices.

While the number of cadaver donors has increased in the last ten years, the demand for organs has increased even more rapidly. Efforts to ease this organ shortage through public campaigns and advertisements designed to enlarge the pool of potential organ donors have been only moderately successful. Increased automotive safety has adversely affected the donation rate by reducing the number of deaths resulting from automobile accidents. In addition, we believe the decline in the quality of organs available for transplant may reduce organ graft half-lives, thereby increasing the need for additional organs to be used in repeated transplantation procedures. The potential donor pool has also been limited by the risk that allotransplantation, which is the transplantation of

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organs between different individuals of the same species, can spread infectious disease. Advances have been made in the procedures used to obtain multiple organs from a single donor and in organ preservation techniques, but a severe shortage of organs still exists and the backlog of patients awaiting transplantation continues to grow. The shortage of donor organs restricts the number of transplant procedures performed and forces many patients to undergo costly and less effective alternatives to transplantation. This delay renders transplant candidates much sicker at the time of transplantation than they would have been if the organ transplant had been possible sooner.

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### PRODUCTS UNDER DEVELOPMENT

The following table summarizes the status of our, and our collaborator's and joint venture's, product research and development programs:

PRODUCT UNDER DEVELOPMENT	INDICATION	STATUS*	COLLABORATOR
MEDI-507.....	Psoriasis	Phase II	MedImmune
	Graft-Versus-Host Disease	Phase I/II	MedImmune
ALLOMUNE SYSTEM FOR CANCER.....	Lymphoma	Phase I/II	None
	Kidney Cell Tumors	Investigational new drug application in preparation	None
	Melanoma	Investigational new drug application in preparation	None
	Other cancers	Preclinical	None
ALLOMUNE SYSTEM FOR TRANSPLANTATION.....	Kidney Transplantation	Phase I	None
	Congenital Blood Disorders	Preclinical	None
	Autoimmune Diseases	Preclinical	None
	Metabolic Diseases	Preclinical	None
XENOTRANSPLANTATION.....	Animal to Human Transplantation	Preclinical	Joint Venture with Novartis

\* Preclinical means that the product is being evaluated or optimized in animal models. Phase I means an investigational new drug application, or IND, has been filed with the United States Food and Drug Administration and that the product candidate is in clinical trials to evaluate safety. Phase I/II means that the product candidate is in clinical trials for safety and potential efficacy.

#### MEDI-507

MEDI-507 is a novel and proprietary humanized monoclonal antibody derived from the BII-322 monoclonal antibody. A monoclonal antibody is a single antibody that reacts to a specific antigen and can trigger or block an immune response. Drs. Herve Bazin and Dominique Latinne of the Experimental Immunology Unit of



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the Catholic University of Louvain, Belgium, discovered the BTI-322 monoclonal antibody, the rodent precursor of MEDI-507. In early 1993, we obtained exclusive rights to develop and commercialize the BTI-322 monoclonal antibody. We modified the BTI-322 monoclonal antibody to create MEDI-507, a molecule more similar to a human antibody, and in 1995 we formed a collaboration with MedImmune to develop and commercialize products derived from MEDI-507. We are also independently developing MEDI-507 as an important component of our AlloMune System and have sublicensed to our joint venture with Novartis our rights to develop MEDI-507 as part of a xenotransplantation system.

MedImmune is focusing its initial development efforts with MEDI-507 for the treatment of psoriasis and graft-versus-host disease. In psoriasis, an autoimmune response leads to chronic inflammation and hyperproliferating skin, as well as other more serious consequences. Graft-versus-host disease is an often fatal outcome of bone marrow transplantation where white blood cells from the donor bone marrow attack the tissue of the recipient.

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We believe that MEDI-507 could be used to reduce undesired immune system activity by binding to CD2, which is a receptor found on T cells. T cells are immune cells that act as the agents of the immune system and are responsible for part of the body's primary immune response to foreign antigens. When these immune cells come in contact with foreign tissue, they become activated and proliferate. The immune cells then attack and destroy the targeted foreign tissue, or in the case of autoimmune disease, mistakenly attack the body's own tissue. The theory behind MEDI-507's development plan is tied to its ability to bind to the T cell and block activation of these cells. We expect that through this process, MEDI-507 can either turn off the T cells completely or selectively eliminate them from the body, while allowing other immune cells to respond normally to other antigens.

Clinical studies conducted by us and by others have demonstrated that MEDI-507 has the potential to be a safe and effective agent for the prevention and treatment of graft-versus-host disease, as well as transplant rejection. For example, during 1999, MedImmune concluded a multicenter Phase I/II trial of MEDI-507 in patients with severe acute graft-versus-host disease who had failed previous treatment with corticosteroids, the most commonly used initial treatment in this patient population. Seventeen patients with moderate to severe graft-versus-host disease were given four doses of MEDI-507. Over the 100-day observation period, 71 percent of the patients experienced a reduction in grade of graft-versus-host disease; over half of the patients resolved their disease at some point during the follow up.

MedImmune is currently conducting additional Phase I/II clinical trials to evaluate MEDI-507 for the treatment of graft-versus-host disease. One study of this type, which was completed in 2000, examined the effect of adding MEDI-507 to conventional steroid treatment at the onset of graft-versus-host disease. In this study, 34 adult patients who developed severe acute graft-versus-host disease following a stem cell transplant or bone marrow transplant were treated with steroids in addition to either four doses of MEDI-507 or a placebo. The results demonstrated that the addition of MEDI-507 to steroid treatment at the onset of graft-versus-host disease was well tolerated. In another study, MedImmune is using an open label trial to assess the ability of MEDI-507 to treat graft-versus-host disease in pediatric stem cell transplant or bone marrow transplant patients. Currently, there are no agents approved for the treatment of graft-versus-host disease in children. MedImmune did not design these initial clinical trials to allow retreatment of the patient with MEDI-507.

We believe that MEDI-507 may also be effective in treating T cell mediated diseases such as psoriasis, inflammatory bowel disease, multiple sclerosis and rheumatoid arthritis. Presently, MedImmune has completed a Phase I clinical

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trial evaluating MEDI-507 and is conducting two Phase II clinical trials for the treatment of psoriasis as a proof-of-concept for its use in autoimmune disease. The results of the Phase I study showed that MEDI-507 was well tolerated by the patients.

In 1998, MedImmune received orphan drug designation from the Office of Orphan Products Development of the FDA for the use of MEDI-507 in the treatment of graft-versus-host disease. Congress enacted the Orphan Drug Act to encourage development of drugs for rare diseases and conditions affecting a small patient population, generally less than 200,000 people. Orphan drug designation of a product can potentially provide a company with seven years of market exclusivity if the company is the first to receive FDA product marketing approval for the orphan drug in the designated indication. Additionally, this designation provides a company with tax credits of 50% for clinical research expenses and the opportunity for clinical research grants.

### ALLOMUNE SYSTEMS

We are designing our AlloMune Systems to re-educate a patient's immune system so that it does not reject transplanted cells, tissues and organs. We are currently evaluating the use of our AlloMune Systems in the treatment of blood cell cancers and to reduce the need for lifelong immunosuppressive therapy in connection with human organ transplants.

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The AlloMune System is a proprietary system that we are developing to incorporate multiple components. We are designing it to allow a milder procedure for allogeneic bone marrow transplantation and to reduce or eliminate the need for lifelong immunosuppressive therapy in human-to-human organ transplantation. Because the AlloMune System is expected to be suitable for elderly and relatively infirm patients, as well as patients without tissue-matched donors, we expect that it will enable a significantly expanded pool of patients to be considered for transplantation. We expect that the AlloMune System will expand the pool of eligible transplantation recipients by reprogramming the immune system to recognize donor and patient as self, thereby overcoming the complications that result when the patient or the donor recognizes the other's cells, tissues and organs as non-self. This reprogramming of the immune system is expected to be created by establishing a state of mixed bone marrow chimerism between the donor and the patient with the use of MEDI-507.

Mixed bone marrow chimerism refers to bone marrow in which the cells of both the donor and the patient co-exist. 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 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, in the case of cancer patients, chemotherapy, 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 and others have conducted studies that demonstrate that the creation of the 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 the cancer cells rather than the patient's own cells.

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ALLOMUNE SYSTEM FOR CANCER. We are developing our AlloMune System to treat several types of blood cancers, such as lymphomas, leukemias and myelomas, as well as other malignancies such as kidney cell tumors, melanoma and other cancers. We are designing our AlloMune System for Cancer to re-program a patient's immune defenses so that the patient can benefit from potentially life saving bone marrow transplantation. By using a combination of chemotherapy and the AlloMune System, we are seeking to make bone marrow transplants more successful by allowing the transplanted bone marrow to aggressively attack cancer cells but not the patient's own immune defenses, and without the side effects of graft-versus-host disease or the morbidity caused by destroying the patient's own bone marrow, as is done in conventional bone marrow transplants.

We are designing the AlloMune System for Cancer to employ a less-intensive, non-ablative amount of chemotherapy, which we believe will increase the types of disease conditions that can be treated, as well as patients' ability to tolerate the treatment. We believe that doctors can administer this regimen safely to patients who, because of their age or concomitant other medical problems, would not have been suitable transplant candidates with ablative regimens.

In 1999, our research collaborator, Massachusetts General Hospital, performed a study under an investigational new drug application using a prototype of the AlloMune System for Cancer with 21 patients having therapy-resistant blood cancers, including lymphomas. Results of the study demonstrated that treatment led to an overall positive response rate of 67% (38% complete response, 29% partial response). In a recent extension of that study, Massachusetts General Hospital demonstrated the feasibility of using this prototype AlloMune System for transplantation using donors who were not fully tissue matched.

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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 expect to complete our Phase I/II clinical trial in late 2001. We are planning to file an investigational new drug application and begin studies in patients with solid tumors in 2001.

ALLOMUNE SYSTEM FOR TRANSPLANTATION. We are also developing the AlloMune System for Transplantation to re-program the patient's immune system to accept a transplanted donor organ without the need for life-long immunosuppressive therapy. During 1999, we received clearance of an investigational new drug application with the FDA to begin a Phase I clinical trial of the AlloMune System for Transplantation in living-donor kidney transplantation. Recent results from our cancer clinical studies have led us to make changes to the protocol for this Phase I clinical trial.

Our academic collaborators at the Massachusetts General Hospital have initiated a hospital internal review board-approved Phase I/II proof-of-principle evaluation of the prototype AlloMune System for transplantation in humans. Physicians at Massachusetts General Hospital treated the initial patient under the investigational new drug application for myeloma, a blood cell cancer, and end-stage kidney disease using a prototype AlloMune System approach. The patient received both a kidney transplant and a bone marrow transplant more than two years ago. The patient has been free of immunosuppressive drugs for nearly two years and has normal kidney function, no evidence of graft-versus-host disease, and her myeloma is at nearly undetectable levels.

### XENOTRANSPLANTATION

Xenotransplantation refers to the transplantation of cells, tissues or organs from one species to another. Xenotransplantation is intended to address

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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. Since 1993, we have collaborated with Novartis to research and develop xenotransplantation products.

In September 2000, we entered into a joint venture with Novartis 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. This joint venture 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 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 the Massachusetts General Hospital. 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 reprogram the recipient's immune system to recognize the donor tissue as self.

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Our objective is to extend the current survival times for swine organs transplanted into primates from approximately one month post-transplant to three to six months by destroying the pre-existing antibody-producing cells in combination with pig thymus tissue transplantation. We refer to this process as transplantation tolerance. Previous studies have demonstrated the ability of porcine, or pig, thymic tissue transplanted into a mouse to induce transplantation tolerance. In these studies, researchers documented permanent acceptance of pig skin transplants in mice with an otherwise normal immune system and specific T cell unresponsiveness to pig antigens in culture. Allogeneic large animal studies using inbred miniature swine have also demonstrated the ability of allogeneic pig thymic transplants to induce tolerance to kidney grafts from the donor of the thymic tissue in the absence of chronic immunosuppressive drug use.

- Second, the joint venture will continue studies begun by us to examine the safety of porcine to human xenotransplantation. Others have demonstrated that a type of porcine viruses, referred to as porcine endogenous retroviruses, have the potential to infect human cells. We previously reported on the results of studies that documented the ability of one strain of miniature swine to be free of the porcine endogenous retrovirus types that have been shown to be capable of infecting human cells in culture.
- Third, the joint venture will focus on adapting recent successes in porcine nuclear transfer technology in which a genetically modified

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miniature swine has been cloned with modifications that are believed to enhance the survival rates of porcine organs in primates.

### COLLABORATIONS AND AGREEMENTS

As part of our strategy, we have established alliances with pharmaceutical and other biotechnology companies, academic institutions, scientists and government laboratories. Since inception, substantially all of our revenues have been derived from our strategic alliances. For the fiscal year ended December 31, 2000, revenues from our strategic alliance with Novartis accounted for all of our revenues. 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 rejection. 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 allotransplantation. 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 depend, in part, 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.

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#### DR. DAVID H. SACHS/THE MASSACHUSETTS GENERAL HOSPITAL

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.

#### 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,

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Immerge BioTherapeutics AG, and terminated our prior collaborations in xenotransplantation.

Novartis has committed to provide an aggregate of \$30.0 million in research funding over three years to the joint venture. 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 expects to enter into a contract research agreement with us, under which we will commit approximately 20 full-time employees to perform research for the joint venture and we will also agree to provide administrative services for the joint venture, all at a rate to be negotiated.

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. 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. 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 the joint venture will have exclusive rights to use miniature swine that Charles River Laboratories is developing for use in the allotransplantation and xenotransplantation programs, respectively. The joint venture and BioTransplant will bear their 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 five-year period.

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### STEM CELL SCIENCES LTD.

According to the terms of a strategic alliance with Stem Cell Sciences Ltd., our joint venture with Novartis 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. We have made equity investments in Stem Cell Sciences that represented 30% 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. We made additional investments in Stem Cell Sciences in 1996, 1997 and 1998 to maintain our 30% ownership position and to support additional research through December 31, 1999. Stem Cell Sciences raised additional equity during 2000, resulting in a dilution of our ownership to approximately 25%.

### ALBERTA RESEARCH COUNCIL

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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 expect to exclusively sublicense our rights under this agreement to our joint venture with Novartis. 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 a non-exclusive, worldwide, royalty-bearing license to use any of its information, data, formulas or processing information that pertain to the manufacture, development or use of any products resulting from the licensed patents in the field of xenotransplantation.

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

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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.

### MANUFACTURING AND SUPPLY

We currently have no manufacturing facilities or staff for clinical or commercial production of any products or systems under development. We plan to rely initially on third parties to manufacture our product candidates for research, preclinical testing, clinical trials and commercialization, if any, with a long-term objective to develop internal manufacturing capability where

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appropriate.

MedImmune is manufacturing supplies of MEDI-507 required for preclinical studies, clinical trials and commercial products using its own manufacturing facilities. We have the option to continue to use MedImmune as a supplier or to use an alternative manufacturer or supplier.

Novartis has exclusive worldwide rights to manufacture xenotransplantation products arising from the research program conducted by our joint venture with Novartis.

### SALES AND MARKETING

Due to the early stage of our development efforts, we presently have no marketing or sales personnel.

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 allotransplantation.

We currently hold all marketing rights to the AlloMune System, although we may seek a corporate partner to support the development and commercialization of the AlloMune System. In the United States, we currently intend to market the AlloMune System for solid organ transplantation and cancer related products and systems 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 intend to hire a limited number of sales and marketing personnel. 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.

Novartis has exclusive worldwide rights to market and sell xenotransplantation products arising from the research program conducted by our joint venture with Novartis.

### RESEARCH AND DEVELOPMENT

We estimate that our total Company-sponsored research and development expenses were approximately \$14.7 million, \$15.7 million and \$15.0 million for 1998, 1999 and 2000, respectively. We estimate that collaborator-sponsored research and development expenses were approximately \$6.7 million, \$5.2 million and \$4.6 million for 1998, 1999 and 2000, respectively.

### PATENTS AND PROPRIETARY RIGHTS

As of February 28, 2001, we owned or had been licensed 37 issued United States patents and 39 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.



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We are aware of granted patents that claim monoclonal antibodies that bind to T cells. Johnson & Johnson, which manufactures and sells OKT3, a T cell-binding monoclonal antibody, owns these patents. We believe that the BTI-322 monoclonal antibody is distinguishable from other monoclonal antibodies claimed in Johnson & Johnson's patents, and does not infringe these patents either literally or under the doctrine of equivalents.

We have reviewed issued patents which 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 which 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. For example, the development of superior immunosuppressant therapeutics, mechanical organ systems and other improvements in therapies for end-stage organ disease could adversely affect the size of our available markets. We are aware that Chimeric Therapies, Inc. plans to develop mixed bone marrow chimerism to include tolerance for allogeneic solid organ and bone marrow transplants. In addition, we are aware of other companies that are pursuing research and development of alternative products or technologies addressing the same disease categories as our development programs. In particular, there are several commercially available anti-rejection drugs that may compete with the MEDI-507 product under development, including:

- OKT3 (marketed by Ortho Biotech, Inc, a subsidiary of Johnson & Johnson);
- ATGAM (marketed by Pharmacia Upjohn);
- ThymoGlobulin-Registered Trademark- (marketed by SangStat Medical Corporation);
- Zenapax-Registered Trademark- (marketed by Roche Laboratories); and
- Simulect-Registered Trademark- (marketed by Novartis).

To the extent that these therapeutics address the problems associated with 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

testing pharmaceutical and other therapeutic products and obtaining FDA and other regulatory approvals of products for use in health care. Accordingly, our competitors may succeed more rapidly than we will in obtaining FDA approval 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 in our industry 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.

#### GOVERNMENT REGULATION

The development and commercialization of our products will be subject to regulation in the United States by numerous regulatory authorities including the Federal Food and Drug Administration and Federal Trade Commission 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 and clinical testing, safety, effectiveness, approval, clearance, manufacturing, labeling, packaging, export, storage, recordkeeping, adverse event reporting, and promotion and advertising of our products.

We will require FDA approval or clearance 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. However, biological products are also drugs and must meet drug standards under the Federal Food, Drug and Cosmetics Act. These federal drug standards include good manufacturing practices regulations and regulations governing clinical trials.

The manufacture of xenograft products for human transplantation can be expected to raise issues concerning both the safety and effectiveness of the products and compliance with and further development of standards for good manufacturing practices of these products. The Public Health Service published draft guidance in 1996 on infectious disease issues related to xenotransplantation and in 1999 on the infectious disease implication of blood donation from recipients of xenotransplants. In January 1998, PHS held a public meeting on emerging policy issues, but final guidance and/or regulations do not

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yet exist. 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.

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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. If a product is found to be reasonably safe and potentially effective in preclinical trials, the next step in the process is human clinical trials. 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 and allowed to become effective by the agency before clinical trials may begin. There can be no assurance that submission of an investigational new drug application will result in the ability to commence clinical trials. In addition, the FDA may place a clinical trial on hold or terminate it if, among other reasons, it concludes that clinical subjects are being exposed to an unacceptable health risk.

Clinical trials typically involve three phases, although those phases can overlap:

PHASE I. 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. Phase I studies may also evaluate various routes, dosages and schedules of product administration.

PHASE II. If acceptable product safety is demonstrated in Phase I, Phase II studies are initiated. In 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. If Phase II studies yield satisfactory results and no hold is placed on further studies by the FDA, Phase III studies begin. 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.

It is not possible to estimate the time in which Phase I, II and III studies will be completed with respect to a given product, if at all, and the time period may last as long as several years.

Following completion of clinical investigations, the preclinical and clinical data that have been accumulated, together with chemistry, manufacturing and controls specifications and information, are submitted to the FDA in a biologics license application. To approve a product regulated under a biologics license application, 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. There can be no assurance that the FDA will approve a product in a timely manner, if at all. The approval process can be very lengthy and depends, among other things, upon the time it takes to review the submitted data, the FDA's comments on the application and the time required for us to provide satisfactory answers or additional clinical data if requested.

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If the FDA approves a biologics license application, 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. Changes to approved biological products that affect safety or effectiveness require approved supplemental applications, as do changes in manufacturing that have a substantial potential to adversely affect product safety or effectiveness. These supplemental applications may require the submission of clinical or comparability data and must be approved before the product may be marketed as modified.

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In addition, the nature of marketing claims that the FDA will permit us to make in the labeling and advertising of our products will be limited to those specified in an FDA clearance or approval, and claims exceeding those that are cleared or approved will constitute a violation of the FDA's Food, Drug and Cosmetics Act. Violations of the Food, Drug and Cosmetics Act or regulatory requirements at any time during the product development process, approval process or after approval may result in agency enforcement actions, including recall, license suspension or revocation, 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. FTC enforcement can result in orders requiring, among other things, limits on advertising, corrective advertising, consumer redress and rescission of contracts. Violations of FTC enforcement orders can result in substantial fines or other penalties.

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 System. In addition, orphan drug exclusivity can be terminated for a number of reasons, including that the manufacturer cannot provide an adequate supply of the drug.

We also face several regulatory obstacles in the European Union. 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

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United States to any foreign country or territory, applicable FDA export requirements must be met.

### EMPLOYEES

As of December 31, 2000, we had 62 full-time employees, 50 of whom were engaged in research, development, clinical and quality assurance/quality control activities. Of our full time employees, we expect that approximately 20 will 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.

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### INFORMATION CONCERNING ELIGIX

On December 8, 2000, we entered into a definitive agreement to acquire Eligix. The merger is expected to close in the second quarter of 2001, subject to the satisfaction of closing conditions, including BioTransplant and Eligix stockholder approval.

Eligix is a biomedical company engaged in the research and development of cellular therapies to enhance human immune response to cancers, autoimmune disorders and solid organ transplants and to reduce the risk of infection and hypersensitivity reactions in blood transfusions. Eligix' technology is the result of research at Coulter Corporation, in collaboration with physicians at Harvard University's Dana-Farber Cancer Institute.

Eligix' patented High Density Microparticles, or HDM, technology, in conjunction with its portfolio of blood and immune cell-specific and tumor cell-specific monoclonal antibodies is designed to enable the highly efficient selection and/or immune activation of specific populations of human cells from blood and bone marrow. Eligix is pursuing research and development of high density microparticle products for:

- the removal of malignant cells from stem cell transplants;
- the removal of immune rejection-causing cells from stem cell transplants and immune cell infusions;
- the removal of potentially infectious cells from blood transfusions; and
- the selection and activation of disease-specific immune cells to enhance a patient's immune response to disease.

Eligix' lead product candidates, BCell-HDM and TCell-HDM, will target bone marrow and stem cell transplant procedures. Sources estimate that there are approximately 44,000 bone marrow and stem cell transplant procedures performed annually in Europe and the U.S. Eligix is targeting these products for the purging of stem cell transplants and related blood products to reduce the risk of relapse or graft-versus-host disease following bone marrow stem cell transplantation or donor leukocyte infusion therapy for cancer and other diseases, including autoimmune and genetic disorders. Eligix' BCell-HDM product received CE mark approval in February 2001, and Eligix is currently preparing its TCell-HDM product for CE marking. CE mark approval indicates compliance with European standards for safety and allows certified products to be marketed and sold in Europe. Eligix expects to receive the CE mark for its TCell-HDM product by December 31, 2001, permitting near-term introduction of the products into the European market. In the U.S., both products are poised to enter pivotal trials.

Eligix is pursuing research and development of other product candidates,

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including PanT-HDM, BrCa-HDM, Neu/RBC-HDM, React-HDM, ActCell-HDM, Act-IV and Leuko-HDM, that will target the bone marrow and stem cell transplant market as well as solid organ transplants and blood collection procedures. Sources estimate that there are approximately 30,000 solid organ transplants performed annually in the United States and Western Europe and 70 million blood collection procedures performed annually worldwide. Eligix is also targeting what it believes to be significant long-term opportunities in ex vivo and in vivo immune therapies for cancer, autoimmune disorders and infectious disease. These products are targeted for the following:

- removal of potential relapse-causing cancer or autoimmune cells from autologous bone marrow stem cell transplants;
- the removal of T cells and T cell subsets which cause graft-versus-host disease in mismatched transplants;
- the removal of disease-causing cells and pathogens from blood transfusions;

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- 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 tolerization to prevent chronic immune rejection and resultant organ failure in solid organ and tissue transplants.

Eligix believes that its focus on approaches to providing the patient with a normal immune system to mount an effective attack against malignancies is likely to improve patient outcomes and reduce disease relapse rates, while enhancing overall cost effectiveness. Eligix expects its technology under development to facilitate new approaches in transplantation with minimal toxicity, including "mini" transplants to eliminate the risks of myeloablative therapy, donor leukocyte infusions following allogeneic transplants to enhance immune response against cancer, and the enablement of successful transplants between tissue mismatched donors and patients.

Eligix intends to build value by product development and timely commercialization to meet significant, unmet clinical needs representing high therapeutic value in established areas of medicine, focusing on promising technologies to improve human immune response. To advance its products, Eligix has recruited and trained a qualified technical and management team with expertise in biochemistry, cell biology, immunology, protein chemistry, microbiology, cell culture, protein purification, analytical chemistry and mechanical engineering, including medical device as well as pharmaceutical product development. Eligix also employs persons that it believes have significant expertise in marketing, manufacturing, clinical development, quality assurance, regulatory affairs, finance, administration and business development. As of December 31, 2000, Eligix had 30 full-time employees, five of whom hold Ph.D.s, at its facility in Medford, Massachusetts.

### 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 elsewhere in this Annual Report on

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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.

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### FACTORS THAT MAY AFFECT RESULTS

#### RISKS RELATING TO BIOTRANSPLANT'S FINANCIAL RESULTS AND NEED FOR FINANCING

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

We anticipate that our existing funds, including the \$17.9 million of funds raised in our June 2001 private equity offering, will be sufficient to fund our operating and capital requirements as currently planned through the second quarter of 2002. We expect to use rather than generate funds from operations for the foreseeable future. In particular, we will require substantial funds to conduct research and development, including preclinical testing and clinical trials of our AlloMune System, and to manufacture and market any products that are approved for commercial sale. If we cannot raise more funds, we could be required to reduce our capital expenditures, scale back our research and product developments, reduce our workforce and/or license to others products or technologies we would otherwise seek to commercialize ourselves.

We may seek additional funding through collaborative arrangements, borrowing money and by the sale of 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, 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.

Even if we are able to raise additional funds in a timely manner, our future capital requirements will vary depending on many factors, including the following:

- continued progress in our research and development programs, as well as the magnitude of these programs;
- the resources required to successfully complete our clinical trials;
- the time and costs involved in obtaining regulatory approvals;
- the cost of manufacturing and commercialization activities;
- the cost of any additional facilities requirements;
- the timing, receipt and amount of milestone and other payments from collaborative partners;
- the timing, receipt and amount of sales and royalties from our potential products in the market; and
- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims and other patent-related costs, including litigation costs and the costs of obtaining any required licenses to technologies.

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WE HAVE INCURRED SUBSTANTIAL LOSSES, EXPECT TO CONTINUE TO INCUR ADDITIONAL LOSSES AND WILL NOT BE SUCCESSFUL UNTIL WE REVERSE THIS TREND.

We have incurred losses in each year since our date of organization. We expect to incur operating losses for the foreseeable future.

To date, we have not successfully commercialized and sold the types of products we are currently developing. The products that we are developing will require additional research and development, extensive preclinical studies and clinical trials and regulatory approval before they can be sold commercially. In particular, we may need to successfully develop several new technologies in order to

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complete development of our AlloMune System. If we do not successfully develop and commercialize any products, we will never become profitable.

To date, we have generated substantially all of our revenues from payments from our collaborative partners. In 2000, we generated \$4,563,475, or 100% of our total revenue, from our collaboration with Novartis, which was terminated in October 2000 in connection with the formation of our joint venture with Novartis. We have not received any revenues from the sale of products. We anticipate that it may be a number of years, if ever, before we will receive significant revenues from product sales or royalties.

### RISKS RELATED TO OUR BUSINESS, INDUSTRY AND STRATEGY

THERE ARE UNCERTAINTIES AS TO THE EFFECTIVENESS OF OUR TECHNOLOGICAL APPROACHES AND, AS A RESULT, WE MAY NOT BE ABLE TO SUCCESSFULLY DEVELOP AND COMMERCIALIZE ANY PRODUCTS.

Our future success depends on the successful development of our ImmunoCognance technology. The MEDI-507 antibody product under development and the prototype AlloMune System 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 or our collaborators' potential products will be effective in treating any of the disorders we have targeted. In addition, these products 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 accepted, then neither we nor our collaborators will be able to develop or commercialize these products.

WE ARE DEPENDENT ON MEDIMMUNE AND NOVARTIS TO DEVELOP, MANUFACTURE AND SELL TECHNOLOGIES EXCLUSIVELY LICENSED BY US, AND IF THESE PARTIES ARE NOT SUCCESSFUL, THEN WE WILL NOT ACHIEVE SIGNIFICANT REVENUES BASED ON THESE 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. In addition, our joint venture, 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



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on product sales. Our ability to achieve royalty revenue under these arrangements is heavily dependent on the efforts and activities of MedImmune and Novartis. Our arrangements with MedImmune and, through our joint venture, with Novartis allow them significant discretion in determining the efforts and resources that they will apply to the development and commercialization of products based upon our technologies. Accordingly, we are unable to control whether or not products based upon our technologies will be scientifically or commercially successful.

The risks that we face in connection with our agreements with MedImmune and Novartis include the following:

- These agreements are subject to termination on short notice. Specifically, MedImmune may terminate the agreement with us, and Novartis has the right to terminate the agreement with the joint venture, on 60 days' notice as a result of an uncured material breach by us or the joint venture, as the case may be. If either MedImmune or Novartis terminates its collaboration with us, or the joint venture, in the case of Novartis, it may be difficult for us to attract a new partner to develop and commercialize products based on our technologies and may adversely affect the perception of us in the business and financial communities.

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- If MedImmune or Novartis were to breach or terminate its agreement with us, or the joint venture, in the case of Novartis, reduce its funding or otherwise fail to conduct the collaboration successfully, we could be required to devote additional internal resources to the program that is the subject of the collaboration, scale back or terminate the program or seek an alternative partner.
- MedImmune and Novartis may pursue higher priority programs or change the focus of their research and/or development programs, which could affect either party's commitment to us.
- After a product has been approved for marketing, any reductions in marketing or sales efforts or a discontinuation of marketing or sales of that product by MedImmune or Novartis would reduce our revenues, which will be based on a percentage of net sales.

THE MARKET MAY NOT BE RECEPTIVE TO OUR PRODUCTS UPON THEIR INTRODUCTION, WHICH WILL PREVENT US FROM BEING PROFITABLE.

The commercial success of our products when and if they are approved for marketing will depend upon their acceptance by the medical community and third-party payors as clinically useful, cost effective and safe. All of the products that we are developing are based upon new technologies or therapeutic approaches. As a result, it may be more difficult for us to convince the medical community and third-party payors to accept and use our products.

Other factors that we believe will materially affect market acceptance of our products include:

- the timing of our receipt of marketing approvals and the countries in which approvals are obtained;
- the safety, efficacy and ease of administration of our products;
- the success of our physician education programs; and
- the availability of government and third-party payor reimbursement of our products.

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THE PROGRESS OF THE XENOTRANSPLANTATION RESEARCH PROGRAM OF OUR JOINT VENTURE COULD BE DELAYED BY DISRUPTIONS IN ITS SUPPLY OF MINIATURE SWINE.

Our joint venture's xenotransplantation research program is based upon the transplantation of tissues and organs from swine into humans. Charles River Laboratories has been supplying miniature swine for our research programs since our inception in 1991 and is currently the only supplier of the miniature swine organs that the joint venture uses in its research. Although the miniature swine from which the joint venture with Novartis will receive organs are located at several different facilities, a disease epidemic or other catastrophe could destroy all or a portion of the miniature swine herd, which would interrupt or significantly delay the joint venture's research. We believe there is presently only one other suitable supplier of miniature swine for research purposes such as ours. If Charles River Laboratories terminates or breaches its agreement with the joint venture, the joint venture may not have the resources or capabilities to maintain the miniature swine herds itself and may experience difficulties in establishing a supply arrangement with an alternative source of miniature swine on acceptable terms, if at all. If the joint venture fails to procure a third-party source of miniature swine or is unable to maintain its own herd, the joint venture could be required to delay or curtail its research efforts with respect to the xenotransplantation program.

XENOTRANSPLANTATION INVOLVES RISKS WHICH HAVE RESULTED IN ADDITIONAL FDA OVERSIGHT AND WHICH IN THE FUTURE MAY RESULT IN ADDITIONAL REGULATION.

Xenotransplantation poses a risk that viruses or other animal pathogens may be unintentionally transmitted to a human patient. The United States Food and Drug Administration will require testing to determine whether infectious agents, including specific viruses referred to as porcine endogenous retroviruses, also known as PERV, are present in patients who have received cells, tissues or organs from miniature swine. While porcine endogenous retroviruses have not been shown to cause any disease in pigs, it is not known what effect, if any, these retroviruses may have on humans.

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Other companies are currently conducting clinical trials involving the transplantation of pig cells into humans. The FDA requires lifelong monitoring of these transplant recipients. If porcine endogenous retroviruses or any other virus or infectious agent is detected in tests or samples from these transplant recipients, the FDA may require Novartis to halt its clinical trials and perform additional tests to assess the risk of infection to potential patients. This could result in delays in the successful development and commercialization of any xenotransplantation products.

The FDA has proposed, but not yet established, definitive regulatory guidelines for xenotransplantation. We and Novartis may not be able to comply with any final guidelines the FDA may issue.

### RISKS RELATING TO CLINICAL AND REGULATORY MATTERS

IF OUR CLINICAL TRIALS ARE NOT SUCCESSFUL OR ARE NOT COMPLETED ON A TIMELY BASIS, WE WILL NOT BE ABLE TO DEVELOP AND COMMERCIALIZE ANY RELATED PRODUCTS AND, THEREFORE, WE WILL NOT ACHIEVE PROFITABILITY.

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

Prior to commencing new clinical trials, we must submit investigational new

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drug and/or investigational device exemption applications to the FDA. 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 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 upon other third parties to conduct future clinical trials of our AlloMune System. 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.

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 development activities and before marketing or selling any of our products. 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.

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. Any delay in

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obtaining or failure to obtain 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 regulatory approval.

There is limited regulatory precedent for the approval of products based upon the technologies that we are employing to develop products. The AlloMune System is based on new technologies and/or new therapeutic approaches that have not been extensively tested in humans. Accordingly, the regulatory requirements governing this product may be more rigorous than for conventional products. In addition, the FDA has not yet established final or comprehensive guidelines for

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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.

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, approval by the FDA does not ensure approval by regulatory authorities in other countries.

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

### RISKS RELATING TO INTELLECTUAL PROPERTY

WE MAY NOT BE ABLE TO OBTAIN PATENT PROTECTION FOR OUR DISCOVERIES AND WE MAY INFRINGE PATENT RIGHTS OF THIRD PARTIES.

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

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.

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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 and the Alberta Research Council. We expect to enter into additional

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licenses in the future. These in-licenses relate to important technologies that may be necessary for the development and 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.

### RISKS RELATING TO PRODUCT MANUFACTURING, MARKETING AND SALES

WE HAVE NO SALES AND MARKETING EXPERIENCE AND MAY DEPEND SIGNIFICANTLY ON THIRD PARTIES WHO MAY NOT SUCCESSFULLY COMMERCIALIZE OUR PRODUCTS.

We have no sales, marketing and distribution experience. We plan to rely significantly on sales, marketing and distribution arrangements with third parties, including our collaborative partners. For example, we have granted MedImmune exclusive marketing rights to the MEDI-507 product under development and have granted Novartis 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. Our future revenues will be materially dependent upon the success of the efforts of these third parties.

We may seek to independently market products that are not already subject to marketing agreements with other parties, including our high density microparticle products, which are our nearest-term products under development. 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 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.

WE HAVE LIMITED MANUFACTURING CAPABILITIES AND WILL DEPEND ON THIRD-PARTY MANUFACTURERS WHO MAY NOT SUCCESSFULLY MANUFACTURE OUR PRODUCTS.

We have limited manufacturing experience. To continue to develop products, apply for regulatory approvals and, ultimately, commercialize any products, we will need to develop, contract for or otherwise arrange for the necessary manufacturing capabilities.

We currently rely upon MedImmune to produce material for preclinical and clinical testing purposes and expect to continue to do so in the future. In addition, if we receive the necessary regulatory approvals for our products, we also expect to rely upon third parties, including our collaborative partners, to produce materials required for commercial production. There are a limited number of manufacturers capable of manufacturing these products that are able to comply with the FDA's regulations for good manufacturing practices. If we are unable to manufacture our own products or arrange for third-party manufacturing of our products, or unable to do so on commercially reasonable terms, we may not be able to complete development of or market our products.

To the extent that we enter into manufacturing arrangements with third

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parties, we will be dependent upon these third parties to perform their obligations in a timely manner. If third-party

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manufacturers with whom we contract fail to perform their obligations, we 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 its products; and
- ultimately, we may not be able to meet commercial demands for its products.

### RISKS RELATING TO THE ELIGIX MERGER

THE MERGER WITH ELIGIX MAY NOT BE SUCCESSFULLY COMPLETED AND, EVEN IF IT IS COMPLETED, WE MAY FACE CHALLENGES IN INTEGRATING ELIGIX INTO BIOTRANSPLANT AND, AS A RESULT, MAY NOT REALIZE THE EXPECTED BENEFITS OF THE ANTICIPATED MERGER.

In December 2000, we entered into a definitive agreement to acquire Eligix through a merger. The merger is subject to the satisfaction of closing conditions, including approval by BioTransplant's and Eligix' stockholders, and may not be successfully completed. The merger involves the integration of two different companies that have previously operated independently. Even if successfully completed, integrating Eligix' operations, technologies and personnel with those of BioTransplant will be a complex process. We may not be able to complete the integration rapidly. After the integration, the combined company may not achieve the expected benefits of the merger. The diversion of the attention of our management and any difficulties encountered in the process of combining our companies could lead to unanticipated liabilities and costs and cause the disruption of, or a loss of momentum in, the business activities of the combined company. Further, the process of combining our companies could negatively affect employee morale and the ability of the combined company to retain some of its key employees after the merger. As a consequence, we may not successfully integrate Eligix or profitably manage the combined company. In addition, following the transaction, the combined company may not achieve revenues, net income or loss levels, efficiencies or synergies that justify the merger, and the merger may not result in increased earnings for the combined company in any future period.

SIGNIFICANT MERGER-RELATED CHARGES AGAINST EARNINGS WILL INCREASE OUR LOSSES IN THE QUARTER IN WHICH WE CONSUMMATE THE MERGER AND DURING THE POST-MERGER INTEGRATION PERIOD AND, ADDITIONALLY, WE MAY ALSO INCUR SIGNIFICANT CHARGES IF THE MERGER IS NOT CONSUMMATED.

We expect to incur charges of approximately \$3.7 million in connection with the consummation of the merger, including charges of approximately \$1.375 million expected to be incurred by Eligix. The charges include legal, accounting and financial advisory fees and other integration costs. These costs may be higher than we anticipate. In addition, we may incur other additional unanticipated merger costs. For example, if the merger agreement is terminated by Eligix as a result of our failure to perform or comply in all material respects with the agreements and covenants under the merger agreement, we will be required to pay Eligix \$2.0 million in cash. Some of these nonrecurring costs will be charged to operations in the fiscal quarter in which the merger is consummated or terminated, as the case may be, while others will be expensed as incurred during the post-merger integration period.

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THE LOSS OF KEY ELIGIX OR BIOTRANSPLANT PERSONNEL COULD MAKE IT DIFFICULT TO COMPLETE EXISTING PROJECTS AND UNDERTAKE NEW PROJECTS.

The success of the combined company depends on our ability to identify, hire and retain our employees, and a significant component of the value of the merger is in the know-how and experience of the Eligix and BioTransplant employees that we expect to employ following the merger. None of the employees of Eligix or BioTransplant will be bound by a long-term agreement with the combined company or be covered by key-man life insurance after the merger. If key Eligix or BioTransplant employees were to leave after the merger, we may be unable to integrate Eligix' delivery systems into our product offerings, complete existing Eligix projects or undertake new projects.

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Under the terms of Eligix' stock incentive plan, the vesting of stock options to purchase an aggregate of approximately 864,999 shares of Eligix stock held by Eligix employees automatically accelerates as a result of the merger. In addition, options to purchase an aggregate of 2,749,100 shares of Eligix common stock issued on May 25, 2000, which were exercisable in full on the date of issuance but subject to a right of repurchase by Eligix, will no longer be subject to the repurchase right in the event of a merger. These options have substantial value to the Eligix employees. Because a substantial number of options will vest in full and be immediately exercisable after the merger, Eligix employees will not be incentivized through these stock options to remain employed after the merger as a condition to the continued vesting of their options. Consequently, we face the risk that Eligix employees will leave following the merger. In addition, BioTransplant employees had vested options as of February 28, 2001 to purchase an aggregate of approximately 923,000 shares of BioTransplant common stock and, thus, may not be incentivized through stock options to remain employed following the merger.

WE MAY INCUR SIGNIFICANT SEVERANCE-RELATED COSTS AFTER THE MERGER IF ELIGIX MANAGEMENT MEMBERS LEAVE FOR GOOD REASON OR WE TERMINATE THEM WITHOUT CAUSE.

Each of the twelve management members of Eligix will be entitled to receive severance-related payments if he or she leaves for good reason or is terminated without cause after the merger. Consequently, we may incur significant severance-related costs, including:

- cash severance payments of up to an aggregate of approximately \$1,173,000 if all twelve Eligix management members leave; and
- the acceleration in full of the vesting of the 990,000 shares of BioTransplant common stock to be issued under the Eligix management equity incentive plan, which shares had a value of \$5,445,000 based on the closing price of BioTransplant's common stock on February 28, 2001.

### RISKS RELATING TO OUR COMMON STOCK

OUR STOCK PRICE IS HIGHLY VOLATILE, WHICH COULD CAUSE YOU TO LOSE PART OR ALL OF YOUR INVESTMENT.

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 \$1.00 in the quarter ended December 31, 1998 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 variations in our financial results and investors' perceptions of us, as well as their perceptions of general economic, industry and market conditions. Broad 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

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common stock.

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

#### OVERVIEW

Since commencement of BioTransplant's operations in 1990, we have been engaged primarily in the research and development of pharmaceutical products and systems to enable the body's immune system to better tolerate the transplantation of foreign 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 a term loan. We have not generated any revenues from the sale of products to date, and do not expect to receive any product revenues for several years, if ever. We will be required to conduct 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.

From 1993 through October 2000, we were a 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, which began operations in January 2001, and terminated our prior collaborations in xenotransplantation.

Novartis has committed to provide an aggregate of \$30.0 million in research funding over three years to the joint venture. 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 the joint venture's 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. We expect to enter into a contract research agreement with the Delaware subsidiary, under which we will commit approximately 20 full-time employees to perform research and will agree to provide administrative services, all at a rate to be agreed upon.

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 upon our respective equity ownership of the joint venture in effect in the period in which these items accrue. Initially, the board of directors of Immerge BioTherapeutics, Inc. will consist of four directors: one selected by BioTransplant, one selected by Novartis and two additional directors, one each designated by BioTransplant 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.

In October 1995, we entered into a collaborative research agreement with MedImmune for the development of products to treat and prevent organ rejection. 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



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commercialization of the BTI-322 monoclonal antibody and other related products. 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. Any milestone payments which are received are repayable from royalties on the BTI-322 monoclonal antibody and other related products.

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### RESULTS OF OPERATIONS

#### YEARS ENDED DECEMBER 31, 2000 AND 1999

Revenues decreased to \$4.6 million in 2000 from \$8.7 million in 1999. The decrease in revenues was primarily due to \$4.6 million in sponsored research payments received under the Novartis agreement in 2000, 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.

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

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.

#### YEARS ENDED DECEMBER 31, 1999 AND 1998

Revenues increased to \$8.7 million in 1999 from \$6.7 million in 1998. The increase in revenues was primarily due to \$8.7 million in sponsored research, milestone payments and license revenue from the Novartis agreements in 1999, compared to \$6.7 million in sponsored research and license revenue from Novartis during 1998.

Research and development expenses increased to \$15.7 million in 1999 from \$14.7 million in 1998. This increase was primarily due to additional external research support combined with increases in research and development staff and associated increases in supplies and support services.

General and administrative expenses decreased slightly to \$2.4 million in 1999 from \$2.5 million in 1998. This decrease was primarily due to decreased outside professional services rendered in connection with market research and business development.

Interest income decreased to \$0.8 million in 1999 compared to \$1.3 million in 1998. The decrease was due to lower average cash balances available for investment during 1999.

As a result of the above factors, we incurred a net loss in 1999 of \$8.7 million, or \$1.01 per share, compared to a net loss of \$9.2 million, or \$1.07 per share, in 1998.

### QUARTERLY RESULTS OF OPERATIONS

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The following table sets forth unaudited selected operating results for each of the eight fiscal quarters in the two years ended December 31, 2000. We believe that the following selected quarterly 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

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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, 1999	JUNE 30, 1999	SEPT. 30, 1999	DEC. 31, 1999	MARCH 31, 2000	JUNE 30 2000
	-----					
	(IN THOUSANDS, EXCEPT PER SHARE AMOUNTS)					
Revenue.....	\$ 1,239	\$ 1,238	\$ 3,735	\$ 2,477	\$ 1,488	\$ 1,488
Operating expenses.....	4,355	4,379	4,497	4,896	4,302	4,251
Net loss.....	(2,892)	(2,968)	(602)	(2,213)	(2,499)	(2,408)
Basic and diluted net loss per common share.....	\$ (0.34)	\$ (0.35)	\$ (0.07)	\$ (0.26)	\$ (0.23)	\$ (0.21)

### LIQUIDITY AND CAPITAL RESOURCES

Since our inception, our operations have been funded principally through the net proceeds of an aggregate of \$81.9 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 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 and MedImmune have been used to fund operating losses of approximately \$68.8 million and the investment of approximately \$5.6 million in equipment and leasehold improvements through December 31, 2000. During 1999, we extended and increased our term note with a bank from \$500,000 to \$1.0 million for certain equipment and fixtures borrowing. There were \$486,000 in borrowings outstanding under this term note at December 31, 2000. We had no significant commitments as of December 31, 2000 for capital expenditures.

On February 11, 2000, we issued and sold to a group of investors an aggregate of 1,215,000 shares of our common stock, at a purchase price of \$8.00 per share, for net proceeds of approximately \$9.0 million.

On June 8, 2001, we sold to a group of investors an aggregate of 3,022,457 shares of our common stock, at a purchase price of \$6.30 per share, for net proceeds of approximately \$17.9 million.

We have entered into sponsored research and consulting agreements with certain hospitals, academic institutions and consultants, requiring periodic payments by us. Aggregate minimum funding obligations under these agreements, each of which includes cancellation provisions, total approximately \$4.9 million, which includes approximately \$3.4 million in 2001.

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We had cash, cash equivalents and short-term investments of \$14.9 million as of December 31, 2000 as compared to \$21.4 million as of December 31, 1999.

We anticipate that our existing cash, cash equivalents and short-term investments and the \$17.9 million of funds we received in our June 2001 private equity financing will be sufficient to fund our operating and capital requirements as currently planned through the second quarter of 2002. We will need to raise substantial additional funds in the near term, 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.

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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.

We expect to incur substantial additional costs, including costs related to research and development activities, preclinical studies, clinical trials, obtaining regulatory approvals, manufacturing and the expansion of our facilities.

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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 (a Delaware corporation in the development stage) and subsidiary as of December 31, 1999 and 2000, and the related consolidated statements of operations, stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2000, and for the period from inception (March 20, 1990) to December 31, 2000. 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.

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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 subsidiary as of December 31, 1999 and 2000, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2000, and for the period from inception (March 20, 1990) to December 31, 2000, in conformity with accounting principles generally accepted in the United States.

ARTHUR ANDERSEN LLP

Boston, Massachusetts

February 15, 2001 (except with respect to the matter discussed in Note 15, as to which the date is June 8, 2001)

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### BIOTRANSPLANT INCORPORATED AND SUBSIDIARY

(A DEVELOPMENT STAGE COMPANY)

#### CONSOLIDATED BALANCE SHEETS

	DECEMBER 31,	
	1999	2000
Assets		
Current assets:		
Cash and cash equivalents.....	\$17,648,789	\$11,481,297
Short-term investments.....	3,718,033	3,391,568
Other receivables.....	400,500	18,995
Prepaid expenses and other current assets.....	169,733	823,899
	21,937,055	15,715,759
Property and equipment, at cost:		
Equipment under capital leases.....	--	119,772
Laboratory equipment.....	3,707,833	3,726,821
Leasehold improvements.....	795,017	795,017
Office equipment.....	792,605	932,706
	5,295,455	5,574,316
Less -- Accumulated depreciation.....	3,813,455	4,237,110
	1,482,000	1,337,206

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Investment in Stem Cell Sciences Ltd.....	--	105,000
	-----	-----
	\$23,419,055	\$17,157,965
	=====	=====
Liabilities and Stockholders' Equity		
Current liabilities:		
Current portion of long-term debt.....	\$ 233,333	\$ 233,333
Current obligation under capital leases.....	--	37,486
Accounts payable.....	433,067	408,115
Accrued expenses.....	2,516,173	1,721,745
Deferred revenue.....	4,125,000	--
	-----	-----
Total current liabilities.....	7,307,573	2,400,679
	-----	-----
Long-term debt, net of current portion.....	466,667	252,778
Long-term obligation under capital leases, net of current portion.....	--	82,285
	-----	-----
Total long-term liabilities.....	466,667	335,063
	-----	-----
Commitments (Notes 9 and 13)		
Stockholders' equity:		
Preferred stock, \$.01 par value -- Authorized -- 2,000,000 shares Issued and outstanding -- no shares.....	--	--
Common stock, \$.01 par value -- Authorized -- 25,000,000 and 50,000,000 shares at December 31, 1999 and December 31, 2000, respectively Issued and outstanding -- 10,300,890 and 11,796,120 shares at December 31, 1999 and 2000, respectively.....	103,010	117,962
Additional paid-in capital.....	72,688,036	83,129,855
Deficit accumulated during the development stage.....	(57,146,231)	(68,825,594)
	-----	-----
Total stockholders' equity.....	15,644,815	14,422,223
	-----	-----
	\$23,419,055	\$17,157,965
	=====	=====

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

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BIOTRANSPLANT INCORPORATED AND SUBSIDIARY

(A DEVELOPMENT STAGE COMPANY)

CONSOLIDATED STATEMENTS OF OPERATIONS

	FOR THE YEARS ENDED DECEMBER 31,			CUMULATIVE
	1998	1999	2000	SINCE
	-----	-----	-----	INCEPTION
	-----	-----	-----	-----
Operating revenues:				
License fees.....	\$ 1,000,000	\$ 3,500,000	\$ --	\$ 18,500,000

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Research and development.....	5,688,500	5,188,475	4,563,475	36,815,45
	-----	-----	-----	-----
Total revenues.....	6,688,500	8,688,475	4,563,475	55,315,45
Operating Expenses:				
Research and development.....	14,729,825	15,680,281	14,973,719	107,915,27
General and administrative.....	2,477,460	2,445,912	2,543,624	21,375,61
	-----	-----	-----	-----
Total expenses.....	17,207,285	18,126,193	17,517,343	129,290,89
	-----	-----	-----	-----
Operating loss.....	(10,518,785)	(9,437,718)	(12,953,868)	(73,975,44
Interest income.....	1,317,780	782,182	1,334,486	6,987,32
Interest expense.....	(9,602)	(17,914)	(59,981)	(1,837,47
	-----	-----	-----	-----
Net loss.....	\$ (9,210,607)	\$ (8,673,450)	\$ (11,679,363)	\$ (68,825,59
	=====	=====	=====	=====
Net loss per common share:				
Basic and diluted.....	\$ (1.07)	\$ (1.01)	\$ (1.01)	
	=====	=====	=====	
Weighted average common shares				
outstanding:				
Basic and diluted.....	8,578,941	8,598,085	11,547,262	
	=====	=====	=====	

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

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BIOTRANSPLANT INCORPORATED AND SUBSIDIARY

(A DEVELOPMENT STAGE COMPANY)

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)

	COMMON STOCK		ADDITIONAL	DEFICIT
	NUMBER	\$.01	PAID-IN	ACCUMULATED
	OF SHARES	PAR VALUE	CAPITAL	DURING
	-----	-----	-----	DEVELOP
				STAG
	-----	-----	-----	-----
Inception, March 20, 1990.....	--	\$ --	\$ --	\$ --
Net loss.....	--	--	--	(14,000)
	-----	-----	-----	-----
Balance, December 31, 1990.....	--	--	--	(14,000)
Sale of common stock.....	102,572	1,026	3,077	
Issuance of warrants.....	--	--	22,000	
Net loss.....	--	--	--	(2,630)
	-----	-----	-----	-----
Balance, December 31, 1991.....	102,572	1,026	25,077	(2,770)
Net loss.....	--	--	--	(6,180)
	-----	-----	-----	-----
Balance, December 31, 1992.....	102,572	1,026	25,077	(8,950)
Issuance of warrants.....	--	--	476,800	
Exercise of stock options.....	63	1	46	

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Deferred compensation on stock options.....	--	--	105,546	
Net loss.....	--	--	--	(7,74)
	-----	-----	-----	-----
Balance, December 31, 1993.....	102,635	1,027	607,469	(16,71)
Exercise of stock options.....	17,406	174	1,448	
Restricted stock sold to Directors.....	1,250	12	8,738	
Issuance of warrants.....	--	--	165,937	
Deferred compensation on stock options.....	--	--	170,225	
Net loss.....	--	--	--	(11,26)
	-----	-----	-----	-----
Balance, December 31, 1994.....	121,291	1,213	953,817	(27,98)
Issuance of warrants.....	--	--	99,000	
Exercise of stock options.....	5,303	53	7,301	
Deferred compensation on stock options.....	--	--	170,225	
Net loss.....	--	--	--	(2,08)
	-----	-----	-----	-----
Balance, December 31, 1995.....	126,594	1,266	1,230,343	(30,07)
Conversion of preferred stock into common stock.....	4,770,430	47,704	36,154,586	
Issuance of common stock in initial public offering, net of issuance costs of \$2,681,920.....	3,220,000	32,200	27,875,880	
Issuance of common stock pursuant to antidilution rights.....	431,724	4,317	(4,317)	
Exercise of stock options.....	10,154	102	28,546	
Net loss.....	--	--	--	(6,03)
	-----	-----	-----	-----
Balance, December 31, 1996.....	8,558,902	85,589	65,285,038	(36,10)
Exercise of stock options.....	15,238	153	45,407	
Restricted stock sold to directors.....	1,250	12	38	
Net loss.....	--	--	--	(3,15)
	-----	-----	-----	-----
Balance, December 31, 1997.....	8,575,390	85,754	65,330,483	(39,26)
Exercise of stock options.....	6,073	61	14,745	
Net loss.....	--	--	--	(9,21)
	-----	-----	-----	-----
Balance, December 31, 1998.....	8,581,463	85,815	65,345,228	(48,47)
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.....	--	--	--	(8,67)
	-----	-----	-----	-----
Balance, December 31, 1999.....	10,300,890	103,010	72,688,036	(57,14)
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.....	--	--	--	(11,67)
	-----	-----	-----	-----
Balance, December 31, 2000.....	11,796,120	\$117,962	\$83,129,855	\$ (68,82)
	=====	=====	=====	=====

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

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(A DEVELOPMENT STAGE COMPANY)

## CONSOLIDATED STATEMENTS OF CASH FLOWS

	FOR THE YEARS ENDED DECEMBER 31,		
	1998	1999	2000
Cash flows from operating activities:			
Net loss.....	\$ (9,210,607)	\$ (8,673,450)	\$ (11,679)
Adjustments to reconcile net loss to net cash used in operating activities-			
Depreciation and amortization.....	358,052	392,865	430
Noncash interest expense on convertible notes payable to stockholders.....	--	--	
Noncash expenses related to options and warrants.....	33,186	1,541	
Changes in current assets and liabilities-			
Accounts receivable.....	--	(400,500)	381
Prepaid expenses and other current assets.....	26,206	1,042,561	(654)
Accounts payable.....	(62,179)	205,711	(24)
Accrued expenses.....	(69,558)	403,514	(794)
Deferred revenue.....	(750,000)	750,000	(4,125)
Net cash used in operating activities.....	(9,674,900)	(6,277,758)	(16,465)
Cash flows from investing activities:			
Purchases of property and equipment.....	(812,828)	(416,839)	(299)
Disposal of property and equipment, net.....	--	--	12
Purchases of investments.....	(8,887,022)	(4,086,657)	(6,508)
Proceeds from sale of investments.....	22,921,877	7,211,587	6,835
(Increase) decrease in investment in Stem Cell Sciences Ltd.....	--	--	55
Net cash provided by (used in) investing activities.....	13,222,027	2,708,091	95
Cash flows from financing activities:			
Proceeds from convertible notes payable to stockholders.....	--	--	
Payments of obligations under capital leases.....	(177,666)	(10,042)	
Proceeds from sale/leaseback of equipment.....	--	--	
Payments on long-term debt.....			(213)
Proceeds from equipment leases.....	--	--	119
Proceeds from long-term debt.....	--	700,000	
Net proceeds from sale of redeemable convertible preferred stock.....	--	--	
Net proceeds from sale of common stock.....	14,806	7,360,002	10,296
Net cash provided by (used in) financing activities.....	(162,860)	8,049,960	10,202
Net increase in cash and cash equivalents.....	3,384,267	4,480,293	(6,167)
Cash and cash equivalents, beginning of period.....	9,784,229	13,168,496	17,648
Cash and cash equivalents, end of period.....	\$13,168,496	\$17,648,789	\$ 11,481

Supplemental disclosure of noncash investing and financing



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transactions:			
Equipment acquired under capital leases.....	\$	--	\$ -- \$
	=====	=====	=====
Net gain related to investment in Stem Cell Sciences Ltd.....	\$	--	\$ -- \$ 160
	=====	=====	=====
Conversion of convertible notes payable to stockholders and accrued interest into redeemable convertible preferred stock.....	\$	--	\$ -- \$
	=====	=====	=====
Conversion of preferred stock into common stock.....	\$	--	\$ -- \$
	=====	=====	=====
Issuance of warrants.....	\$	--	\$ -- \$
	=====	=====	=====
Leasehold improvements acquired through issuance of redeemable convertible preferred stock.....	\$	--	\$ -- \$
	=====	=====	=====
Supplemental disclosure of cash flow information:			
	=====	=====	=====
Interest paid during the period.....	\$	6,975	\$ 16,159 \$ 54
	=====	=====	=====

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

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### BIOTRANSPLANT INCORPORATED AND SUBSIDIARY

(A DEVELOPMENT STAGE COMPANY)

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

##### (1) OPERATIONS

BioTransplant Incorporated (the "Company") was incorporated on March 20, 1990. The Company is developing pharmaceutical products and systems to enable the body's immune system to better tolerate the transplantation of foreign cells, tissues and organs. Based on BioTransplant's proprietary technology, both alone and in collaboration with others, BioTransplant is seeking to develop a portfolio of products designed to improve therapies associated with organ and bone marrow transplantation as well as to improve the treatment of cancer, autoimmune disease and blood disorders.

The Company is in the development stage and is devoting substantially all of its efforts toward product research and development and raising capital. The Company is subject to a number of risks similar to those of other development stage 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 of its products.

The Company incurred a net loss of approximately \$11.7 million for the year ended December 31, 2000, and had an accumulated deficit of approximately \$68.8 million as of December 31, 2000. The Company has funded these losses principally through equity financing. Additionally, the Company has entered into an agreement to purchase Eligix, Inc. (See Note 13). In June 2001, the Company received approximately \$17.9 million in net proceeds from the sale of common stock. Management believes that these proceeds, along with existing resources,

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will be adequate to fund operations through the second quarter of 2002.

### (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 subsidiary. 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. In accordance with Statement of Financial Accounting Standards (SFAS) No. 115, "Accounting for Certain Investments in Debt and Equity Securities", the

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### BIOTRANSPLANT INCORPORATED AND SUBSIDIARY

(A DEVELOPMENT STAGE COMPANY)

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

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

Company's investments are classified as held-to-maturity and are stated at amortized cost, which approximates market value.

The Company held the following cash equivalents and investments at December 31, 1999 and 2000:

	1999	2000
	-----	-----
Cash and cash equivalents.....	\$17,648,789	\$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, 1999 and 2000, respectively).....	3,718,033	1,493,928
	-----	-----
	3,718,033	3,391,568
	-----	-----

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Total cash, cash equivalents and investments.....	\$21,366,822	\$14,872,866
	=====	=====

There were no realized gains or losses in the years ended December 31, 1998, 1999 and 2000.

### (D) 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 a three to five-year life. 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.

### (E) REVENUE RECOGNITION

Substantially all of the Company's license and research and development revenues have been derived from three collaborative research arrangements (see Note 7). 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 technology transfer fees received for rights to certain technology of the Company. Prior to the adoption 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. Deferred revenue represents amounts received in advance for research and development. Research and development expenses in the accompanying consolidated statements of operations include funded and unfunded expenses.

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 three collaborative research agreements described in Note 7. The Company was required to adopt this new accounting principle through a cumulative charge to the statement of operations, in accordance with Accounting Principle Board Opinion (APB) No. 20, "Accounting Changes," no later than the fourth quarter of 2000, effective January 1, 2000. The adoption of this statement, consisting of

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## BIOTRANSPLANT INCORPORATED AND SUBSIDIARY

(A DEVELOPMENT STAGE COMPANY)

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

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

the cumulative effect of the accounting change and the current year effect, did not have a material impact on the Company's financial statements for the year ended December 31, 2000. As required under SAB 101, the Company is required to disclose the pro forma effect of applying the principles of SAB 101 for all periods presented. The application of SAB 101 for the years ended December 31, 1999 and 2000 did not result in a material change in reported revenues. For the year ended December 31, 1998, the application of SAB 101 would have resulted in revenues of \$5,833,000 as compared to the \$4,750,000 of revenues reported.

#### (F) 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

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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:

	1998	1999	2000
	-----	-----	-----
Net loss.....	\$ (9,210,607)	\$ (8,673,450)	\$ (11,679,363)
	=====	=====	=====
Weighted average common shares outstanding -- basic and diluted....	8,578,941	8,598,085	11,547,262
	=====	=====	=====
Basic and diluted net loss per common share.....	\$ (1.07)	\$ (1.01)	\$ (1.01)
	=====	=====	=====
Antidilutive securities not included-- Common stock options.....	48,266	296,396	853,297
	=====	=====	=====
Common stock warrants.....	133,007	151,998	282,471
	=====	=====	=====

### (G) COMPREHENSIVE INCOME

SFAS No. 130, "Reporting Comprehensive Income," requires disclosure of all components of comprehensive income. Comprehensive income 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 net loss other than its net loss.

### (H) 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 believes that it operates in one operating segment.

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BIOTRANSPLANT INCORPORATED AND SUBSIDIARY

(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

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

#### (I) RECENT ACCOUNTING PRONOUNCEMENTS

In March 2000, the Financial Accounting Standards Board (FASB) issued FASB Interpretation No. 44 "Accounting for Certain Transactions Involving Stock Compensation"--An Interpretation of APB Opinion No. 25. The interpretation clarifies the application of APB Opinion No. 25 in specified events, as defined. The interpretation is effective July 1, 2000 but covers certain events occurring during the period after December 15, 1998, but before the effective date. To the

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extent that events covered by this interpretation occur during the period after December 31, 1998, but before the effective date, the effects of applying this interpretation would be recognized on a prospective basis from the effective date. Accordingly, upon initial application of the final interpretation, (i) no adjustments would be made to the financial statements for periods before the effective date and (ii) no expense would be recognized for any additional compensation cost measured that is attributable to periods before the effective date. The adoption of this statement did not have a material impact on the Company's financial statements.

In June 1999, the FASB issued SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities" ("SFAS 133"). SFAS No. 133, as amended by SFAS No. 137, is effective for all fiscal quarters of all fiscal years beginning after June 15, 2000. SFAS 133 establishes accounting and reporting standards for derivative instruments including certain derivative instruments embedded in other contracts (collectively referred to as derivatives) and for hedging activities. The Company does not expect that the adoption of this statement will have a material impact on the Company's financial statements.

### (3) TERM NOTE

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 (9.25% at December 31, 2000) 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") (6.578% at December 31, 2000) plus 2.25%. Borrowings under the term note are secured by equipment and fixtures purchased using the proceeds of the note. There were \$486,111 in borrowings outstanding under this term note at December 31, 2000. The Company is required to maintain certain financial covenants under the agreement. As of December 31, 2000, the Company was in compliance with these covenants.

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## BIOTRANSPLANT INCORPORATED AND SUBSIDIARY

(A DEVELOPMENT STAGE COMPANY)

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

#### (4) ACCRUED EXPENSES

Accrued expenses consist of the following at December 31, 1999 and 2000:

	1999	2000
	-----	-----
Consulting and contract research.....	\$1,067,988	\$ 748,342
Payroll and payroll related.....	309,209	4,148
Professional fees.....	538,646	587,587
Other.....	600,330	381,668
	-----	-----
	\$2,516,173	\$1,721,745
	=====	=====

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### (5) COMMON STOCK

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.

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.

As of December 31, 1999 and 2000, the Company has reserved the following shares of common stock for issuance:

	1999	2000
	-----	-----
1991 Stock Option Plan.....	688,364	552,382
1994 Directors' Equity Plan.....	99,375	52,064
1997 Stock Option Plan.....	1,496,757	1,417,350
Outstanding warrants.....	425,147	463,179
	-----	-----
	2,709,643	2,484,975
	=====	=====

### (6) OPTIONS AND WARRANTS

#### (A) COMMON STOCK PLANS

In May 1997, the 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 May 1999, the stockholders approved an amendment to increase the number of shares of common stock reserved for issuance under the 1997 Plan to 1,500,000 from 750,000. These options generally vest ratably over a four-to-five-year period.

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. Future grants to the the board of directors will be 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

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BIOTRANSPLANT INCORPORATED AND SUBSIDIARY

(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

#### (6) OPTIONS AND WARRANTS (CONTINUED)

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.

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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, 1997.....	1,014,425	\$5.65
Granted.....	493,290	2.79
Exercised.....	(6,073)	2.43
Canceled.....	(129,188)	6.98
	-----	-----
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
	=====	=====
Exercisable, December 31, 1998.....	472,608	\$4.70
	=====	=====
Exercisable, December 31, 1999.....	747,266	\$4.70
	=====	=====
Exercisable, December 31, 2000.....	862,733	\$4.92
	=====	=====

The following tables summarize certain information about options outstanding at December 31, 2000:

RANGE OF EXERCISE PRICES	OPTIONS OUTSTANDING	WEIGHTED AVERAGE REMAINING CONTRACTUAL LIFE IN YEARS	WEIGHTED AVERAGE EXERCISE PRICE
-----	-----	-----	-----
\$0.04- 4.00	638,554	6.43	\$2.72
4.13- 6.75	702,054	6.89	6.20
6.88-18.63	337,105	9.15	9.76
	-----	-----	-----
\$0.04-18.63	1,677,713	7.17	\$5.59
	=====	=====	=====

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(6) OPTIONS AND WARRANTS (CONTINUED)

The following tables summarize certain information about options exercisable at December 31, 2000:

RANGE OF EXERCISE PRICES	OPTIONS EXERCISABLE	WEIGHTED AVERAGE EXERCISE PRICE
\$0.04- 4.00	365,722	\$2.96
4.13- 6.75	460,452	6.22
6.88-18.63	36,559	8.18
-----	-----	-----
\$0.04-18.63	862,733	\$4.92
=====	=====	=====

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, 1998, 1999 and 2000 are as follows: risk-free interest rates of 4.73%, 6.72% and 4.93%; expected common stock volatility factors of 85%, 87% and 92%; 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 1998, 1999 and 2000 are assumed to be 0%. The weighted average fair value of options granted in 1998, 1999 and 2000 was \$2.18, \$3.57 and \$8.14, 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 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, 1998, 1999 and 2000 was computed as approximately \$1,074,000, \$1,177,000 and \$2,619,000, 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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(A DEVELOPMENT STAGE COMPANY)

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

(6) OPTIONS AND WARRANTS (CONTINUED)

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, 1998, 1999 and 2000 is as follows:

	1998	1999	2000
Net loss			
As reported.....	\$ (9,210,607)	\$ (8,673,450)	\$ (11,679,363)
Pro forma.....	(10,123,353)	(9,769,704)	(13,032,181)
Basic and diluted net loss per common share			
As reported.....	\$ (1.07)	\$ (1.01)	\$ (1.01)
Pro forma.....	(1.18)	(1.14)	(1.13)

(B) WARRANTS

In connection with certain financing and facility leasing transactions that occurred in 1991 through 1995, the Company issued warrants to purchase 377,133 shares of common stock at prices ranging from \$.04 to \$17.52. 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. As of December 31, 2000, warrants to purchase 23,829 shares of common stock had expired or been cancelled. During 2000, warrants to purchase 58,716 shares of common stock were exercised for net proceeds of approximately \$393,000.

The following table summarizes certain information about warrants outstanding at December 31, 2000:

RANGE OF EXERCISE PRICES	WARRANTS OUTSTANDING	WEIGHTED AVERAGE REMAINING CONTRACTUAL LIFE IN YEARS	WEIGHTED AVERAGE EXERCISE PRICE
\$ 0.04-10.00	451,350	3.53	\$ 3.97
10.80-17.52.....	11,829	0.87	14.89
\$ 0.04-17.52.....	463,179	3.46	\$ 4.24

(7) COLLABORATIVE RESEARCH AGREEMENTS

(A) NOVARTIS

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.

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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

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BIOTRANSPLANT INCORPORATED AND SUBSIDIARY

(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

### (7) COLLABORATIVE RESEARCH AGREEMENTS (CONTINUED)

technology. Under this agreement, Novartis committed up to \$36.0 million in research funding, license fees and milestone payments, assuming the agreement continues for 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.

In September 2000, the Company entered into an agreement with Novartis to combine their respective expertise in the field of xenotransplantation into a newly-formed, independently-run company named Immerge BioTherapeutics AG ("Immerge"). The formation of Immerge supersedes and terminates the 1993 and 1997 Novartis agreements as amended and restated. 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 retains a 67% ownership share of Immerge and retains 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, BioTransplant retains a 33% share of Immerge and will receive royalty payments from Novartis sales of xenotransplantation products, if any.

In December 2000, Immerge BioTherapeutics AG formed a wholly-owned Delaware subsidiary, Immerge BioTherapeutics, Inc. BioTransplant expects to enter into a contract research agreement with the Delaware subsidiary, under which BioTransplant will commit approximately 20 full-time employees to perform research and will agree to provide administrative services, all at a rate to be agreed upon.

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.

### (B) 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 allotransplantation. 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. MedImmune had provided

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\$2.0 million in non-refundable research support through December 31, 1997. Additionally, MedImmune has 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. MedImmune is entitled to a credit against royalty payments for certain milestone payments that it makes. In the event that the Company receives milestone payments from MedImmune that are creditable against future royalties, the Company will defer recognition of revenue upon receipt of the milestone payment and recognize royalty revenue as it is earned.

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### BIOTRANSPLANT INCORPORATED AND SUBSIDIARY

(A DEVELOPMENT STAGE COMPANY)

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

##### (8) INCOME TAXES

The Company accounts for income taxes in accordance with SFAS No. 109, "Accounting for Income Taxes." At December 31, 2000 the Company had net operating loss carryforwards for income tax purposes of approximately \$64,562,000. The Company also has available tax credit carryforwards of \$2,000,000 at December 31, 1999 to reduce future federal income taxes, if any. The net operating loss carryforwards and tax credit carryforwards expire commencing in the year 2006 through 2020, 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.

The components of the deferred tax asset as of December 31, 1999 and 2000 are approximately as follows:

	1999	2000
	-----	-----
Operating loss carryforwards.....	\$19,350,000	\$25,999,000
Tax credit carryforwards.....	2,000,000	2,200,000
Other temporary differences.....	1,550,000	607,000
	-----	-----
	22,900,000	28,806,000
Less--Valuation allowance.....	22,900,000	28,806,000
	-----	-----
	\$ --	\$ --
	=====	=====

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.

##### (9) 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

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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 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.

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### BIOTRANSPLANT INCORPORATED AND SUBSIDIARY

(A DEVELOPMENT STAGE COMPANY)

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

##### (9) COMMITMENTS (CONTINUED)

Commitments as of December 31, 2000, pursuant to these research and license agreements are as follows:

	TOTAL
	-----
Year Ending December 31,	
2001.....	\$3,390,000
2002.....	777,000
2003.....	775,000
	-----
	\$4,942,000
	=====

##### (B) OPERATING LEASE COMMITMENTS

The Company leases its facility under an operating lease that expires in 2009. In addition, the Company is responsible for the real estate taxes and operating expenses related to this facility. Minimum annual rental payments, excluding taxes and operating costs, under this lease agreement are as follows:

2001.....	\$1,025,000
2002.....	1,025,000
2003.....	1,025,000
2004.....	1,025,000
2005.....	1,025,000
Thereafter.....	4,100,000
	-----

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\$9,225,000  
 =====

Rental expense, which includes facility lease, ground lease and real estate tax costs, for the years ended December 31, 1998, 1999 and 2000 was approximately \$1,219,000, \$1,192,000 and \$1,188,000, respectively.

(C) CAPITAL LEASE COMMITMENTS

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

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BIOTRANSPLANT INCORPORATED AND SUBSIDIARY

(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

(9) COMMITMENTS (CONTINUED)

Future minimum payments under these capital lease agreements as of December 31, 2000 are as follows:

YEAR ENDING DECEMBER 31, -----	AMOUNT -----
2001.....	\$ 50,396
2002.....	50,396
2003.....	37,797
Total minimum payments.....	138,589
Less--Amount representing interest.....	18,818
	-----
Present value of minimum lease payments.....	119,771
Less--Current obligation under capital leases.....	37,486
	-----
	\$ 82,285
	=====

Equipment under capital leases collateralize these lease obligations.

(10) 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 support of certain research in the field of animal genetic engineering and an option to maintain its pro rata equity ownership at 30% through December 31, 1998.

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

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operations. The amount of research and development expense relating to Stem Cell losses for 1998 and 1999 was \$700,000 and \$825,000, respectively.

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

### (11) 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

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## BIOTRANSPLANT INCORPORATED AND SUBSIDIARY

(A DEVELOPMENT STAGE COMPANY)

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

#### (11) EMPLOYMENT RETIREMENT/SAVINGS PLAN (CONTINUED)

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 \$82,000.

#### (12) 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, 1999 and 2000, the Company paid CRL approximately \$940,000 and \$988,000, respectively, under this agreement. James C. Foster, President and Chief Executive Officer of CRL, is a director of the Company.

#### (13) PENDING ACQUISITION

On December 8, 2000, the Company entered into a definitive agreement to acquire Eligix, Inc. through a reverse triangular merger. Upon consummation of the merger, Eligix will become a wholly-owned subsidiary of the Company. Under the terms of the merger, the Company will issue up to 5,610,000 shares of common stock in exchange for the fully diluted common stock of Eligix and 990,000 shares of common stock to members of Eligix management over a one-year period. The Company will account for the merger as a purchase of Eligix. The merger is expected to close in the second quarter of 2001, subject to BioTransplant and Eligix stockholder approval. Based upon the Company's average trading price for the period from two days before to two days after the date the merger was announced, December 11, 2000, of \$8.3565, the transaction is valued at approximately \$55,000,000. Additionally, the Company anticipates the closing

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costs of the merger to total approximately \$3.7 million.

If the Company or Eligix terminates the merger agreement in accordance with its terms, all obligations of the parties under the merger agreement terminate and there will be no liability, except that if the merger agreement is terminated by either party as a result of the other party's failure to perform or comply in all material respects with the agreements and covenants under the merger agreement, the nonterminating party will pay the terminating party \$2.0 million.

Additionally, the Company has entered into a promissory note with Eligix whereby Eligix may borrow up to \$2.0 million to fund operations through the closing date of the merger. The loan bears interest at the prime rate. Upon consummation of the merger, the loan will be forgiven, provided that if the merger does not close on or before June 30, 2001, the note will become immediately due and payable in full.

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### BIOTRANSPLANT INCORPORATED AND SUBSIDIARY

(A DEVELOPMENT STAGE COMPANY)

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

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

The following tables present a condensed summary of quarterly results of operations for the years ended December 31, 2000 and 1999 (in thousands, except per share data).

	YEAR ENDED DECEMBER 31, 2000			
	FIRST QUARTER	SECOND QUARTER	THIRD QUARTER	FOURTH QUARTER
Total revenues.....	\$ 1,488	\$ 1,488	\$ 1,476	\$ 1,476
Net loss.....	\$ (2,499)	\$ (2,408)	\$ (2,501)	\$ (4,208)
Basic and diluted net loss per share.....	\$ (0.23)	\$ (0.21)	\$ (0.21)	\$ (0.21)

	YEAR ENDED DECEMBER 31, 1999			
	FIRST QUARTER	SECOND QUARTER	THIRD QUARTER	FOURTH QUARTER
Total revenues.....	\$ 1,239	\$ 1,238	\$ 3,735	\$ 2,408
Net loss.....	\$ (2,892)	\$ (2,968)	\$ (602)	\$ (2,208)
Basic and diluted net loss per share.....	\$ (0.34)	\$ (0.35)	\$ (0.07)	\$ (0.07)

##### (15) SUBSEQUENT EVENT (UNAUDITED)

On June 8, 2001, the Company sold 3,022,457 shares of common stock at \$6.30 per share, resulting in gross proceeds to the Company of approximately \$17.9 million.

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## 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.....	33
Consolidated Balance Sheets as of December 31, 1999 and 2000.....	34
Consolidated Statements of Operations for the years ended December 31, 1998, 1999 and 2000, and for the period from inception (March 20, 1990) through December 31, 2000.....	35
Consolidated Statements of Stockholders' Equity (Deficit) since inception (March 20, 1990).....	36
Consolidated Statements of Cash Flows for the years ended December 31, 1998, 1999 and 2000 and for the period from inception (March 20, 1990) through December 31, 2000.....	37
Notes to Consolidated Financial Statements.....	38

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 October 11, 2000 to report, pursuant to Item 5, the issuance of a press release announcing an agreement with Novartis Pharma AG.
2. A Current Report on Form 8-K was filed on December 11, 2000 to report, pursuant to Item 5, the issuance of a press release announcing the Company's plans to acquire Eligix, Inc. pursuant to an Agreement and Plan of Merger dated December 8, 2000.

BIOTRANSPLANT-TM-, IMMUNOCOGNANCE-TM-, ALLOMUNE-TM- AND BTI-322-REGISTERED TRADEMARK- ARE BIOTRANSPLANT'S TRADEMARKS. BCELL-HDM-TM-, TCELL-HDM-TM-, PANT-HDM-TM-, BRCA-HDM-TM-, NEU/RBC-HDM-TM-, ACT-IV-TM-, LEUKO-HDM-TM-, REACT-HDM-TM-, ACTCELL-HDM-TM- AND HDM-TM- ARE TRADEMARKS OF ELIGIX. THIS ANNUAL REPORT ON FORM 10-K ALSO CONTAINS 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 Amendment No. 2 on Form 10-K/A to be signed on its behalf by the undersigned, thereunto duly authorized.





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10.9(3)	Form of Common Stock Warrant issued to certain investors in October 1994 and Schedule of Warrantholders.
10.10(3)	Form of Common Stock Warrant issued to certain investors in August 1995 and Schedule of Warrantholders.
10.11(3)	Convertible Promissory Note and Warrant Purchase Agreement by and among the Registrant, HealthCare Ventures II, L.P. and Everest Trust dated December 20, 1991.
10.12(3)	Convertible Promissory Note and Warrant Purchase Agreement by and among the Registrant and the parties signatory thereto dated October 31, 1994.
10.13(3)	Third Amended and Restated Stockholders Agreement by and among the Registrant and the parties signatory thereto, as amended by a Consent, Waiver and Amendment dated January 23, 1996.
10.14(3)	Form of Consent, Waiver and Amendment Agreement to the Third Amended and Restated Stockholders' Agreement by and among the Registrant and the parties signatory thereto.
**10.15(3)	Amended 1991 Stock Option Plan.
**10.16(4)	1994 Directors' Equity Plan, as amended.

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EXHIBIT NO.	DESCRIPTION
**10.17(1)	1997 Stock Incentive Plan, as amended
10.18(3)	Consulting Agreement between the Registrant and Dr. David H. Sachs dated January 1, 1991.
10.19(12)	Amendments to Consulting Agreement between the Registrant and Dr. David H. Sachs dated December 1, 1998, January 5, 2000 and January 8, 2001.
10.20(3)	Lease between the Registrant and BioLease, Inc. dated March 17, 1994.
10.21(5)	First Amendment to Lease between the Registrant and BioLease, Inc. dated November 17, 1998.
+10.22(6)	Development and Supply Agreement between the Registrant and Dendreon Corporation (formerly, Activated Cell Therapy), dated August 22, 1996.
10.23(1)	Agreement to further vary Shareholders' Agreement among the Registrant and Castella Research, Secure Sciences and Stem Cell Sciences Pty., Ltd., dated December 20, 1996.
10.24(1)	Agreement to further vary Shareholders' Agreement among the Registrant and Castella Research, Secure Sciences and Stem Cell Sciences Pty., Ltd., dated March 16, 1997, as amended.

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- 10.25(8) Letter Agreement, Security Agreement and Promissory Note between the Registrant and Fleet National Bank, dated August 10, 1999.
- +10.26(7) Miniature Swine Transfer and Maintenance Agreement dated January 1, 1998 by and between Charles River Laboratories, Inc., Wilmington Partners, L.P. and the Registrant.
- +10.27(9) Shareholder Agreement dated September 24, 2000 by and between the Registrant, Novartis AG and Immerge BioTherapeutics AG (formerly known as Loxo AG), together with exhibits.
- +10.28(10) Patent License Agreement (MEDI-507), dated July 17, 1997 by and between Protein Design Labs and MedImmune, Inc.
- 10.29(11) Promissory Note made by Eligix, Inc. in favor of the Registrant.
- 21(1) Subsidiaries of the Registrant.
- 23.1 Consent of Arthur Andersen LLP.

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- + Confidential treatment granted as to certain portions.
- \* The Registrant agrees to furnish supplementally a copy of any omitted schedules to this agreement to the Securities and Exchange Commission upon its request.
- \*\* 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 to the Registrant's Registration Statement on Form S-4, as amended (File No. 333-53386).
- (2) Incorporated herein by reference from the Registrant's Form 8-K dated July 18, 2000.
- (3) Incorporated herein by reference to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-02144).
- (4) Incorporated herein by reference to the Registrant's Definitive Proxy Statement for the 1999 Annual Meeting of Stockholders filed on Schedule 14A.
- (5) Incorporated herein by reference to the Registrant's Form 10-K for the year ended December 31, 1999.
- (6) Incorporated herein by reference to the Registrant's Form 10-Q for the quarter ended September 30, 1996.
- (7) Incorporated herein by reference to the Registrant's Form 10-Q for the quarter ended June 30, 1998.
- (8) Incorporated herein by reference to the Registrant's Form 10-Q for the quarter ended September 30, 1999.

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- (9) Incorporated herein by reference to the Registrant's Form 10-Q for the quarter ended September 30, 2000.
- (10) 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.
- (11) Incorporated herein by reference to the Registrant's Current Report on Form 8-K dated March 9, 2001.
- (12) Previously filed.