

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

Form 10-K

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

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2004

OR

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

COMMISSION FILE NUMBER 0-50626

Xcyte Therapies, Inc.

(EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)

DELAWARE

(State or other jurisdiction of incorporation or organization)

91-1707622

(I.R.S. Employer Identification Number)

1124 COLUMBIA STREET, SUITE 130 SEATTLE, WASHINGTON 98104

(ADDRESS OF PRINCIPAL EXECUTIVE OFFICES AND ZIP CODE)

(206) 262-6200

(REGISTRANT'S TELEPHONE NUMBER, INCLUDING AREA CODE)

SECURITIES REGISTERED PURSUANT TO SECTION 12(B) OF THE ACT: NONE

SECURITIES REGISTERED PURSUANT TO SECTION 12(G) OF THE ACT:

Common Stock, par value \$0.001 per share

6% Convertible Exchangeable Preferred Stock, par value \$0.001 per share

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

The registrant has been subject to the filing requirements of the Securities Exchange Act of 1934 since March 16, 2004, the effective date of its Registration Statement on Form S-1, as amended (File No. 333-109653), and has filed all required reports since such effective date.

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulations S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of June 30, 2004, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately \$37.0 million based on the closing sales price of the registrant's common stock on the Nasdaq National Market on that date. Shares of common stock held by each officer and director and by each person who owns 5% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 21, 2005, the registrant had an aggregate of 19,664,897 shares of common stock issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Information required in response to Part III of Form 10-K (Items 10, 11, 12, 13 and 14) is hereby incorporated by reference to the specified portions of the registrant's Definitive Proxy Statement for the Annual Shareholders Meeting to be held on June 9, 2005, which Definitive Proxy Statement shall be filed with the Securities and Exchange Commission within 120 days of the end of the fiscal year to which this Report relates.

[Table of Contents](#)

XCYTE THERAPIES, INC., FORM 10-K

XCYTE THERAPIES, INC.
ANNUAL REPORT ON FORM 10-K
For the Fiscal Year Ended December 31, 2004

TABLE OF CONTENTS	PAGE
PART I	
ITEM 1. Business	3
ITEM 2. Properties	22
ITEM 3. Legal Proceedings	22
ITEM 4. Submission of Matters to a Vote of Securities Holders	22
PART II	
ITEM 5. Market For Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	22
ITEM 6. Selected Financial Data	23
ITEM 7. Management's Discussion and Analysis of Financial Condition and Results of Operations	24
ITEM 7A. Quantitative and Qualitative Disclosures About Market Risk	46
ITEM 8. Financial Statements and Supplementary Data	48
ITEM 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure	68
ITEM 9A. Controls and Procedures	68
ITEM 9B. Other Information	68
PART III	
ITEM 10. Directors and Executive Officers of the Registrant	69
ITEM 11. Executive Compensation	69
ITEM 12. Security Ownership of Certain Beneficial Owners and Management	69
ITEM 13. Certain Relationships and Related Transactions	69
ITEM 14. Principal Accountant Fees and Services	69
PART IV	
ITEM 15. Exhibits and Financial Statement Schedules	70
SIGNATURES	
EXHIBIT 23.1	
EXHIBIT 31.1	
EXHIBIT 31.2	
EXHIBIT 32.1	
EXHIBIT 32.2	

PART I

ITEM 1. BUSINESS

Overview

We are a biotechnology company developing a new class of therapeutic products designed to enhance the body's natural immune responses to treat cancer, infectious diseases and other medical conditions associated with weakened immune systems. We derive our therapeutic products from a patient's own T cells, which are cells of the immune system that orchestrate immune responses and can detect and eliminate cancer cells and infected cells in the body. We use our patented and proprietary Xcellerate Technology to generate activated T cells, which we call Xcellerated T Cells, from blood that is collected from the patient. Activated T cells are T cells that have been stimulated to carry out immune functions. Our Xcellerate Technology is designed to rapidly activate and expand the patient's T cells outside of the body. These Xcellerated T Cells are then administered to the patient.

We believe, based on clinical trials to date, our Xcellerate Technology can produce Xcellerated T Cells in sufficient numbers to generate rapid and potent immune responses to treat a variety of medical conditions. In our ongoing clinical studies using our Xcellerate Technology, we have observed an increase in the quantity and a restoration of the diversity of T cells in patients with weakened immune systems. We have submitted the findings on the increase in quantity of T cells to the FDA and plan to submit additional data in our next annual report. We believe we can efficiently manufacture Xcellerated T Cells for therapeutic applications. We expect Xcellerated T Cells may be used alone or in combination with other complementary treatments. We and other clinical investigators have completed or are conducting clinical trials in the following indications:

- **CHRONIC LYMPHOCYTIC LEUKEMIA, OR CLL.** In our ongoing Phase I/II clinical trial in CLL, treatment with Xcellerated T Cells resulted in a 50% to 100% reduction in the size of enlarged lymph nodes in 12 of 17 (71%) patients based on the latest clinical data, which was collected on October 1, 2004, which is the most recent date that data was available. In addition, there was a 50% or greater reduction in spleen size as measured below the rib cage by physical examination in 11 of the 13 patients (85%) with enlarged spleens. Results from this trial were submitted to the FDA in the Information Packet for a Type B End of Phase II meeting held on September 23, 2004. At this meeting we discussed with the FDA our plans for a Phase II/III clinical trial of Xcellerated T Cells in patients with CLL who have been previously treated with chemotherapy and have failed treatment with Campath, an FDA-approved drug used to treat CLL. Based on feedback from the FDA during and subsequent to this meeting, we modified our planned protocol for this Phase II/III clinical trial to provide the FDA with data we believed would address the FDA's concerns regarding the subcutaneous route of Campath administration and the dose and schedule of Xcellerated T Cells. We submitted the protocol to the FDA on December 23, 2004. On February 1, 2005, the FDA requested the withdrawal of the protocol to allow additional discussion of the design of the trial. The protocol has been resubmitted to the FDA as a draft protocol. We also met with the FDA on February 16, 2005 to discuss the chemistry, manufacturing and controls submission that has been made related to this trial and our planned transfer of our manufacturing operations to our new facility in Bothell, Washington in the second quarter of 2005. We are also providing additional information and clarification to the FDA regarding our chemistry, manufacturing and controls submission. Until we receive acceptance of our chemistry, manufacturing and controls submission, and feedback from the FDA regarding our proposed protocol, we cannot predict when we will initiate this Phase II/III trial.
- **MULTIPLE MYELOMA.** In our ongoing Phase I/II clinical trial, we have shown that treatment with Xcellerated T Cells led to rapid recovery of T cells and lymphocytes in all 36 treated patients with multiple myeloma following treatment with high-dose chemotherapy and autologous stem cell transplantation. Previous independent clinical studies have demonstrated a correlation between patient survival and the speed of recovery of lymphocytes following treatment with chemotherapy and stem cell transplantation. Preliminary clinical results of our clinical trial show that, of the 35 patients evaluable for tumor responses based on the latest clinical data, which was collected on October 1, 2004, 21 patients (60%) had a greater than 90% decrease in the tumor marker, which is used to measure disease. We have submitted some of these findings to the FDA, and will submit additional data in our next annual report. Additional follow-up will be required to determine the therapeutic effects of Xcellerated T Cells after transplant. In independent clinical trials, a greater than 90% decrease in the tumor marker has been associated with increased survival in multiple myeloma patients. We are also conducting a Phase II trial to treat patients who have advanced disease with Xcellerated T Cells without other anti-tumor therapy.
- **NON-HODGKIN'S LYMPHOMA.** In an independent clinical trial, conducted by one of our scientific founders under a physician-sponsored investigational new drug application, or IND, 16 non-Hodgkin's lymphoma patients undergoing high-dose chemotherapy and autologous stem cell transplantation were treated with T cells activated with an earlier version of our proprietary technology. As reported in the peer-reviewed journal, *Blood*, in September 2003, 8 out of these 16 patients with a very poor prognosis were still alive with a median follow-up of 33 months. These data were derived from an independent clinical trial, which we did not control and which was not designed to produce statistically significant results as to efficacy or to ensure the results were due to the effects of

T cells activated using an earlier version of our proprietary technology. We have been advised that these data have been submitted to the FDA. We are also conducting a Phase II clinical trial in patients with low-grade non-Hodgkin's lymphoma who have failed prior therapies. We plan to enroll a total of 40 patients in this trial with most of the common forms of low-grade non-Hodgkin's lymphoma, including small lymphocytic, follicular, marginal zone and mantle cell types. Accrual is currently ongoing in this trial.

- *HIV.* In an independent clinical trial in HIV patients with low T cell counts conducted by one of our scientific founders under a physician-sponsored IND, treatment with T cells activated using an earlier version of our proprietary technology increased the patient population's average T cell count to within normal levels and maintained this normal count for at least one year following therapy. These data were derived from an independent clinical trial, which we did not control, and which was not designed to produce statistically significant results as to efficacy or to ensure the results were due to the effects of T cells activated using an earlier version of our proprietary technology. We have been advised that these data have been submitted to the FDA for review. The results of this study were published in a peer-reviewed journal, *Nature Medicine*, in January 2002. In several independent clinical studies, increased levels of T cells have been shown to correlate with increased patient survival and improved clinical outcome. Our collaborative partner, Fresenius Biotech GmbH, is conducting a Phase I clinical trial to treat HIV patients with genetically-modified T cells produced using our Xcellerate Technology. In addition, we are currently conducting laboratory studies in HIV and plan to initiate a clinical trial using Xcellerated T Cells in patients with HIV in late 2005.

In clinical trials, we have observed few side effects in most patients. As of February 28, 2005, in over 207 infusions of Xcellerated T Cells in 157 patients, we have had only three serious adverse events reportable to the FDA that were judged as possibly or probably related to the treatment. The first of these was a rash that resolved following treatment. The second of these was congestive heart failure in a patient with pre-existing severe anemia that resolved approximately two hours following treatment. We subsequently amended our protocol to identify patients with anemia prior to administering Xcellerated T Cells. The third was an exacerbation of chronic obstructive pulmonary disease occurring one day following treatment which required that the patient be kept on a respirator for three days. This patient recovered from this event and was discharged from the hospital. This patient had an extensive prior history of lung disease and had been on a respirator in the past for exacerbations of the disease. In general, side effects were similar to those observed with infusions of other kinds of cells, such as red blood cells or frozen cell products, and typically minor, including fever, chills, increased heart rate, nausea and sweating. Our clinical trials and independent clinical trials using an earlier version of our technology, to date, have involved small numbers of patients, and we have not designed nor been required to design such trials to produce statistically significant results as to efficacy. These trials have neither been randomized nor blinded to ensure that the results are due to the effects of the Xcellerated T Cells. Success in early clinical trials neither ensures that large-scale trials will be successful nor predicts final results.

Based on these clinical results, we believe there are several important clinical opportunities for Xcellerated T Cells. We plan to initially focus our development efforts in those clinical indications that we believe have significant commercial opportunities and offer the most rapid path to regulatory approval. We believe hematological malignancies, including CLL, multiple myeloma and non-Hodgkin's lymphoma, and HIV represent significant potential markets for Xcellerated T Cells. In addition, these disease indications are generally incurable, which means that Xcellerated T Cells may qualify for fast track approval by the FDA, which could shorten the time to potential regulatory approval and commercialization. However, because we have limited resources to pursue clinical opportunities for Xcellerated T Cells, we are currently focusing most of our clinical development resources on our planned Phase II/III trial in CLL and planned Phase I/II trial in HIV. In addition, we will conclude our ongoing trials in multiple myeloma and non-Hodgkin's lymphoma and complete the preclinical work necessary to initiate a Phase I/II trial in patents with HIV.

Corporate Restructuring

As a result of the plan to limit clinical development primarily to the planned Phase II/III trial in CLL and planned Phase I/II trial in HIV, we reduced our workforce by approximately 24%, to 81 employees on March 22, 2005. We believe the remaining staff will be sufficient to conduct the two planned clinical trials and to transfer manufacturing operations for the Phase II/III trial to our new facility in Bothell, Washington.

Background

T Cells and the Immune System

T cells are critically important to a properly functioning immune system. The immune system is responsible for protecting the body from foreign invaders and eliminating tumor cells and pathogens, including bacteria, viruses and fungi. Classically, the immune system is divided into two arms, known as humoral immunity and cell-mediated immunity. Humoral immune responses are mediated by antibodies, which several biopharmaceutical companies have developed into major commercial products to treat a range of diseases, including cancer, infectious diseases and autoimmune diseases. Cell-mediated immunity also plays a critical role in fighting many of these illnesses. T cells, the most common type of lymphocyte, play the central role in cell-mediated immunity. We believe T cells may be used to treat cancer, infectious diseases and autoimmune diseases.

Healthy individuals have a few hundred billion T cells that circulate throughout the body. Upon encountering tumor cells or pathogens, T cells become activated and recognize and eliminate them from the body. They do this by performing several important functions. First, T cells stimulate many other components of the immune system that are required for effective immune responses. For example, activated T cells control the proliferation and differentiation of other lymphocytes, B cells, which make antibodies that help fight infections. Additionally, activated T cells recognize and mark abnormal cells, such as tumor cells or infected cells, for destruction by the immune system. Activated T cells also participate directly in killing tumor cells and infectious agents, such as viruses. Finally, T cells also produce substances that stimulate the production of important blood cells including neutrophils and natural killer cells that may help fight infections, platelets that prevent bleeding, and red blood cells that carry oxygen to tissues.

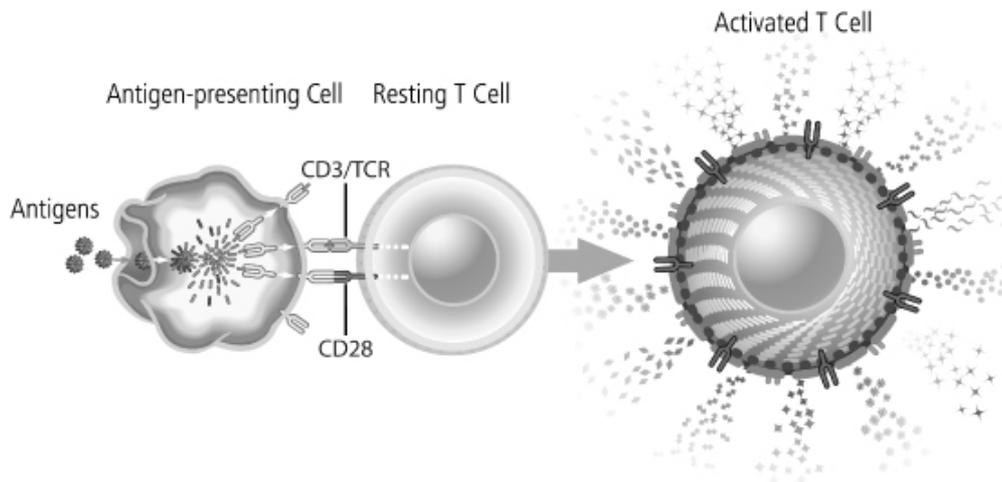
Every T cell carries its own distinct receptor, the T cell receptor, which is capable of recognizing a specific antigen. Antigens are substances produced by tumor cells, viruses, bacteria or other pathogens that cause disease and may be distinguishable from substances produced by healthy cells. Healthy individuals have a population of T cells that expresses millions of different T cell receptors. It is this broad spectrum of T cell receptors that provides the diverse T cell repertoire that makes it possible for the immune system to recognize and respond to a wide variety of harmful pathogens that cause disease.

Activation of T Cells

T cells remain in a resting state until they become activated upon encountering antigens expressed by infected cells or tumor cells. Although activation depends on the specificity of binding of an antigen to a T cell receptor, all T cells display similar characteristics upon activation. For example, when T cells undergo activation, they become more sensitive to stimulation by antigens. This makes activated T cells especially effective at eradicating pathogens that would otherwise escape recognition from the immune system. In addition, upon activation, T cells rapidly multiply to large numbers in the body. Accordingly, it is the process of activation that makes T cells potent therapeutic agents.

Two signals are required to activate T cells, Signal 1 and Signal 2, which are delivered by two molecules, CD3 and CD28, present on the surface of T cells. Signal 1 occurs when the CD3 molecule, which is tightly associated with the T cell receptor, is stimulated by engagement of the receptor by an antigen taken up, processed and presented by an antigen-presenting cell. Signal 2 occurs when the same antigen-presenting cell engages the CD28 molecule on the T cell. When the CD3 and CD28 molecules are stimulated, T cells become activated and produce an immune response. If only Signal 1 is generated, T cells are only partially activated and die quickly. If only Signal 2 is generated, no immune response occurs at all. Only the simultaneous delivery of both Signal 1 and Signal 2 generates activated T cells that can function properly in the body and survive for prolonged periods.

When a T cell becomes activated, it produces a number of different molecules to carry out its many functions. Some of these molecules, known as cytokines, are secreted by the T cell while other molecules are expressed on the surface of the T cell. Many of these molecules activate other cellular elements of the immune system. The activated T cell also produces several toxic substances that are responsible for directly killing pathogens. Several different molecules that a T cell produces in proper amounts work together to generate an effective immune response. Many of these molecules are extremely potent and would be extremely toxic if they were administered intravenously or by other routes that allow them to circulate throughout the body. The activated T cell is able to control the production and site of delivery of these molecules in order to generate a safe immune response that is concentrated at the site of disease.



The Dangers of T Cell Deficiencies

The quantity, quality and diversity of T cells are critically important for a properly functioning immune system.

- **QUANTITY.** A variety of treatments for cancer and autoimmune diseases destroy T cells, including chemotherapy, radiation and some monoclonal antibodies. In addition, many diseases, such as HIV and several kinds of primary immunodeficiencies, are associated with low numbers of T cells. When the number of T cells decreases significantly, the human immune system is less able to defend the body against cancer and infectious diseases.
- **QUALITY.** In many diseases, such as cancer and HIV, T cells have a reduced ability to generate effective immune responses. Many chemotherapy drugs and immunosuppressive agents also depress the activity and function of T cells. Defective T cells may not be able to respond to normal signals required for an effective immune response. These T cells may produce insufficient numbers of molecules required either to mark tumor cells for destruction or to directly destroy them.
- **DIVERSITY.** A decreased diversity of T cell receptors is observed in many diseases, including cancer, HIV and autoimmune diseases. This decreased spectrum of T cell receptors narrows the ability of T cells to recognize a broad array of antigens. This may reduce a patient's ability to respond to and eliminate cancer and infectious diseases.

In many patients, decreases in the quantity, quality and diversity of T cells occur together. This puts patients at an increased risk of developing serious and often life-threatening infectious diseases as well as cancer. For example, patients with autoimmune diseases treated with immunosuppressive drugs have an increased risk of infections. Additionally, transplant patients treated with similar drugs have an increased risk of infections and non-Hodgkin's lymphoma. Patients with HIV have an increased risk of developing non-Hodgkin's lymphoma and multiple myeloma. Patients with certain types of primary immunodeficiencies have an increased risk of developing infections as well as non-Hodgkin's lymphoma and gastric cancer. In each of these medical conditions, patients often have poorly functioning T cells that are reduced in number and have limited diversity, which makes these patients particularly susceptible to infection and cancer.

Conversely, the presence of a sufficient number of healthy T cells is associated with improved therapeutic outcome in patients with cancer, HIV and autoimmune diseases. At the time of diagnosis, patients with non-Hodgkin's lymphoma who have higher lymphocyte counts have better survival. Several recent independent clinical studies have shown that cancer patients who experience more rapid and complete recovery of lymphocytes after chemotherapy have improved survival and clinical outcome. Improved prognosis has been well documented in HIV patients whose T cell counts significantly increased after anti-HIV therapy. These patients demonstrate improvements in T cell function as well as in T cell receptor repertoire diversity after successful treatment. Restoring healthy T cell diversity has also been associated with remission of disease in patients with certain autoimmune diseases.

Current Approaches to Activate the Immune System and Their Limitations

There has been a major clinical focus on developing therapeutic agents to strengthen and activate a patient's immune system. Many of these agents are used to activate the patient's T cells inside the body. These therapeutic agents include:

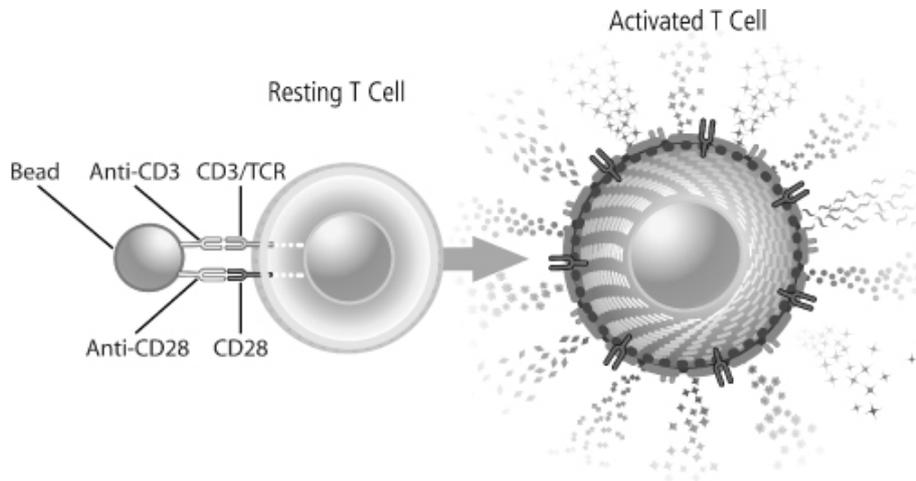
- **CYTOKINES.** Cytokines, such as IL-2, are potent chemical messengers produced by the immune system that stimulate T cells and generate an immune response. Although cytokines have demonstrated therapeutic effects in cancer and infectious diseases, they are associated with serious and sometimes life-threatening side effects when administered to patients. In order to reduce adverse effects, these drugs are often given at decreased doses, which may compromise their therapeutic effects.
- **MONOCLONAL ANTIBODIES.** A variety of different monoclonal antibodies are being developed that target molecules expressed on the surface of T cells. Some of these target molecules activate T cells, while others inhibit T cell activation. By blocking the molecules that inhibit T cell activation, T cell activity can be increased. These antibodies have demonstrated limited therapeutic activity, and some of these molecules have been associated with serious side effects due to overactive T cells.
- **ADJUVANTS.** Other therapeutic agents known as adjuvants have also been developed to stimulate immune responses. Some of the most potent adjuvants are derived from bacteria that make a variety of molecules that stimulate immune responses. Adjuvants are used for some clinical applications, but their use is limited due to toxicity. Recently, several of the molecules produced by bacteria that activate the immune system have been identified, and some are being developed as immunotherapeutic agents. However, it is unclear whether these individual molecules will retain the therapeutic effects of whole adjuvants.
- **VACCINES.** A number of different vaccines are under development to treat cancer and HIV. These vaccines are made up of antigens expressed by tumor cells or HIV and are often administered with adjuvants. Patients are treated with the goal of stimulating T cells to respond to antigens, so that the T cells become activated and destroy the cancer or virus. However, many patients with cancer or HIV have deficiencies in the quantity, quality or diversity of their T cells, which may limit their ability to generate an effective response to the vaccine. This may be one reason vaccines have been ineffective in treating cancer and HIV.

- **DENDRITIC CELLS.** Cells of the immune system known as dendritic cells are being used to stimulate immune responses in patients with cancer. In healthy individuals, dendritic cells deliver both Signal 1 and Signal 2, which activate T cells. For most clinical applications, a patient's own dendritic cells are grown outside of the body and then administered back to the patient. However, the ability to generate dendritic cells varies from patient to patient. Recently, it has been documented that dendritic cells under some circumstances may also make molecules that inhibit T cell responses. In addition, many patients with cancer or HIV have T cell deficiencies, which may limit their ability to respond to dendritic cells. Accordingly, dendritic cells may be limited in their ability to activate patients' T cells and generate effective immune responses.
- **ACTIVATED T CELLS GENERATED USING OTHER METHODS.** To overcome the limitations of activating T cells inside of the body, researchers have attempted to activate and grow patients' T cells *ex vivo*, or outside of the body, before administering them for therapeutic applications. The development of monoclonal antibodies, which are proteins derived from a single clone of antibody-producing cells that bind to well-defined targets, made it possible to develop reagents that bind to the CD3 molecule and deliver Signal 1 to T cells. These antibodies are used to activate and grow T cells outside of the body. However, the process generates only one of the two signals required to activate T cells. Without Signal 2, this results in limited activity, growth and survival of T cells in the laboratory as well as after their administration into patients. Some recent approaches use antigens to target T cell receptors to generate antigen-specific T cells. However, these approaches result in a restricted T cell response that may not be effective for many clinical applications requiring broader T cell responses.

Our Solution

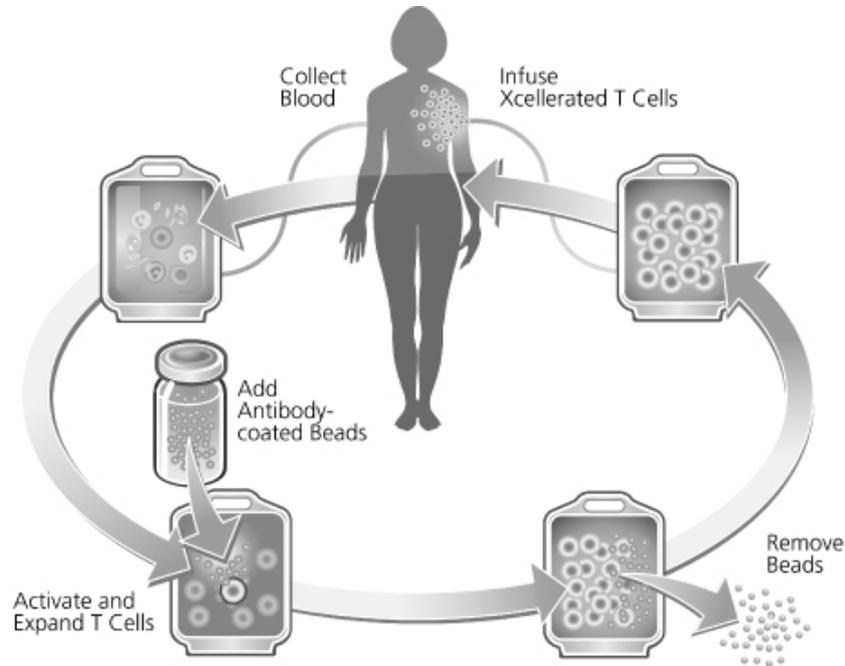
Our Therapeutic Approach

We have developed our patented and proprietary Xcellerate Technology, which can be used to consistently activate and grow large numbers of T cells outside of the body for therapeutic applications. The cells generated with this process, which we call Xcellerated T Cells, have been observed to have the broad diversity of T cell receptors that we believe are required to recognize and eliminate cancer and infectious diseases. These activated T cells secrete a wide spectrum of molecules, such as cytokines, and express a broad range of molecules on their cell surfaces to generate an effective immune response. In addition, T cells generated using an earlier version of our proprietary technology have been shown to survive for more than one year after infusion in patients. We believe the long-term survival of these cells may lead to sustained therapeutic responses.



Our patented Xcellerate Technology is used in a process that employs magnetic beads, which are plastic-coated magnetic microspheres, densely covered with two monoclonal antibodies that deliver Signal 1 and Signal 2 to activate T cells. One of the monoclonal antibodies delivers Signal 1 to T cells by binding directly to the CD3 molecule. Our Xcellerate Technology also uses another monoclonal antibody that binds to the CD28 molecule to deliver Signal 2 to T cells. We attach both of these monoclonal antibodies to the surface of magnetic beads. When T cells bind to the monoclonal antibodies on these magnetic beads, they become activated and significantly increase in number. We believe these magnetic beads can provide the signals required to activate and grow a broad spectrum of T cells characterized by a diverse T cell receptor repertoire. These Xcellerated T Cells are then administered to the patient with the goal of restoring the health of the patient's immune system and ability to eliminate cancer and infectious diseases.

To produce Xcellerated T Cells, white blood cells, a rich source of T cells, are first collected from a patient's blood in an outpatient clinical setting using a standard procedure called leukapheresis. These cells are sent to our cGMP manufacturing facility, where they are frozen and stored. When needed, the cells are thawed and processed in a closed system to avoid exposure to the outside environment, reducing the risk of microbial contamination. In this process, the patient's white blood cells are mixed with our microscopic magnetic beads and then placed in a sterile, custom disposable bioreactor containing a solution of nutrients and a low level of IL-2 that sustains the growth of the T cells. These beads are covered with our two monoclonal antibodies, which deliver Signal 1 and Signal 2 to activate the T cells in the solution. During an approximate 10-13 day period after the application of the beads, the T cells become activated and rapidly increase in number. At the end of this period, the antibody-coated magnetic beads are substantially removed with a magnetic device. The Xcellerated T Cells are then frozen for increased shelf life. We have documented that we can store the Xcellerated T Cells in a frozen state for at least 12 months without significant loss of activity. When requested by the physician, the frozen Xcellerated T Cells are shipped to the outpatient clinic where they are thawed and administered by intravenous infusion in approximately two hours.



For purposes of safety and regulatory compliance, we have established procedures designed to track patients' cells during the manufacture and shipment of Xcellerated T Cells. Each patient receives a unique identifying number that also contains a code for the clinical site where they are being treated. This unique identifying number is used to track, monitor and record all documentation, labels and materials relating to the production of the patient's Xcellerated T Cells from blood collection through infusion of the final product. Before the product is shipped to the clinical site, we conduct quality control procedures in our laboratory. These procedures are designed to assure that Xcellerated T Cells meet strict quality control criteria such as T cell purity, dosage, potency, safety and sterility.

Benefits of Xcellerated T Cells

We believe Xcellerated T Cells may be an effective treatment for cancer and infectious diseases and may have the following clinical benefits:

- INCREASED T CELL QUANTITY.** Using our Xcellerate Technology, we have documented the activation and growth of more than 100 billion T cells, representing a 100-fold to 300-fold increase in T cells during the manufacturing process. The results of this process for manufacturing Xcellerated T Cells for multiple myeloma patients and CLL patients were published in the peer-reviewed *BioProcessing Journal* in November 2003 and in the peer-reviewed journal *Cytotherapy* in December 2004, respectively. We have submitted some of these data to the FDA and plan to submit additional data for their review. One hundred billion T cells represents approximately 25% to 30% of the total number of T cells found in healthy individuals. We believe this number of Xcellerated T Cells is sufficient to generate therapeutic effects in patients with cancer, infectious diseases and autoimmune diseases. In our ongoing Phase III clinical trial in multiple myeloma, we have evidence that treatment with Xcellerated T Cells leads to rapid T cell and lymphocyte recovery in patients treated with high-dose chemotherapy and autologous stem cell transplantation.

- **PROLONGED T CELL SURVIVAL.** In an independent clinical trial, T cells activated using an earlier version of our proprietary technology have been documented to survive in the body for more than a year after their administration. We have been advised that these data have been submitted to the FDA for review. We believe the prolonged survival of Xcellerated T cells may enable less frequent administration than existing therapeutic products for cancer and infectious diseases.
- **IMPROVED T CELL QUALITY.** We have documented that Xcellerated T Cells produce a broad spectrum of cytokines and express many important surface molecules required to generate an effective immune response. We have submitted these data to the FDA for review. In laboratory studies, our Xcellerate Technology has been used to restore healthy immune responses in T cells from patients with leukemia activated and grown using our Xcellerate Technology. These Xcellerated T Cells have been shown in the laboratory to mark patients' leukemic cells for destruction by the immune system. These results were recently published in the peer-reviewed *Journal of Immunology* in February 2005. We have also observed that the Xcellerated T Cells can directly kill the patients' tumor cells. These results were published in the *Journal of Immunology* in February 2005. In our ongoing Phase I/II clinical trial in CLL, treatment with Xcellerated T Cells resulted in a 50% to 100% reduction in the size of enlarged lymph nodes in 12 of 17 patients (71%) evaluated and a 50% or greater reduction in spleen size as measured below the ribcage by physical examination in 11 of the 13 patients (85%) with enlarged spleens. We have submitted some of these findings to the FDA for review.
- **INCREASED NUMBERS OF WHITE BLOOD CELLS, RED BLOOD CELLS AND PLATELETS.** In our ongoing Phase I/II trial in CLL, we have observed that the infusion of Xcellerated T Cells results in increased numbers of white blood cells including T cells, neutrophils and natural killer cells, which may help fight infections and cancer, increased numbers of red blood cells, as measured by hemoglobin levels, which carry oxygen to tissues, and increased numbers of platelets, which prevent bleeding. We have submitted these findings to the FDA for review.
- **FAVORABLE SIDE EFFECT PROFILE.** Xcellerated T Cells are produced from T cells originating from the patient. We believe that using a patient's own cells may result in a safer product than chemotherapy drugs. Xcellerated T Cells and T cells generated using an earlier version of our proprietary technology have been administered to over 240 patients in clinical trials. We have observed few side effects in most patients. The side effects associated with administration of Xcellerated T Cells are typically minor and similar to those observed with infusions of other kinds of cells, such as red blood cells or frozen cell products. To date, there have been only three serious adverse events reportable to the FDA that were judged as possibly or probably related to the therapy, all of which were resolved. The first of these was a rash that resolved following treatment. The second of these was congestive heart failure in a patient with pre-existing severe anemia that resolved approximately two hours following treatment. We subsequently amended our protocols to identify patients with anemia prior to administering Xcellerated T Cells. The third was an exacerbation of chronic obstructive pulmonary disease occurring one day following treatment, which required that the patient be kept on a respirator for three days. This patient recovered from this event and was discharged from the hospital. This patient had an extensive prior history of lung disease and had been on a respirator in the past for exacerbations of the disease.
- **COMPLEMENTARY TO OTHER THERAPIES.** Based on our clinical observations to date, we believe Xcellerated T Cells may be complementary to current therapies, such as chemotherapy, radiation and monoclonal antibodies. Xcellerated T Cells may help repair the damage to the immune system caused by chemotherapy or other drugs that suppress the immune system. In addition, we believe Xcellerated T Cells may be combined with anti-viral drugs as well as therapies that activate the immune system, such as cancer vaccines. We and other clinical investigators have performed both preclinical animal studies as well as laboratory studies using patients' tissues demonstrating the feasibility of using this approach to improve the potential efficacy of combining T cells activated with our proprietary technology with cancer vaccines.

Benefits of Our Xcellerate Technology

We believe our Xcellerate Technology may have the following benefits:

- **EX VIVO PROCESS.** We designed our Xcellerate Technology to be used *ex vivo*, or outside of the body. This allows us to grow and monitor Xcellerated T Cells in a controlled environment where we can provide optimal conditions for the activation and growth of T cells.
- **BROAD CLINICAL APPLICATIONS.** Based on recent clinical trials, we believe our Xcellerate Technology can be applied to a variety of diseases. We have demonstrated in the laboratory as well as in our cGMP manufacturing facility that our Xcellerate Technology can be used to activate and grow T cells from patients with a variety of cancers, including kidney cancer, prostate cancer, non-Hodgkin's lymphoma, multiple myeloma and leukemia. Other clinical investigators have used an earlier version of our proprietary technology to activate and grow T cells from HIV patients for clinical applications. In addition, we have entered into a collaboration under which Fresenius Biotech GmbH has treated ten HIV patients with genetically-modified T cells produced using our Xcellerate Technology. Recently, we have demonstrated in the laboratory that we can use our Xcellerate Technology to activate and grow T cells from

patients with autoimmune diseases, including rheumatoid arthritis, systemic lupus erythematosus and scleroderma. In addition, we have demonstrated that we can modify our Xcellerate Technology for potential application in other areas of immunotherapy, including vaccines and antigen-specific T cell approaches. These findings were recently published in the peer-reviewed *Journal of Immunotherapy* in September 2004.

- **EASE OF ADMINISTRATION.** We initially collect a patient's white blood cells, a rich source of T cells, in a standard outpatient procedure called leukapheresis. After our process is completed, Xcellerated T Cells are administered in approximately two hours using a routine intravenous procedure in an outpatient clinic. This is similar to what is performed today in most oncology practices where chemotherapy, monoclonal antibodies and red blood cell transfusions are administered intravenously.
- **REPRODUCIBLE AND COST-EFFECTIVE MANUFACTURING.** We use the same standardized process to produce Xcellerated T Cells for all patients. Other than our proprietary components, our Xcellerate Technology incorporates commercially available products and standard clinical and blood bank supplies, which enables us to efficiently manufacture Xcellerated T Cells. We do not require materials that must be obtained by surgery, such as samples of the patient's tumor. We can freeze the cells we initially collect from our patients as well as freeze the Xcellerated T Cells we generate from those cells. We have documented storage of Xcellerated T Cells in our facility for at least 12 months without significant loss of activity. Freezing may enable us to generate several Xcellerated T Cell treatments from one manufacturing procedure. In addition, we believe freezing should allow us to supply Xcellerated T Cells to patients throughout the United States from a central manufacturing site.

Our Strategy

Our goal is to be a leader in the field of T cell therapy and to leverage our expertise in T cell activation to develop and commercialize products to treat patients with cancer, infectious diseases, autoimmune diseases and compromised immune systems. Key elements of our strategy include the following:

- **MAXIMIZE SPEED TO MARKET.** We will focus on advancing clinical trials for clinical indications that provide the most rapid and cost-effective commercialization strategy for Xcellerated T Cells. We believe that focusing on life-threatening diseases can facilitate rapid entry into the market for Xcellerated T Cells. The FDA has adopted fast track approval and priority trial procedures for therapies that address life-threatening diseases, and we may apply for fast track designation.
- **EXPAND THE THERAPEUTIC APPLICATIONS OF XCELLERATED T CELLS.** In addition to cancer and HIV, we believe Xcellerated T Cells can be used to treat patients with other illnesses, including infectious diseases, such as hepatitis. In addition, we are studying the potential therapeutic benefits of Xcellerated T Cells in patients with autoimmune diseases treated with immunosuppressive drugs and in patients with compromised immune systems. We may also expand the application of Xcellerated T Cells to other types of cancer. In addition to our own clinical trials, our scientific founders are conducting a number of independent clinical studies using an earlier version of our proprietary technology for additional clinical applications. Based on the results of their studies, we may pursue some of these clinical opportunities using Xcellerated T Cells.
- **LEVERAGE COMPLEMENTARY TECHNOLOGIES AND THERAPIES.** Xcellerated T Cells may be effective in combination with current treatments for cancer and infectious diseases, such as chemotherapy. We believe Xcellerated T Cells may help ameliorate the effects of immunosuppression associated with treatment of autoimmune diseases. We also intend to explore opportunities to combine complementary technologies and therapies, such as cancer vaccines and monoclonal antibodies, with Xcellerated T Cells. In addition, we may supplement our internal efforts by acquiring or licensing technologies and product candidates that complement our Xcellerate Technology.
- **RETAIN SELECTED U.S. COMMERCIALIZATION RIGHTS IN CANCER.** We intend to retain marketing and commercialization rights in North America for products in specialized markets, such as cancer. We may seek development and marketing support for clinical indications that have broader patient populations in North America. In addition, we plan to pursue strategic partnerships with biopharmaceutical companies to obtain development and marketing support for territories outside North America, such as Europe and Asia.
- **ENHANCE OUR MANUFACTURING CAPABILITIES.** We have a major focus on developing an efficient and cost-effective process to manufacture Xcellerated T Cells. We currently produce T cells for clinical trials using a cost-effective process that is readily scaleable. We intend to make additional improvements to our manufacturing procedures and components, which should further reduce the costs of manufacturing. In addition, we plan to optimize our manufacturing process for other disease indications in the future.
- **EXPAND AND ENHANCE OUR INTELLECTUAL PROPERTY.** We have a portfolio of issued patents and patent applications that we own or exclusively license, which we believe provides patent coverage for our Xcellerate Technology. As we continue to improve our Xcellerate Technology, including developing process improvements and improving the activity and the specificity of Xcellerated T Cells, we intend to file patents to protect these improvements.

Clinical Applications

The table below summarizes the current status of clinical trial applications that use our proprietary technology:

DISEASE AND INDICATION	CLINICAL TRIAL STATUS	SPONSOR
Cancer—Hematological malignancies		
Chronic Lymphocytic Leukemia		
• Progressive disease	Ongoing Phase I/II	Xcyte
• Post-Campath	Planned Phase II/III	Xcyte
Multiple myeloma		
• Post-autologous stem cell transplant	Ongoing Phase I/II	Xcyte
• Relapsed	Completed Phase I/II	Physician
Non-Hodgkin's lymphoma	Ongoing Phase II	Xcyte
	Completed Phase I	Physician
	Ongoing Phase I	Fresenius
	Ongoing Phase II	Physician
	Planned Phase I/II	Xcyte
HIV		
	Completed Phase I	Physician
	Ongoing Phase I	Fresenius
	Ongoing Phase II	Physician
	Planned Phase I/II	Xcyte
Cancer—Solid tumors		
Kidney cancer	Completed Phase I/II	Xcyte
Prostate cancer	Completed Phase I/II	Xcyte

Cancer—Hematological Malignancies

Hematological malignancies are cancers of the blood or bone marrow. The American Cancer Society estimates that there will be approximately 114,530 new cases of hematological malignancies and 54,480 deaths due to these diseases in the United States in 2005. Hematological malignancies include leukemia, non-Hodgkin's lymphoma, multiple myeloma and Hodgkin's lymphoma. Because hematological malignancies have usually spread throughout the body by the time of diagnosis, they typically require treatment with chemotherapy. Recently, immune-based therapeutic products have been developed to treat some hematological malignancies. Most kinds of hematological malignancies, including CLL, multiple myeloma and the vast majority of non-Hodgkin's lymphomas, are cancers of lymphocytes known as B cells. In healthy individuals, T cells control the proliferation of B cells. However, in patients with B cell malignancies, T cells are abnormal, and this may contribute to uncontrolled B cell proliferation and tumor progression.

Chronic Lymphocytic Leukemia

According to third-party sources, approximately 75,000 patients have CLL in the United States, and there will be 8,730 new cases of CLL and 4,600 deaths due to this disease in the United States in 2005. The disease is characterized by proliferation of malignant lymphocytes in the bone marrow, lymph nodes and spleen, which leads to an increase in white blood cell counts, as well as enlarged lymph nodes and spleens in most patients. A number of chemotherapy drugs can be used to treat leukemia. Recently, the FDA approved two drugs, fludarabine, a chemotherapy agent, and Campath, a monoclonal antibody, to treat CLL. These drugs are effective in some patients but do not cure the disease. Both fludarabine and Campath are powerful drugs that destroy all lymphocytes. Consequently, patients treated with these drugs suffer from severe T cell deficiencies, which increase the risk of infection.

In 2003, we began treating patients with CLL with a single infusion of Xcellerated T Cells with no other therapy in a Phase I/II clinical trial. We treated a minimum of three patients at each of three different dose levels of 10, 30 and 60-100 billion Xcellerated T Cells. Serious injury has sometimes occurred with other therapeutic agents used to treat CLL due to rapid destruction of leukemic cells. To reduce this risk, we started with a low dose in this trial and have gradually increased the dose of Xcellerated T Cells. A total of 22 patients have been treated as of February 28, 2005. We have observed few side effects in most patients. As of February 28, 2005, we have reported one serious adverse event to the FDA for this trial, which involved a patient who developed an abnormal heart rhythm 17 days following treatment. In the judgment of the attending physician, the event was "unlikely related" to the therapy. In addition, we have documented a 50% to 100% reduction in the size of enlarged lymph nodes in 12 of 17 patients (71%) evaluated and a 50% or greater reductions in spleen size as measured below the ribcage by physical examination in 11 of the 13 patients (85%) with enlarged spleens. To date, we have not observed any significant decrease in leukemia counts in the blood of these patients. We have also documented increases in white blood cells including T cells, neutrophils and natural killer T cells, which may help fight infections and cancer, increases in platelets, which prevent bleeding, and increases in red blood cells as measured by hemoglobin, which carry oxygen. Results from this trial have been submitted to the FDA in the Information Packet for a Type B End of Phase II meeting held on September 23, 2004. In July 2004, we amended the protocol for the Phase I/II clinical trial to allow patients to receive a second infusion of Xcellerated T Cells and to enroll additional patients in this trial. As of

February 28, 2005, six patients have received a second infusion of Xcellerated T Cells from 6 to 11 (median 10) months after the first infusion. Five of the 6 patients had measurable disease in their lymph nodes and spleen at the time of the second infusion. In four of these patients, there was a decrease in the size of the involved organs. Decreases in leukemic cell counts were not observed.

Our clinical trials to date have involved small numbers of patients, and we have not designed or been required to design such trials to produce statistically significant results as to efficacy. These trials have neither been randomized nor blinded to ensure that the results are due to the effects of the Xcellerated T Cells. Success in early clinical trials neither ensures that large-scale trials will be successful nor predicts final results.

We plan to initiate a Phase II/III clinical trial in which patients who have previously received chemotherapy and who have failed treatment with Campath will be treated with Xcellerated T Cells. Use of Campath is a standard treatment for CLL but increases the risk of infection in part because Campath eradicates nearly all T cells for several months following treatment. In addition, although Campath can decrease leukemic cell counts in the blood, it has less therapeutic activity in the lymph nodes and spleens of CLL patients. Accordingly, we believe there is a strong clinical rationale for combining Xcellerated T Cells with Campath. We discussed our plans for this trial with the FDA at an End of Phase II meeting on September 23, 2004. Based on feedback from the FDA during and subsequent to this meeting, we modified our planned protocol for this Phase II/III clinical trial to provide the FDA with data we believed would address the FDA's concerns regarding the subcutaneous route of Campath administration and the dose and schedule of Xcellerated T Cells. We submitted the protocol to the FDA on December 23, 2004. On February 1, 2005, the FDA requested the withdrawal of the protocol to allow additional discussion of the design of the trial. The protocol has been resubmitted to the FDA as a draft protocol. We also met with the FDA on February 16, 2005 to discuss the chemistry, manufacturing and controls submission that has been made related to this trial and our planned transfer of our manufacturing operations to the Bothell facility in the second quarter of 2005. We are also providing additional information and clarification to the FDA regarding our chemistry, manufacturing and controls submission. Until we receive acceptance of our chemistry, manufacturing and controls submission, and feedback from the FDA regarding our proposed protocol, we cannot predict when we will initiate this Phase II/III trial.

Multiple Myeloma

Multiple myeloma is a form of cancer that usually originates in the bone marrow and has metastasized to multiple bone sites by the time of diagnosis. According to third-party sources, approximately 50,000 patients have multiple myeloma in the United States, approximately 15,980 new patients will be diagnosed with multiple myeloma and 11,300 patients will die of the disease in 2005. Chemotherapy has been the most common form of treatment for multiple myeloma. More recently, physicians started using drugs such as Velcade and thalidomide to treat this disease. These drugs can temporarily reduce the tumor load in patients with myeloma but only rarely eradicate the disease. The most effective therapeutic approach for treatment of multiple myeloma is high-dose chemotherapy followed by autologous stem cell transplantation. However, this therapy is not curative, and only approximately 25% of patients achieve a complete response. In addition, patients whose lymphocyte counts recover slowly after transplant have a poor clinical outcome. We believe that administering Xcellerated T Cells may be able to accelerate lymphocyte recovery and improve the clinical outcome of these patients.

We have completed treatment of all 36 of the planned patients in our ongoing Phase I/II clinical trial in patients with multiple myeloma. Patients received a single infusion of Xcellerated T Cells three days following high-dose chemotherapy and autologous stem cell transplantation. Treatment with Xcellerated T Cells has resulted in few side effects in most patients and two serious adverse events reportable to the FDA. Of these two events only one, which involved a patient who developed a rash after treatment that subsequently resolved, was judged to be possibly or probably related to the therapy. Lymphocyte recovery and T cell recovery in all 36 patients has been much more rapid than observed in a comparable group of patients who did not receive Xcellerated T Cells after stem cell transplantation. Rapid lymphocyte recovery has been correlated with improved prognosis and increased survival in previous independent clinical studies. We believe the improvements in the time to lymphocyte recovery may lead to a better clinical outcome in these patients. We are currently monitoring these patients for infections, days in hospital and other clinical parameters that may be associated with immune recovery. Preliminary results of our clinical trial show that, of the 35 patients evaluable for tumor responses, 21 patients (60%) had a greater than 90% decrease in the tumor marker used to measure disease. We have submitted some of these findings to the FDA and will submit additional data in our next annual report. Additional follow-up will be required to determine the therapeutic effects of Xcellerated T Cells after transplant. In independent clinical trials, a greater than 90% decrease in the tumor marker has been associated with increased survival in multiple myeloma patients.

In an ongoing independent Phase I clinical trial, one of our scientific founders and his collaborators have treated 40 multiple myeloma patients with activated T cells following high-dose chemotherapy and autologous stem cell transplantation. These patients received T cells activated using an earlier version of our proprietary technology. Administration of activated T cells resulted in few side effects in most patients and was associated with rapid lymphocyte and T cell recovery. In addition, tumor responses have been documented in a majority of these patients.

We are conducting a Phase II clinical trial in multiple myeloma in which we have enrolled approximately 30 patients who have failed prior therapies. Patients in this trial are randomized to treatment with either a single infusion of Xcellerated T Cells alone or treatment with the drug fludarabine followed by a single infusion of Xcellerated T Cells. This trial is designed to evaluate whether treatment with Xcellerated T Cells is effective as a stand-alone therapy and whether fludarabine can enhance the anti-tumor effects of Xcellerated T Cells in patients with multiple myeloma. As of February 28, 2005, we have treated 27 patients in this trial, of whom 16 are evaluable as of October 1, 2004. Infusion of Xcellerated T Cells led to increases in both T cells and natural killer cells, which are known to help fight infection and cancer. No significant decreases in serum M-protein, the standard biological marker for multiple myeloma, were identified with a minimum follow-up of 28 days. There has been one serious adverse event reported to the FDA in this trial in a patient who had an exacerbation of chronic obstructive pulmonary disease occurring one day following treatment which required that the patient be kept on a respirator for three days. This patient recovered from this event and was discharged from the hospital. This patient had an extensive prior history of lung disease and had been on a respirator in the past for exacerbations of the disease. Our clinical trials to date have involved small numbers of patients and we have not designed nor been required to design such trials to produce statistically significant results as to efficacy. These trials have neither been randomized nor blinded to ensure that the results are due to the effects of the Xcellerated T Cells. Success in early clinical trials neither ensures that large-scale trials will be successful nor predicts final results.

Non-Hodgkin's Lymphoma

Non-Hodgkin's lymphoma is a cancer that originates in the lymph nodes of the body. According to third-party sources, approximately 310,000 patients have non-Hodgkin's lymphoma, and approximately 56,390 new patients will be diagnosed with this disease and 19,200 patients will die of the disease in the United States in 2005. About 60% of newly diagnosed patients have an aggressive disease course, while approximately 40% of patients have a slow growing, low-grade form of the disease. Chemotherapy and radiation are used to treat patients with non-Hodgkin's lymphoma. More recently, immune-based therapeutic products, such as the monoclonal antibody Rituxan, have increasingly been used alone or in combination with chemotherapy. Patients with low-grade lymphoma often respond to Rituxan treatment, but they cannot be cured with any form of therapy. These patients eventually become refractory to all forms of therapy and die from their disease. Patients with aggressive non-Hodgkin's lymphoma may be cured with chemotherapy treatment. However, most patients relapse or fail to respond to therapy and have a poor prognosis. Some of these patients may be treated with high-dose chemotherapy followed by an autologous stem cell transplant, but there are few patients with long-term survival.

An independent clinical trial was conducted by one of our scientific founders under a physician-sponsored IND with the FDA in 16 non-Hodgkin's lymphoma patients with aggressive disease and a poor prognosis. The patients were treated with high-dose chemotherapy and an autologous stem cell transplant followed by administration of a single infusion of activated T cells generated using an earlier version of our proprietary technology. As reported in the medical journal *Blood* in September 2003, 8 out of these 16 patients with a very poor prognosis were still alive with a median follow-up of 33 months. These data were derived from an independent clinical trial, which we did not control and which was not designed to produce statistically significant results as to efficacy or to ensure the results were due to the effects of T cells activated using an earlier version of our proprietary technology. We have been advised that these data have been submitted to the FDA for review.

We believe administration of Xcellerated T Cells may increase the lymphocyte counts of patients with low-grade lymphoma. Recent studies have demonstrated a correlation between lymphocyte counts in patients with low-grade lymphoma and their survival. In addition, low-grade lymphoma has many similar characteristics to CLL. However, in contrast to CLL, tumor cells are rarely found on routine examination of the blood in patients with lymphoma. The primary site of disease in patients with low-grade lymphoma is the lymph nodes. There is one type of low-grade lymphoma, known as small lymphocytic lymphoma, which is classified as the same disease as CLL, except for the absence of tumor cells in the blood. Because of similarities between some of these low-grade lymphomas and CLL and the effects that we have documented in the lymph nodes in patients with CLL, we have initiated a Phase II clinical trial to test whether Xcellerated T Cells can be used to treat patients with the most common forms of low-grade lymphomas, including small lymphocytic, follicular, marginal zone and mantle cell types. As of January 7, 2005, which is the most recent date that data was available, 27 of a planned 40 patients with small lymphocytic (n=9), mantle cell (n=5), marginal zone (n=2) and follicular cell (n=11) lymphoma have been enrolled. Patients received two infusions of Xcellerated T Cells separated by 6-8 weeks. The infusions were well tolerated and no serious adverse events related to therapy were reported in the 11 patients for whom data are available. Sustained increases in T cell counts were observed (n=17). Early response results are available for 16 patients, 11 after one infusion and 5 after two infusions of Xcellerated T Cells. One patient had an unconfirmed complete response, 13 patients had stable disease, and 2 patients had progressive disease. In this disease, an unconfirmed complete response means the patient's lymph nodes have responded but the patient has not had a bone marrow biopsy, which is required to document a complete response. Our clinical trials to date have involved small numbers of patients, and we have not designed nor been required to design such trials to produce statistically significant results as to efficacy. These trials have neither been randomized nor blinded to ensure that the results are due to the effects of the Xcellerate Technology. Success in early clinical trials neither ensures that large-scale trials will be successful nor predicts final results.

HIV

According to third-party sources, there are estimated to be approximately 950,000 individuals infected with HIV in the United States at the end of 2003. HIV patients are at increased risk of infections and cancer. In HIV, patients' T cells become infected with the virus, leading to low numbers of T cells and an extremely narrow T cell receptor repertoire. According to independent clinical studies, it has been shown that increasing T cell count and restoring T cell repertoire are associated with improved clinical outcome. Patients with HIV are currently treated with combinations of anti-viral drugs known as highly active antiretroviral therapy, or HAART. Although HAART is effective in suppressing the virus and delaying the onset of acquired immunodeficiency syndrome, or AIDS, HAART often ceases to be effective in a significant number of patients over time. HAART is also associated with serious side effects.

One of our scientific founders independently demonstrated in the laboratory that T cells activated using an earlier version of our proprietary technology were resistant to infection with HIV. In an independent clinical trial conducted by one of our scientific founders under a physician-sponsored IND with the FDA, eight HIV patients were administered T cells activated using an earlier version of our proprietary technology. The results were published in the medical journal *Nature Medicine* in January 2002, where it was reported that the treatment increased the average of the patient population's T cell counts to within the normal range for at least one year following initiation of therapy. We have been advised that these data have been submitted to the FDA. In laboratory studies, the investigators also demonstrated that they were able to restore a broad T cell receptor diversity in the T cells that were produced using this technology.

We have entered into a collaboration under which Fresenius Biotech GmbH has treated HIV patients with genetically-modified T cells produced using our Xcellerate Technology. Ten patients have been enrolled in a Phase I clinical trial under this collaboration. In addition, one of our scientific founders is independently conducting clinical trials using genetically modified T cells grown using an earlier version of our proprietary technology to treat patients infected with HIV, the results of which are not yet publicly available. We do not control independent clinical trials, including physician-sponsored trials, and such trials have not been designed nor are they required to be designed to produce statistically significant results as to efficacy. These trials have neither been randomized nor blinded to ensure that the results are due to the effects of the T cells activated by an earlier version of our proprietary technology. Success in early clinical trials neither ensures that large-scale trials will be successful nor predicts final results.

One of our scientific founders and his collaborators conducted a preclinical study in an HIV model in monkeys in which he demonstrated that T cells activated using proprietary technology administered after one month of anti-viral drug therapy suppressed viral infection for more than a year. The results of this study were published in the medical journal *Blood* in January 2002. We have been advised that these data have been submitted to the FDA. Based on this study, we are conducting laboratory studies in HIV with the goal of pursuing a similar approach in HIV patients. We plan to initiate a clinical trial using Xcellerated T Cells in patients with HIV in late 2005.

Cancer—Solid Tumors

Solid tumors are cancers that originate in organs of the body. The American Cancer Society estimates that there will be over one million new patients with solid tumors, such as breast, prostate, kidney, lung, liver and colon cancers and approximately 450,000 people will die from these types of cancers in the United States in 2004. These cancers are typically treated with surgery or radiation. Chemotherapy is used with limited success in treating solid tumors such as breast cancer, but it is generally ineffective in curing patients once the cancer has spread or metastasized. Recently, immune-based therapeutic products, including monoclonal antibodies, such as Herceptin, are being used to treat patients with solid tumors, such as breast cancer and ovarian cancer.

Kidney Cancer

The American Cancer Society estimates that approximately 36,160 patients will be diagnosed with kidney cancer in the United States in 2005. Approximately one-third of the patients with kidney cancer will develop metastatic disease. Once patients develop metastatic disease, they have a very poor prognosis with an average survival of approximately one year. According to third-party sources, the five-year survival for patients with metastatic kidney cancer is less than 5%, and approximately 12,600 deaths were expected to occur in the United States in 2005. The only drug currently approved by the FDA for treating metastatic kidney cancer is IL-2, a cytokine that activates T cells and increases lymphocyte counts. However, the FDA-approved regimen requires extremely high doses of IL-2, which are associated with serious and life-threatening side effects. Several recent clinical studies have demonstrated a strong correlation between the increase in lymphocyte counts that occurs with IL-2 therapy and clinical outcome in patients with metastatic kidney cancer. We believe administration of Xcellerated T Cells may improve the clinical outcome in these patients by boosting lymphocyte counts.

In February 2003, we completed a Phase I/II clinical trial of Xcellerated T Cells in 25 patients with metastatic kidney cancer. In this clinical trial, patients were treated with two infusions of Xcellerated T Cells approximately four weeks apart. After each infusion of Xcellerated T Cells, patients were treated with low doses of IL-2. We observed few side effects in most patients and no serious adverse events reportable to the FDA related to the therapy. We also observed the complete elimination of detectable bone metastases in two patients. Furthermore,

there was a statistically significant increase in lymphocyte counts with treatment, and there was an increase in post-infusion survival in patients achieving higher lymphocyte counts. The median survival in these patients was 21 months. Several independent clinical trials have shown that the median survival in patients with metastatic kidney cancer is approximately 12 months. The results of our clinical trial were reported in the medical journal *Clinical Cancer Research* in September 2003, and have been submitted to the FDA for review.

Our clinical trials to date have involved small numbers of patients and we have neither designed nor been required to design such trials to produce statistically significant results as to efficacy. These trials have neither been randomized nor blinded to ensure that the results are due to the effects of the Xcellerated T Cells. Success in early clinical trials neither ensures that large-scale trials will be successful nor predicts final results.

Prostate Cancer

Prostate cancer is the most common form of cancer in men in the United States. The American Cancer Society estimates that there will be 232,090 new cases and approximately 30,350 patients will die of prostate cancer in the United States in 2005. Patients with prostate cancer can be cured by surgery if the disease is localized. However, once the disease spreads to other organs, it cannot be cured with current standard treatments, either hormonal therapy or chemotherapy.

In June 2003, we completed a Phase I/II clinical trial in 19 patients with hormone-refractory prostate cancer. Patients were treated with a single infusion of Xcellerated T Cells. The therapy resulted in few side effects in most patients and led to significant and sustained increases in patients' lymphocyte counts. Two patients demonstrated greater than 50% decreases in serum levels of the tumor marker, PSA. We have submitted these data to the FDA for review. In some independent clinical studies, decreases in PSA levels have been shown to correlate with improved survival in patients with prostate cancer. There was one serious adverse event reportable to the FDA involving a patient with pre-existing severe anemia who suffered congestive heart failure. The patient's symptoms resolved approximately two hours following treatment. We subsequently amended our protocol to identify patients with anemia prior to administering Xcellerated T Cells. Our clinical trials to date have involved small numbers of patients, and we have not designed nor been required to design such trials to produce statistically significant results as to efficacy. These trials have neither been randomized nor blinded to ensure that the results are due to the effects of the Xcellerated T Cells. Success in early clinical trials neither ensures that large-scale trials will be successful nor predicts final results.

Potential Future Applications in Autoimmune Diseases

An overactive immune system is believed to play a central role in a variety of illnesses classified as autoimmune diseases, including rheumatoid arthritis, systemic lupus erythematosus and scleroderma. Attempts to control the disease with therapeutic agents that suppress the immune system are often effective. However, some patients have more serious forms of these diseases and do not respond to conventional therapy, while others experience serious side effects from these chronic immunosuppressive therapies. Recently, high-dose chemotherapy and/or radiation have been used with autologous stem cell transplantation to eradicate these patients' diseased immune systems in an attempt to cure several of these diseases. Although effective in many patients, this form of therapy has been associated with serious and life-threatening toxicities. Many scientists now believe that certain populations of T cells play a central role in causing several autoimmune diseases. This is manifested by narrowing of the T cell receptor repertoire, which has been shown to return to normal when patients with some of these diseases achieve remission. Many therapeutic agents are available that can selectively eliminate T cells without causing the serious toxicities associated with the intensive regimens used with stem cell transplantation. We believe that if our Xcellerate Technology can be used to generate healthy T cells from patients with autoimmune diseases, it may be possible to administer Xcellerated T Cells to restore a healthy immune system after patients are treated with drugs that eliminate T cells in the body.

We have demonstrated in laboratory studies that our Xcellerate Technology can be used to activate and grow T cells from patients with several autoimmune diseases, including rheumatoid arthritis, systemic lupus erythematosus and scleroderma. These studies have also shown that we can restore the narrow T cell repertoire characteristic of many of these patients to a more normal diverse pattern using our Xcellerate Technology.

Research and Development

As of December 31, 2004, we had a total of 30 employees dedicated to research and development, including 9 with advanced degrees. We spent approximately \$14.7 million, \$13.7 million and \$19.7 million during the years ended December 31, 2002, 2003 and 2004, respectively, on the research and development of our Xcellerate Technology and Xcellerated T Cells. Our internal research and development efforts are focused on:

- **IMPROVING OUR XCELLERATE TECHNOLOGY.** We intend to continuously evaluate and improve our Xcellerate Technology. We have developed methods that further simplify our Xcellerate Technology, allowing us to increase our production yield, reduce labor and materials and lower the costs associated with the production of Xcellerated T Cells.

- **INCREASING THE THERAPEUTIC ACTIVITY OF XCELLERATED T CELLS.** We intend to continuously evaluate and improve the therapeutic activity of Xcellerated T Cells. We are currently evaluating whether other molecules of the immune system or genes could be used to improve the therapeutic activity of Xcellerated T Cells. We have worked with several groups to evaluate using Xcellerated T Cells in conjunction with recently discovered antigens to specifically target cancers and infectious diseases associated with those antigens. We have conducted laboratory studies demonstrating that we can generate large numbers of antigen-specific Xcellerated T Cells with anti-tumor activity in several types of cancer, including melanoma, breast cancer, kidney cancer and lung cancer. We expect that some of our collaborators will be conducting physician-sponsored clinical trials with these approaches in the near future.
- **DEVELOPING ADDITIONAL CLINICAL INDICATIONS FOR XCELLERATED T CELLS.** There are many medical conditions that are associated with deficiencies in T cells. For example, patients with autoimmune diseases are treated with immunosuppressive drugs that damage their immune systems. We have demonstrated in laboratory studies that we can activate and grow T cells and restore a normal T cell repertoire in patients with several of these diseases. In addition, we may study the use of Xcellerated T Cells in patients with hepatitis C. Finally, we are interested in exploring the potential therapeutic use of Xcellerated T Cells in the elderly, who often have weakened immune systems.

Manufacturing and Supply

We designed, built and operate our current manufacturing facility in Seattle, Washington in accordance with cGMP. We use this facility to manufacture Xcellerated T Cells for clinical trials. We have completed the construction of the initial phase of an additional leased facility to manufacture Xcellerated T Cells for our planned clinical trials and, if we obtain FDA approval, initial commercialization. This facility is undergoing qualification and validation, and we expect to begin manufacturing Xcellerated T Cells at this facility in the first half of 2005. Except for our antibody-coated beads and custom bioreactor system, all of the components that are required to implement our Xcellerate Technology are commercially available products and standard clinical and blood bank supplies.

In August 1999, we entered into an agreement with Dynal for the cGMP-grade manufacture of our antibody-coated beads for clinical and future commercial uses. In March 2004, we amended our agreement to allow Dynal to sell a research-grade version of our antibody-coated beads. We have paid Dynal \$3.0 million as of July 31, 2004 for completed milestones. Dynal has the right to terminate the contract if we do not purchase a minimum quantity of beads. Either party may terminate the agreement as of August 2009 for any reason, or earlier upon a material breach by, or insolvency of, the other party. If the agreement is not terminated by August 2009, either party can elect to extend the term of the agreement for an additional 5 years. Otherwise, it will automatically renew on a year to year basis.

In June 2000, we entered into two service agreements with Lonza, which were subsequently amended, for the cGMP-grade manufacture of the two monoclonal antibodies for use with our antibody-coated beads. Under the terms of these agreements, we are obligated to make certain payments to Lonza. We have paid \$5.0 million as of December 31, 2004. Assuming development and supply services under our agreements with Lonza are completed as scheduled under our agreements with Lonza, our remaining payments will be approximately \$1.7 million through the end of 2005. These agreements may be terminated by either party for breach or insolvency of the other party or in the event that the manufacturing services cannot be completed for scientific or technical reasons.

We use tissue culture media and a custom bioreactor in our manufacturing process. In March 2005, we entered into a supply agreement with Cambrex Bio Science Walkersville, Inc. with a term of ten years. We have no obligation to purchase media under this agreement. We may terminate the agreement after the initial term for any reason by providing at least six months' notice, and Cambrex may terminate the agreement after the initial term for any reason by providing at least twelve months' notice. Otherwise, it will automatically renew on a year to year basis. We currently do not have an agreement with a third party to supply us with bioreactors.

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. Many entities, including pharmaceutical and biotechnology companies, academic institutions and other research organizations are actively engaged in the discovery, research and development of products that could compete with our products under development. They may also compete with us in recruiting and retaining skilled scientific talent.

There are numerous pharmaceutical and biotechnology companies that are developing therapies for cancer and infectious disease generally, and many of these companies are focused on activating the immune system using therapeutic agents, including monoclonal antibodies, cytokines, vaccines, adjuvants, dendritic cells, nucleotides and cells. We are currently aware of several companies developing *ex vivo* cell-based immunotherapy products as a method of treating cancer and infectious diseases. These competitors include Antigenics, Inc., CancerVax Corporation, Cell Genesys, Inc., CellExSys, Inc. (recently sold to Chromos Molecular Systems, Inc.), Dendreon Corporation, Favril, Inc., Genitope Corporation, IDM, S.A., Kirin Pharmaceutical and Therion Biologics Corporation. Even if our Xcellerate Technology proves successful, we might not be able to remain competitive in this rapidly advancing area of technology. Many of our potential competitors may have more financial and other resources, larger research and development staffs and more experienced capabilities in researching,

developing and testing products. Some of these companies also have more experience than us in conducting clinical trials, obtaining FDA and other regulatory approvals and manufacturing, marketing and distributing medical products. Smaller companies may successfully compete with us by establishing collaborative relationships with larger pharmaceutical companies or academic institutions. Our competitors may succeed in developing, obtaining patent protection for or commercializing their products more rapidly than us. A competing company developing, or acquiring rights to, a more effective therapeutic product for the same diseases targeted by us, or one that offers significantly lower costs of treatment, could render our products noncompetitive or obsolete.

Intellectual Property

We rely on a combination of patent, trademark, copyright and trade secret laws to protect our proprietary technologies and products. We aggressively seek U.S. and international patent protection to further our business strategy and for major components of our Xcellerate Technology, including important antibody components and methods of T cell activation. We also rely on trade secret protection for our confidential and proprietary information. We enter into licenses to technologies we view as necessary.

We have a portfolio of issued patents and patent applications, which we believe provides patent coverage for our Xcellerate Technology. As of March 21, 2005, we owned or held exclusive rights to seven issued patents, five allowed patent applications and numerous pending patent applications in the United States in the field of or directed to *ex vivo* T cell stimulation. Three of the issued patents relate to methods of stimulating T cells utilized by our Xcellerate Technology, two of which expire in 2019 and one of which expires in 2021, while two other issued patents, which expire in 2016, relate to a method of stimulating T cells and an antibody that we are not currently using. Three additional issued patents expire in 2020 and are in the field of or directed to immunosuppression and the treatment and prevention of disorders related to T cells. These three issued patents are directed to the use of a specific compound for these applications, and one of these patents is directed specifically to compositions of matter including likely derivatives of this compound. The final issued patent expires in 2020 and relates to *ex vivo* T cell stimulation to improve uptake of exogenous nucleic acid molecules, thus having gene therapy applications. We also have licensed numerous currently pending foreign patent applications and seven issued foreign patents corresponding to our T cell stimulation technology.

In general, we apply for patent protection of methods and products relating to immunotherapy for treatment of cancer, immune deficiencies, autoimmune diseases and infectious diseases. With respect to proprietary know-how that is not patentable, we have chosen to rely on trade secret protection and confidentiality agreements to protect our interests. We have taken security measures to protect our proprietary know-how, technologies and confidential data and continue to explore further methods of protection.

We require all employees, consultants and collaborators to enter into confidentiality agreements, and all employees and most consultants enter into invention assignment agreements with us. The confidentiality agreements generally provide that all confidential information developed or made known to the individual during the course of such relationship will be kept confidential and not disclosed to third parties, except in specified circumstances. These invention agreements generally provide that all inventions conceived by the individual in the course of rendering services to us will be our exclusive property. We cannot assure you, however, that these agreements will provide meaningful protection or adequate remedies for any breach or that our trade secrets will not otherwise become known or be independently discovered by our competitors. Any of these events could adversely affect our competitive position in the marketplace.

In the case of a strategic partnership or other collaborative arrangement which requires the sharing of data, our policy is to disclose to our partner, under controlled circumstances, only data that is relevant to the partnership or arrangement during the contractual term of the strategic partnership or collaborative arrangement, subject to a duty of confidentiality on the part of our partner or collaborator. Disputes may arise as to the ownership and corresponding rights in know-how and inventions resulting from research by us and our corporate partners, licensors, scientific collaborators and consultants. We cannot assure you that we will be able to maintain our proprietary position or that third parties will not circumvent any proprietary protection we have. Our failure to maintain exclusive or other rights to these technologies could harm our competitive position.

To continue developing and commercializing our current and future products, we may license intellectual property from commercial or academic entities to obtain the rights to technology that is required for our discovery, research, development and commercialization activities.

In preparation for the commercial distribution of our products and services if we obtain FDA approval, we have filed a number of trademark applications.

Corporate Collaborations

Part of our strategy is to establish corporate collaborations with pharmaceutical, biopharmaceutical and biotechnology companies for the development and commercialization of our Xcellerate Technology. We focus our efforts on partnering our technologies in markets and diseases that we do not plan to pursue on our own. We target collaborators that have the expertise and capability to develop, manufacture, obtain regulatory approvals for and commercialize our Xcellerate Technology. In our corporate collaborations, we seek to cover our research

and development expenses through research funding, milestone payments and technology or license fees. We also seek to retain significant downstream participation in product sales through either profit sharing or product royalties paid on annual net sales.

Fresenius Biotech GmbH

In November 2003, we licensed our Xcellerate Technology and some related improvements on an exclusive basis in the field of HIV retroviral gene therapy to Fresenius for research, development, and commercialization in Europe, with a right of first negotiation under some circumstances to expand their territory to include North America. Our agreement with Fresenius requires us to license our Xcellerate Technology, including methods for manufacturing Xcellerated T Cells, to Fresenius, transfer certain enabling technology and supply all proprietary magnetic beads, or Xcyte Dynabeads, ordered by Fresenius to support its development and commercialization efforts. If we do not supply the Xcyte Dynabeads, Fresenius has the right to manufacture such Xcyte Dynabeads on its own or through a third party, until such time that we are able to supply the quantity of Xcyte Dynabeads ordered by Fresenius. Fresenius has agreed to reimburse us for our expenses in transferring the technology and pay us for the Xcyte Dynabeads on a cost-plus basis. In addition, under the agreement Fresenius has granted us a perpetual, irrevocable, non-exclusive, fully paid worldwide license to technology invented by Fresenius that directly relates to our Xcellerate Technology. This agreement includes royalties on net sales as well as up to 5.4 million Euros in potential milestone payments to us, less applicable sublicense fees payable by us to third parties, for each product developed under this agreement. Fresenius' obligation to pay us royalties under this agreement terminates on a country-by-country basis upon the later of the last to expire of the licensed patents or 15 years after the first commercial sale of a product in the country. The agreement is also subject to earlier termination by Fresenius at any time if Fresenius determines it cannot develop a commercially viable product or complete a required manufacturing audit, at any time by Xcyte if Fresenius does not meet certain development and commercialization milestones and by either party for the material breach or insolvency of the other party. The agreement specifies that the termination of certain technology licenses, under which we obtained much of our Xcellerate Technology, is a breach of this agreement.

Fresenius is conducting a Phase I trial to treat HIV patients with genetically-modified T cells produced using our Xcellerate Technology.

Technology Licenses

Where consistent with our strategy, we seek to obtain technologies that complement and expand our existing technology base. We have licensed and will continue to license technology from selected research and academic institutions, as well as other organizations. Under these license agreements, we generally seek to obtain sublicense rights. We are generally obligated under these agreements to pursue product development and pay royalties on any product sales. We have not been required to pay any royalties through September 27, 2004. In addition to license agreements, we seek relationships with other entities that may benefit us and support our business goals.

- **DIACLONE S.A.** In October 1999, we entered into a license agreement with Diaclone. Under the agreement, Diaclone granted us an exclusive, worldwide license to make, use and sell products or services using the monoclonal antibody that binds to the CD28 molecule for all *ex vivo* uses involving therapeutic and research applications. We have an option and right of first refusal to expand our license to include *in vivo* therapeutic and research purposes. We are currently obligated to purchase all our requirements for this monoclonal antibody from Diaclone until we begin preparing for Phase III clinical trials of a product covered by this license. Under certain circumstances, we would be permitted to have the monoclonal antibody made by third parties or manufacture it ourselves. This agreement has a term of 15 years from the date of first approval by the FDA, or its foreign equivalent, of a therapeutic product containing a bead coated with the licensed antibody and may be terminated earlier by either party for material breach or insolvency of either party. We currently do not have FDA approval of any therapeutic products containing a bead coated with the licensed antibody. At the end of the term, we will have a perpetual, irrevocable, royalty-free, exclusive license. We paid initial non-refundable license fees totaling \$75,000 to Diaclone and are required to pay royalties if our products are commercialized.
- **FRED HUTCHINSON CANCER RESEARCH CENTER.** In October 1999, we entered into a license agreement with the Fred Hutchinson Cancer Research Center. Under the agreement, the Fred Hutchinson Cancer Research Center granted us a non-exclusive, worldwide license to make, use and sell products or services using the monoclonal antibody that binds to the CD3 molecule for T cell stimulation for *ex vivo* therapeutic and research uses other than cell separation and selection. We paid a non-refundable up-front licensing fee of \$25,000 to the Fred Hutchinson Cancer Research Center, and we are obligated to pay the Fred Hutchinson Cancer Research Center a royalty fee if we or our sublicensees commercialize products or services that use the licensed monoclonal antibody. We are also required to pay fees to Fred Hutchinson Cancer Research Center under certain circumstances if we sublicense these rights to third parties. We paid sublicense fees in connection with our Fresenius collaboration totaling \$42,227 to the Fred Hutchinson Cancer Research Center. On December 1, 2000, we amended this license agreement to broaden the field of use to include any *ex vivo* use involving therapeutic and research applications in exchange for an additional non-refundable up-front fee of \$25,000 and the issuance of 27,272 shares of our common stock to the Fred Hutchinson Cancer Research Center. Our obligation to pay royalties under this license agreement will remain in effect for 15 years following the first commercial sale of our product and may be terminated earlier by either party for material breach or by Fred Hutchinson Cancer Research Center for Xcyte's insolvency. Thereafter, our license will be fully-paid.

- **GENETICS INSTITUTE.** In July 1998, we entered into a license agreement with Genetics Institute. Under the agreement, Genetics Institute granted us an exclusive license under its rights to patents and patent applications covering methods of *ex vivo* activation or expansion of human T cells for treatment and prevention of infectious diseases, cancer and immunodeficiency. We also granted Genetics Institute an option under certain circumstances to an exclusive worldwide license to certain improvements outside of our field that directly relate to the licensed patents. The technology underlying these methods originated from two of our scientific founders and their collaborators and is incorporated into our Xcellerate Technology. The term of the Genetics Institute license terminates upon the end of the enforceable term of the last licensed patent or the license agreements under which Genetics Institute has sublicensed rights to Xcyte, and may also be terminated earlier by either party for material breach. As of October 1, 2004, two licensed patents whose terms expire in 2016, two other patents whose terms expire in 2019 and one patent whose term expires in 2021, have been issued in the United States for the methods licensed. In consideration of the license, we paid a non-refundable up-front license fee totaling approximately \$53,000, issued 26,522 shares of our common stock to Genetics Institute and issued a warrant under which Genetics Institute has the right to purchase 35,362 additional shares of our common stock. We are also obligated to pay royalties to Genetics Institute on sales of products covered by the patents licensed to us under the agreement. We are also required to pay fees to Genetics Institute if we sublicense these rights to third parties. We paid sublicense fees in connection with our Fresenius collaboration totaling \$9,049 to Genetics Institute. Additionally, if we fail to devote a specified amount of resources to develop a product using these rights, Genetics Institute may convert this license from exclusive to non-exclusive.

Governmental Regulation

Governmental authorities in the United States and other countries extensively regulate the preclinical and clinical testing, approval, manufacturing, labeling, storage, record-keeping, reporting, advertising, promotion, import, export, marketing and distribution, among other things, of immunotherapy products and other drugs and biological products. In the United States, the FDA, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act and other federal statutes and regulations, subjects biopharmaceutical products to rigorous review and regulation. If we do not comply with applicable requirements, we may be fined, our products may be recalled or seized, our clinical trials may be suspended or terminated, our production may be partially or totally suspended, the government may refuse to approve our marketing applications or allow us to distribute our products and we may be subject to an injunction and/or criminally prosecuted. The FDA also has the authority to revoke previously granted marketing authorizations.

In order to obtain approval of a new product from the FDA, we must, among other requirements, submit proof of safety, purity, potency and efficacy as well as detailed information on the manufacture, quality, composition and labeling of the product in a new drug application (NDA) or a biologics license application (BLA). In most cases, this proof entails extensive laboratory tests and preclinical and clinical trials. This testing, the preparation of necessary applications, the processing of those applications by the FDA and review of the applications by FDA and potentially FDA advisory committees of outside experts are expensive and typically take many years to complete. The novelty of cellular therapies may cause delays and additional costs in obtaining regulatory approval of our products or regulatory authorization for our clinical trials. The FDA may not act quickly or favorably in reviewing these applications, or may deny approval altogether, and we may encounter significant difficulties or costs in our efforts to obtain FDA approval, which could delay or preclude us from marketing any products we may develop. The FDA may also require post-marketing testing and surveillance to monitor the effects of approved products or place conditions on any approval that could restrict the commercial applications of these products. The FDA may withdraw product approval if we fail to comply with regulatory standards, if we encounter problems following initial marketing or if new safety or other issues are discovered regarding our products or similar products after approval. With respect to patented products or technologies, delays imposed by the governmental approval process may materially reduce or eliminate the period during which we will have the exclusive right to exploit the products or technologies.

In order to conduct research to obtain regulatory approval for marketing, we must submit information to the FDA on the planned research in the form of an investigational new drug application. The investigational new drug application must contain, among other things, an investigational plan for the therapy, a study protocol, information on the study investigators, preclinical data, such as toxicology data, and other known information about the investigational therapy.

After an investigational new drug application becomes effective, a sponsor may commence its proposed human clinical trial. The sponsor typically conducts human clinical trials in three sequential phases, but the phases may overlap. In Phase I clinical trials, the product is generally tested in a small number of patients or healthy volunteers primarily for safety at one or more doses. In Phase II, in addition to safety, the sponsor typically evaluates the efficacy of the product in a patient population somewhat larger than Phase I clinical trials. It is customary in cancer clinical trials for the FDA to allow companies to combine Phase I and Phase II clinical trials into a Phase I/II clinical trial. Phase III biologics clinical trials typically involve testing for safety, purity, potency and clinical efficacy in an expanded population at geographically dispersed test sites and are intended to generate the pivotal data on which a licensing application will be based. The studies must be adequate and well-controlled and otherwise conform to appropriate scientific and legal standards.

Prior to the commencement of each clinical trial, the sponsor must submit for review to the FDA a clinical plan, or protocol, accompanied by the approval of an institutional review board responsible for protecting the welfare of study subjects and the privacy of their individually identifiable health information for a site participating in the trials. The sponsor must also ensure that investigators obtain informed consent and authorization to use and disclose protected health information from all study subjects prior to commencement of each study, and the sponsor must comply with monitoring, reporting and so-called good clinical practice requirements throughout the conduct of the study, among other legal requirements. The FDA may prevent an investigational new drug application from taking effect, or may order the temporary or permanent discontinuation of a clinical trial, at any time. An institutional review board may also prevent a study from going forward, or may temporarily or permanently discontinue a clinical trial, at any time. If a study is not conducted in accordance with applicable legal requirements and sound scientific standards, the data from the study may be deemed invalid and unusable.

The sponsor must submit to the FDA the results of the preclinical and clinical trials, together with, among other things, detailed information on the manufacture, quality and composition of the product, in the form of an NDA or BLA. The application must also contain proposed labeling for the product setting forth the proposed conditions of use for which the applicant is seeking approval and be accompanied by the payment of a significant user fee. In fiscal year 2005, the user fee for a BLA with clinical data is \$672,000. The FDA can refuse to file an application if it is deemed not sufficiently complete to permit review, or has some other deficiency.

Because the FDA is regulating Xcellerated T Cells as a biologic, we must submit BLAs to the FDA to obtain approval of our products. A BLA requires data showing the safety, purity and potency of the product. In a process which generally takes several years or more, the FDA reviews this application and, when and if it decides that adequate data are available to show that the new product is safe, pure, potent and effective and that other applicable requirements have been met, approves the biologic for marketing. Prior to issuing a denial or an approval, the FDA often will seek recommendations from one of its advisory committees of independent experts. The amount of time taken for this approval process is a function of a number of variables, including the quality of the submission and studies presented, the potential contribution that the product will make in improving the treatment of the disease in question, the recommendations of the FDA advisory committee and the workload at the FDA. It is possible that our Xcellerate Technology will not successfully proceed through this approval process or that the FDA will not approve our applications in any specific period of time, or at all. Any approval, if obtained, could be limited or could be made contingent on burdensome post-approval commitments or could be otherwise restricted.

Congress enacted the Food and Drug Administration Modernization Act of 1997, in part, to ensure the availability of safe and effective drugs, biologics and medical devices by expediting the FDA review process for new products. The Modernization Act establishes a statutory program for the review and approval of fast track products, including qualifying biologics. A fast track product is defined as a new drug or biologic intended for the treatment of a serious or life-threatening disease or condition that demonstrates the potential to address unmet medical needs for this disease or condition. Under the fast track program, the sponsor of a new drug or biologic may request the FDA to designate the drug or biologic as a fast track product at any time during the clinical development of the product. We may, from time to time, decide to request fast track designation for Xcellerated T Cells.

The Modernization Act specifies that the FDA must determine whether the product qualifies for fast track designation within 60 days of receipt of the sponsor's request. The FDA can base approval of a marketing application for a fast track product on an effect on a clinical endpoint or on another "surrogate" endpoint that is reasonably likely to predict clinical benefit. The FDA may subject approval of an application for a fast track product to post-approval studies to validate the surrogate endpoint or confirm the effect on the clinical endpoint and prior review of all promotional materials. In addition, the FDA may withdraw its approval of a fast track designation on a number of grounds, including the sponsor's failure to conduct any required post-approval study with due diligence.

If the FDA's preliminary review of clinical data suggests that a fast track product may be effective, the agency may initiate review of sections of a marketing or license application for a fast track product before the sponsor completes the entire application. This rolling review may be available if the applicant provides a schedule for submission of remaining information and pays applicable user fees. However, the time periods specified under the Prescription Drug User Fee Act concerning timing goals to which the FDA has committed in reviewing an application do not begin until the sponsor submits the entire application.

We may from time to time request orphan drug status for Xcellerated T Cells. Orphan drug designation may be granted to those products developed to treat diseases or conditions that affect fewer than 200,000 persons in the United States. We believe that some of our target cancer patient populations meet these criteria. Under the law, the developer of an orphan drug may be entitled to seven years of market exclusivity following the approval of the product by the FDA, exemption from user fee payments to the FDA and a 50% tax credit for the amount of money spent on human clinical trials. We cannot predict whether the FDA will grant either an orphan drug or fast track designation or whether our products will ultimately receive FDA approval or orphan drug market exclusivity. We also cannot predict the ultimate impact, if any, of the fast track process or orphan drug status on the timing, likelihood or scope of FDA approval of our immunotherapy products. Even if we are able to obtain FDA approval with orphan drug marketing exclusivity, other competing products may still be approved if they are deemed to be sufficiently different than our products, or clinically superior or under certain other circumstances. This could reduce or eliminate the value of any orphan drug marketing exclusivity.

The FDA may, during its review of a new drug application or biologics license application, ask for additional test data. If the FDA does ultimately approve the product, it may require post-marketing testing, including potentially expensive Phase IV studies, and surveillance to monitor the safety and effectiveness of the product. In addition, the FDA may in some circumstances impose restrictions on the use of the product, which may be difficult and expensive to administer, may affect whether the product is commercially viable and may require prior approval of promotional materials.

Before approving a new drug application or biologics license application, the FDA will also inspect the facilities where the product is manufactured and will not approve the product unless the manufacturing facilities are in compliance with cGMP. In addition, the manufacture, holding and distribution of a product must remain in compliance with cGMP following approval. Manufacturers must continue to expend time, money and effort in the area of production and quality control and record keeping and reporting to ensure full compliance with those requirements. In addition, manufacturers are required to report adverse events and errors and accidents in the manufacturing process. Changes to an approved product, or changes to the manufacturing process, may require the filing of a supplemental application for FDA review and approval. Failure to comply with applicable requirements can lead to the FDA demanding that production and shipment cease, and, in some cases, that the manufacturer recall products or to FDA enforcement actions that can include seizures, injunctions and criminal prosecution. These failures can also lead to FDA withdrawal of approval to market the product.

The labeling, advertising, promotion, marketing and distribution of a drug or biologic product must be in compliance with FDA regulatory requirements. Where the FDA determines that there has been improper promotion or marketing, it may require corrective communications such as "Dear Doctor" letters. Even if we comply with FDA and other requirements, new information regarding the safety or effectiveness of a product, or a change in the law or regulations, could lead the FDA to modify or withdraw a product approval.

In addition to FDA requirements, our manufacturing, sales, promotion, and other activities following product approval are subject to regulation by numerous other regulatory authorities, including, in the United States, the Centers for Medicare & Medicaid Services, other divisions of the Department of Health and Human Services and state and local governments. Among other laws and requirements, our sales, marketing and scientific/educational programs must comply with the Federal Medicare-Medicaid anti-fraud and abuse statutes and similar state laws. Our pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

We are also subject to regulation by the Occupational Safety & Health Administration, or OSHA, and the Environmental Protection Agency, or EPA, and to various laws and regulations relating to safe working conditions, laboratory and manufacturing practices and the use and disposal of hazardous or potentially hazardous substances, including radioactive compounds used in connection with our research and development activities, and we may in the future be subject to other federal, state or local laws or regulations. OSHA, the EPA or other regulatory agencies may promulgate regulations that may affect our research and development programs. We are also subject to regulation by the Department of Transportation and to various laws and regulations relating to the shipping of cells and other similar items. We are unable to predict whether any agency will adopt any regulation that could limit or impede our operations.

Depending on the circumstances, failure to meet these other applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, recall or seizure of products, partial or total suspension of production, denial or withdrawal of pre-marketing product approval or refusal to allow us to enter into supply contracts, including government contracts.

Sales of pharmaceutical products outside the United States are subject to foreign regulatory requirements that vary widely from country to country. Whether or not we have obtained FDA approval, we must obtain approval of a product by comparable regulatory authorities of foreign countries prior to the commencement of marketing the product in those countries. The time required to obtain this approval may be longer or shorter than that required for FDA approval. The foreign regulatory approval process includes all the risks associated with FDA regulation set forth above, as well as country-specific regulations, including in some countries price controls.

In May 2000, we submitted our initial Phase I investigational new drug application, or IND, involving Xcellerated T Cells to treat metastatic kidney cancer. The FDA allowed us to start the trial in June 2000. The trial was completed in February 2003. In September 2001, we amended the IND to add a Phase I study of Xcellerated T Cells to treat hormone refractory prostate cancer. The trial was completed in June 2003. In August 2002, we amended the IND to add a Phase I/II to treat multiple myeloma patients post autologous stem cell transplantation. This trial completed accrual in October 2003. In November 2002, we amended the IND to add a Phase I/II study to treat CLL. This CLL study was subsequently amended in July 2004 to allow for additional patients and completed accrual in December 2004. In September 2003, we amended the IND to add a randomized Phase II study to treat multiple myeloma patients with and without fludarabine. We completed accrual of this trial in January 2005. In December of 2003, we amended the IND to add a Phase II study to treat non-Hodgkin's lymphoma patients. Accrual is currently ongoing in this trial.

Legal Proceedings

From time to time, we may be involved in litigation relating to claims rising out of our ordinary course of business. We are not currently a party to any material legal proceedings.

Employees

As of December 31, 2004, we had 105 employees, 30 of whom are directly involved in research and development and 38 of whom are involved in manufacturing operations. We consider our relations with our employees to be good. As a result of our plan to limit clinical development primarily to our planned Phase II/III trial in CLL and Phase I/II trial in HIV, we reduced our workforce by approximately 24%, to 81 employees on March 22, 2005. We believe the remaining staff will be sufficient to conduct these two planned clinical trials and to transfer manufacturing operations for the Phase II/III trial to our new facility.

ITEM 2. PROPERTIES

We currently lease a total of approximately 62,500 square feet of space at two facilities. We lease approximately 22,000 square feet of office and laboratory space and a cGMP manufacturing facility in Seattle, Washington, with monthly payments of approximately \$52,000. The lease on this space expires in October 2006, and we have options to renew for two additional five-year terms. We also lease approximately 40,500 square feet of space in Bothell, Washington, with monthly payments of approximately \$80,000. We have renovated approximately 20,000 square feet of this facility for the manufacture Xcellerated T Cells for our planned clinical trials and, if we obtain regulatory approval, initial commercialization. The initial lease term on this space expires December 2010, and we have options to renew until December 2020. Under the terms of the lease, we also have rights to negotiate for further expansion space in the building. We believe that this facility has sufficient space to accommodate expansion of our operations.

ITEM 3. LEGAL PROCEEDINGS

From time to time, we may be involved in litigation relating to claims rising out of our ordinary course of business. We are not currently a party to any material legal proceedings.

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

No matters were submitted to a vote of the shareholders during the fourth quarter of 2004.

PART II**ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES**

Our common stock began trading March 16, 2004 and is traded on the Nasdaq National Market under the symbol "XCYT." The following table sets forth, for the calendar periods indicated, high and low sales prices per share of our common stock as reported on the Nasdaq National Market.

	HIGH	LOW
2004		
First Quarter (Beginning March 16, 2004)	\$ 8.50	\$ 6.51
Second Quarter	\$ 7.45	\$ 4.00
Third Quarter	\$ 5.04	\$ 2.99
Fourth Quarter	\$ 3.70	\$ 2.00

On March 21, 2005, the closing sales price of our common stock on the Nasdaq National Market System was \$1.40. As of March 21, 2005 we had 109 shareholders of record of our common stock. Because many shares of our common stock are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of stockholders represented by these record holders.

Dividend Policy

We have never declared or paid any cash dividends on our common stock and do not currently anticipate declaring or paying cash dividends on our common stock in the foreseeable future. Except for dividends we anticipate paying on the convertible preferred stock, we currently intend to retain all of our future earnings, if any, to finance operations. Any future determination relating to our dividend policy will be made at the discretion of our board of directors and will depend on a number of factors, including future earnings, capital requirements, financial conditions, future prospects, contractual restrictions and other factors that our board of directors may deem relevant.

Use of Proceeds

Our Registration Statement under the Securities Act of 1933 (File No. 333-109635) was declared effective by the SEC on March 16, 2004. All 4,200,000 shares of common stock offered in the final prospectus were sold at a price per share of \$8.00. The aggregate gross proceeds of the shares offered and sold were \$33.6 million, which resulted in net proceeds to us of approximately \$29.7 million after deducting underwriting discounts and commissions and other offering expenses of \$3.9 million. From the effective date of our initial public offering through December 31, 2004, we have used approximately \$19.3 million of these proceeds to fund clinical trial activities, manufacturing activities, preclinical research and development activities, and capital expenditures, and for other general corporate purposes. The remainder of the net proceeds from our initial public offering are invested in a variety of interest-bearing instruments, consisting of U.S. government and agency securities, high-grade U.S. corporate bonds, municipal bonds, commercial paper and money market accounts.

Sales of Unregistered Securities and Issuer Repurchases of Securities

Other than sales disclosed in previous quarterly reports on Form 10-Q or current reports on Form 8-K, we did not make any unregistered sales of shares of our common stock in 2004. In addition, we did not repurchase any of our equity securities during the fourth quarter of 2004.

ITEM 6. SELECTED FINANCIAL DATA

This section presents our historical financial data. The following should be read with, and is qualified in its entirety by reference to, the financial statements included in this Form 10-K, including the notes to the financial statements, and the information under "Management's Discussion and Analysis of Financial Condition and Results of Operations." The statement of operations data for the years ended December 31, 2002, 2003 and 2004 and the balance sheet data as of December 31, 2003 and 2004 have been derived from our audited financial statements included elsewhere in this Form 10-K. The statement of operations data for the years ended December 31, 2000 and 2001 and the balance sheet data as of December 31, 2000, 2001 and 2002 have been derived from our audited financial statements that are not included in this Form 10-K. Historical results are not necessarily indicative of future results.

YEARS ENDED DECEMBER 31,	2000	2001	2002	2003	2004
(in thousands, except per share data)					
STATEMENT OF OPERATIONS DATA					
Revenue:					
License fee	\$ —	\$ —	\$ —	\$ —	\$ 35
Collaborative agreement	—	—	—	170	27
Government grant	98	30	—	—	—
Total revenue	98	30	—	170	62
Operating expenses:					
Research and development	11,257	14,701	14,663	13,685	19,698
General and administrative	2,403	5,204	4,979	4,322	6,876
Total operating expenses	13,660	19,905	19,642	18,007	26,574
Loss from operations	(13,562)	(19,875)	(19,642)	(17,837)	(26,512)
Other income (expense), net	621	363	189	(620)	(13,076)
Net loss	(12,941)	(19,512)	(19,453)	(18,457)	(39,588)
Accretion of preferred stock	—	(8,411)	(8,001)	—	(8,973)
Net loss applicable to common stockholders	\$(12,941)	\$(27,923)	\$(27,454)	\$(18,457)	\$(48,561)
Basic and diluted net loss per common share	\$ (11.86)	\$ (22.14)	\$ (19.34)	\$ (12.40)	\$ (3.90)
Shares used in basic and diluted net loss per common share calculation	1,091	1,261	1,420	1,488	12,440

[Table of Contents](#)

24

XCYTE THERAPIES, 2005

PART II

ITEM 6

AS OF DECEMBER 31,	2000	2001	2002	2003	2004
(in thousands)					
BALANCE SHEET DATA					
Cash, cash equivalents and short-term investments	\$ 23,926	\$ 21,098	\$ 17,344	\$ 13,540	\$ 47,318
Working capital	21,785	19,135	15,570	(653)	43,947
Total assets	28,479	24,727	21,535	18,498	55,603
Long-term obligations, less current portion	952	1,046	1,514	1,555	4,071
Redeemable convertible preferred stock and warrants	49,053	57,629	65,673	67,071	—
Deficit accumulated during the development stage	(29,173)	(48,685)	(68,138)	(86,595)	(126,183)
Total stockholders' equity (deficit)	(25,384)	(36,260)	(48,125)	(64,840)	44,120

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

The following discussion should be read in conjunction with the financial statements and notes thereto.

In addition to historical information, this Annual Report on Form 10-K contains forward-looking statements, including statements regarding product plans and investing activities, that involve risks and uncertainties that could cause actual results to differ materially. Factors that might cause or contribute to such differences included, but are not limited to, those discussed in the section entitled "Important Factors That May Affect Our Business, Results of Operations and Stock Price." You should carefully review below the risks described herein and in other documents we file from time to time with the Securities and Exchange Commission, including the Form S-1 filed by us in October 2004. When used in this report, the words "expects," "could," "would," "may," "anticipates," "intends," "plans," "believes," "seeks," "targets," "estimates," "looks for," "looks to," and similar expressions, as well as statements regarding our focus for the future, are generally intended to identify forward-looking statements. You should not place undue reliance on these forward-looking statements, which speak only as of the date of this Annual Report on Form 10-K. We undertake no obligation to publicly release any revisions to the forward-looking statements or reflect events or circumstances after the date of this document. We caution our investors that our business and financial performance are subject to substantial risks and uncertainties.

Overview

We are a biotechnology company developing a new class of therapeutic products designed to enhance the body's natural immune responses to treat cancer, infectious diseases and other medical conditions associated with weakened immune systems. We derive our therapeutic products from a patient's own T cells, which are cells of the immune system that orchestrate immune responses and can detect and eliminate cancer cells and infected cells in the body. We use our patented and proprietary Xcellerate Technology to generate activated T cells, which we call Xcellerated T Cells, from blood that is collected from the patient. Activated T cells are T cells that have been stimulated to carry out immune functions. Our Xcellerate Technology is designed to rapidly activate and expand the patient's T cells outside of the body. These Xcellerated T Cells are then administered to the patient. We believe, based on clinical trials to date, that our Xcellerate Technology can produce Xcellerated T Cells in sufficient numbers to generate rapid and potent immune responses to treat a variety of medical conditions.

Since our inception in 1996, we have focused our activities primarily on the development of these therapeutic products. We are a development-stage company and have incurred significant losses since our inception. As of December 31, 2004, our deficit accumulated during the development stage was \$126.2 million. Our operating expenses consist of research and development expenses and general and administrative expenses.

We have recognized revenues from inception through December 31, 2004 of approximately \$476,000 from license fees, payments under a collaborative agreement and income from a National Institutes of Health Phase I Small Business Innovation Research, or SBIR, grant in chronic lymphocytic leukemia. We currently do not market any products and will not for several years, if at all. Accordingly, we do not expect to have any product sales or royalty revenue for a number of years. Our net losses are primarily a result of research and development and general and administrative expenses incurred to support our operations. We anticipate incurring net losses over at least the next several years as we complete our clinical trials, apply for regulatory approvals, continue development of our technology and expand our operations.

Research and Development

To date, our research and development expenses have consisted primarily of costs incurred for drug discovery and research, preclinical development, clinical trials and regulatory activities. Research and development activity-related costs include:

- payroll and personnel-related expenses;
- clinical trial and regulatory-related costs;
- laboratory supplies;
- contractual costs associated with developing antibodies and beads;
- technology license costs;
- rent and facility expenses for our laboratory and cGMP-grade manufacturing facilities; and
- scientific consulting fees.

Our research and development efforts to date have primarily focused on the development of our proprietary Xcellerate Technology and Xcellerated T Cells. From inception through December 31, 2004, we incurred research and development expenses of approximately \$86.5 million, substantially all of which relate to the research and development of this technology. Currently, we are focusing our efforts on advancing our product in a planned Phase II/III trial in CLL and a planned Phase I/II trial in HIV. As a result of our plan to limit clinical development to these two trials, we reduced our workforce by approximately 24%, to 81 employees on March 22, 2005. Although we have recently taken actions to reduce our research and development expenses in the short term, we expect our research and development expenses to increase again in the future if our planned Phase II/III trial in CLL is successful, as we continue to improve our proprietary Xcellerate Technology, and as we develop Xcellerated T Cells for additional clinical indications. Because of the risks and uncertainties inherent in the clinical trials and regulatory process, we are unable to estimate with any certainty the length of time or expenses to continue development of Xcellerated T Cells for commercialization. However, we expect our research and development expenses to increase as we continue to improve our proprietary Xcellerate Technology and develop Xcellerated T Cells for additional clinical indications.

General and Administrative Expenses

Our general and administrative expenses are costs associated with supporting our operations, including payroll and personnel-related expenses and professional fees. In addition, rent and facility expenses for our administrative office area and other general office support activities are also included in our general and administrative expenses.

Critical Accounting Policies

We have based our discussion and analysis of our financial condition and results of operations on our financial statements, which we have prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and assumptions that affect the amounts reported in the financial statements. Actual results could differ from those estimates. While Note 1 to our financial statements summarizes each of our significant accounting policies that we believe is important to the presentation of our financial statements, we believe the following accounting policies to be critical to the estimates and assumptions used in the preparation of our financial statements.

Stock-Based Compensation

We have adopted the disclosure-only provisions of Financial Accounting Standards Board (FASB) Statement of Financial Accounting Standards No. 123, *Accounting for Stock-Based Compensation* (SFAS 123). Accordingly, we apply Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* (APB 25), and related interpretations in accounting for stock options. Pursuant to APB 25, we recognize employee stock-based compensation expense based on the intrinsic value of the option at the date of grant. Deferred stock-based compensation includes amounts recorded when the exercise price of an option is lower than the fair value of the underlying common stock on the date of grant. We amortize deferred stock-based compensation over the vesting period of the option using the graded vesting method.

We record stock options granted to non-employees using the fair value approach in accordance with SFAS 123 and Emerging Issues Task Force Consensus Issue No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*. We periodically revalue the options to non-employees over their vesting terms. We determine the fair value of options granted to non-employees using the Black-Scholes option-pricing model.

Prior to our initial public offering, we determined the fair value of our common stock for purposes of these calculations based on our review of the primary business factors underlying the value of our common stock on the date these option grants were made or revalued, viewed

in light of our initial public offering and the initial public offering price per share. Subsequent to our initial public offering, the fair value is determined based on the price of the common stock as reported by the Nasdaq National Market in *The Wall Street Journal*.

Revenue Recognition

To date, we have generated no revenues from sales of products. Revenues relate to fees received for licensed technology, cost reimbursement contracts and a SBIR grant awarded to us by the National Institutes of Health. We recognize revenue associated with up-front license fees and research and development funding payments ratably over the relevant periods specified in the agreement, which generally is the period we are obligated to perform services. In certain cases, the agreement may specify the delivery of services or goods over a period of time, without a fixed date. In those circumstances, we are required to estimate the period of time over which revenue should be recognized, and reflects our best estimate after evaluating past experience, level of effort and stage of development. We recognize revenue under research and development cost-reimbursement agreements as the related costs are incurred. We recognize revenue related to grant agreements as the related research and development expenses are incurred.

Cash, Cash Equivalents and Investments

We classify all investment securities as available-for-sale, carried at fair value. We report unrealized gains and losses as a separate component of stockholders' equity (deficit). We include amortization, accretion, interest and dividends, realized gains and losses and declines in value judged to be other-than-temporary on available-for-sale securities in interest income. Statement of Financial Accounting Standards No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, and Securities and Exchange Commission (SEC) Staff Accounting Bulletin (SAB) 59, *Accounting for Noncurrent Marketable Equity Securities*, provide guidance on determining when an investment is other-than-temporarily impaired. This evaluation depends on the specific facts and circumstances. Factors that we consider in determining whether an other-than-temporary decline in value has occurred include: the market value of the security in relation to its cost basis; the financial condition of the investee; and the intent and ability to retain the investment for a sufficient period of time to allow for possible recovery in the market value of the investment.

Clinical Trial Accruals

Our cost accruals for clinical trials are based on estimates of the services received and efforts expended pursuant to contracts with numerous academic institutions, site management organizations and clinical research organizations. These costs are a significant component of research and development expenses. In the normal course of business, we contract with third parties to conduct, supervise or monitor some or all aspects of clinical trials involving our Xcellerate Technology. The financial terms of these agreements are subject to negotiation and variation from contract to contract and may result in uneven payment flows. Payments under the contracts depend on factors such as the achievement of certain events, the successful accrual of patients or the completion of portions of the clinical trial or similar conditions. The objective of our accrual policy is to match the recording of expenses in our financial statements to the actual services received and efforts expended. As such, expense accruals related to clinical trials are recognized based on our estimate of the degree of completion of the event or events specified in the specific agreements.

Derivative Instruments

The terms of our November 2004 convertible preferred stock offering include a dividend make-whole payment feature. If we elect to automatically convert, or the holder elects to voluntarily convert, some or all of the convertible preferred stock into shares of our common stock prior to November 3, 2007, we will make an additional payment on the convertible preferred stock equal to the aggregate amount of dividends that would have been payable on the convertible preferred stock through and including November 3, 2007, less any dividends already paid on the convertible preferred stock. This additional payment is payable in cash or, at our option, in shares of our common stock, or a combination of cash and shares of common stock. This dividend make-whole payment feature is considered to be an embedded derivative and has been recorded on the balance sheet at fair value as a current liability. We will be required to recognize other income (expense) in our statements of operations as the fair value of this derivative fluctuates from period to period.

The accounting for derivatives is complex, and requires significant judgments and estimates in determining the fair value in the absence of quoted market values. These estimates are based on valuation methodologies and assumptions deemed appropriate in the circumstances. The fair value of the dividend make-whole payment feature is based on various assumptions, including the estimated market volatility and discount rates used in determination of fair value. The use of different assumptions may have a material effect on the estimated fair value amount and our results of operations.

Results of Operations*Years Ended December 31, 2004 and 2003**Revenue*

Revenue was approximately \$62,000 and \$170,000 for the years ended December 31, 2004 and 2003, respectively. This consisted of revenue recognized related to the amortization of license fees received and reimbursements of our costs incurred under a collaboration agreement.

Research and Development

Research and development expenses represented approximately 74% and 76% of our operating expenses for the years ended December 31, 2004 and 2003, respectively. Research and development expenses increased 44%, from \$13.7 million in the year ended December 31, 2003 to \$19.7 million in the year ended December 31, 2004. The increase was primarily the result of amounts charged to expense for contractual obligations relating to developing our bead technology, in addition to increases in clinical trial costs, laboratory supplies, salary and other personnel-related expenses and non-cash stock compensation expense. Expenses associated with developing our bead technology totaled \$500,000 in the year ended December 31, 2004, with no such costs incurred in the year ended December 31, 2003. Clinical trial and laboratory supplies costs have increased as we continue to advance and expand our clinical testing, with increases of approximately \$1.1 million and \$1.3 million, respectively. As of December 31, 2004, we had 86 employees in research and development and clinical development operations compared to 56 employees in research and development and clinical development operations as of December 31, 2003, with the increase in salary and other personnel-related expenses totaling approximately \$2.2 million. In addition, our non-cash stock compensation expense increased from \$884,000 in the year ended December 31, 2003 to \$1.1 million in the year ended December 31, 2004. These increases were partially offset by a reduction of \$1.1 million in contractual payments to the third-party manufacturer of the antibodies that we use in our Xcellerate Technology. Since we store these antibodies for use when needed in clinical trials and research and development activities, the manufacture of these antibodies occurs periodically, resulting in a corresponding increase in expense from time to time.

General and Administrative

General and administrative expenses represented approximately 26% and 24% of our operating expenses for the years ended December 31, 2004 and 2003, respectively. General and administrative expenses increased 59%, from \$4.3 million in the year ended December 31, 2003 to \$6.9 million in the year ended December 31, 2004. The rise was due primarily to increases in professional fees, insurance costs, salary and other personnel-related expenses and non-cash stock compensation expense. Increases in professional fees, insurance costs and salary and other personnel-related expenses totaled approximately \$991,000, \$478,000 and \$195,000, respectively. In addition, non-cash stock compensation expense increased from \$783,000 in the year ended December 31, 2003 to \$1.2 million in the year ended December 31, 2004.

Other Income (Expense)

Other expense, comprised primarily of interest expense and interest income, totaled \$620,000 in the year ended December 31, 2003, compared to \$12.3 million in the year ended December 31, 2004. Interest income increased 183%, from \$149,000 in the year ended December 31, 2003 to \$421,000 in the year ended December 31, 2004, due to increased average cash and investment balances upon which interest is earned. Interest expense increased from \$768,000 in the year ended December 31, 2003 to \$12.8 million in the year ended December 31, 2004, due to interest expense associated with the convertible promissory notes issued in October 2003. Upon consummation of our initial public offering and conversion of the notes to common stock, we recognized \$11.3 million in interest expense, which represented the beneficial conversion feature of the notes. We also recognized an additional \$1.1 million in interest expense associated with the discount on the notes, representing the value of the proceeds allocated to the warrants received by the note holders.

Also included in other expense in 2004 is the change in the derivative value associated with the make-whole payment on our outstanding convertible exchangeable preferred stock of \$727,000. The valuation of the derivative is dependent upon many factors, including estimated market volatility, and may fluctuate significantly, which may have a significant impact on our statement of operations.

Accretion of Preferred Stock

In the year ended December 31, 2004, we recognized \$9.0 million in accretion of preferred stock to arrive at our net loss applicable to common stockholders. No such accretion was recognized in the year ended December 31, 2003. This accretion represented the remaining discount associated with our Series E and F redeemable preferred stock, which was recognized when the redeemable preferred stock was converted into common stock upon the closing of our initial public offering.

Stock-Based Compensation

During the years ended December 31, 2004, 2003 and 2002, we recorded deferred stock-based compensation totaling \$810,000, \$2.4 million and \$3.2 million, respectively. We amortize the deferred stock-based compensation to expense using the graded vesting method. As of December 31, 2004, there was \$1.4 million of deferred stock-based compensation estimated to be amortized in future periods as follows: \$981,000 in 2005, \$350,000 in 2006 and \$86,000 in 2007. During the years ended December 31, 2004, 2003 and 2002, we granted non-employee stock options and warrants to purchase 11,630, 24,543 and 6,363 shares of our common stock, respectively. We determined the fair value of options and warrants granted to non-employees using the Black-Scholes option-pricing model. We will periodically measure this value as the underlying options vest. Total stock-based compensation expense for non-employees was \$65,000, \$360,000 and \$65,000 for the years ended December 31, 2004, 2003 and 2002, respectively.

Income Taxes

We have incurred net operating losses since inception, and we have consequently not paid any federal, state or foreign income taxes. As of December 31, 2004, we had net operating loss carryforwards of approximately \$97.5 million and research and development tax credit carryforwards of approximately \$3.9 million. If not utilized, the net operating loss and tax credit carryforwards will expire at various dates beginning in 2011. If we do not achieve profitability, our net operating loss carryforwards may be lost. In addition, the change-in-ownership provisions as specified under Section 382 of the Internal Revenue Code of 1986, as amended, may substantially limit utilization of net operating loss and tax credit carryforwards annually.

Our deferred tax assets consist primarily of net operating loss carryforwards. Because of our history of operating losses, we do not have a sufficient basis to project that future income will be sufficient to realize the deferred tax assets during the carryforward period. As a result, we have provided a full valuation allowance on the net deferred tax assets for all periods presented. The valuation allowance has increased each fiscal year primarily due to that fiscal year's net operating loss carryforward.

*Years Ended December 31, 2003 and 2002**Revenue*

Revenue was approximately \$170,000 in the year ended December 31, 2003, consisting of funds received under a cost-reimbursement agreement. We recognized no revenue in the year ended December 31, 2002.

Research and Development

Research and development expenses represented approximately 76% and 75% of our operating expenses for the years ended December 31, 2003 and 2002, respectively. Research and development expenses decreased 6.7%, from \$14.7 million in the year ended December 31, 2002 to \$13.7 million in the year ended December 31, 2003. The decrease was primarily due to a reduction in technology license costs, contractual payments relating to developing our bead technology and non-cash stock compensation expense. Technology license costs totaled \$829,000 in the year ended December 31, 2002, representing the value of stock and cash paid for a license we obtained from an academic institution. We incurred no technology license costs in the year ended December 31, 2003. Expenses associated with developing our bead technology totaled \$500,000 in 2002, with no such costs incurred in 2003. Non-cash stock compensation expense decreased from \$1.3 million in the year ended December 31, 2002 to \$884,000 in the year ended December 31, 2003, as a result of a reduction in the number of options granted. Decreases in research and development expenses were partially offset by an increase of \$220,000 in contractual payments relating to developing our antibody technology, in addition to increases in clinical trial and laboratory supplies costs. The increase in payments related to our antibody technology resulted from the third-party manufacture of the antibodies that we use in our Xcellerate Technology. Since we store these antibodies for use when needed in clinical trials and research and development activities, the manufacture of these antibodies occurs periodically, resulting in a corresponding increase in expense from time to time.

General and Administrative

General and administrative expenses represented approximately 24% and 25% of our operating expenses for the years ended December 31, 2003 and 2002, respectively. General and administrative expenses decreased 13%, from \$5.0 million in the year ended December 31, 2002 to \$4.3 million in the year ended December 31, 2003. The decrease was due primarily to a decrease in non-cash stock compensation expense and the absence of expenses related to an initial public offering registration process that we initiated and terminated in 2002. Non-cash stock compensation expense decreased 40%, from \$1.3 million in the year ended December 31, 2002 to \$783,000 in the year ended December 31, 2003, as a result of a reduction in the number of options granted. Costs we incurred in association with the initial public offering registration process in the year ended December 31, 2002 totaled \$272,000.

Other Income (Expense)

Other income, comprised primarily of interest income and interest expense, totaled \$189,000 in the year ended December 31, 2002, compared to other expense of \$620,000 in the year ended December 31, 2003. Interest income decreased 68%, from \$467,000 in the year

ended December 31, 2002 to \$149,000 in the year ended December 31, 2003, due to decreased cash and investment balances upon which interest is earned and declining interest rates. Interest expense increased 188% from \$267,000 in the year ended December 31, 2002 to \$768,000 in the year ended December 31, 2003, due primarily to interest expense associated with the convertible promissory notes issued in October 2003.

Liquidity and Capital Resources

As of December 31, 2004, we had cash, cash equivalents and short-term investments of \$47.3 million, with cash equivalents being held in commercial paper and highly liquid money market accounts with financial institutions. Cash, cash equivalents and short-term investments were \$13.5 million and \$17.3 million as of December 31, 2003 and 2002, respectively.

Net cash used in operating activities was \$21.1 million, \$15.5 million and \$15.2 million in the years ended December 31, 2004, 2003 and 2002, respectively. Expenditures in these periods were generally a result of research and development expenses and general and administrative expenses in support of our operations. We anticipate that these operating expenditures will continue to increase in the foreseeable future as we expand our research, development and clinical trial activities, support our growth, and incur costs related to being a public company.

Our investing activities, other than purchases and maturities of investments, have consisted primarily of purchases of property and equipment. Purchases of property and equipment totaled \$4.4 million, \$995,000 and \$1.1 million in the years ended December 31, 2004, 2003 and 2002, respectively. The significant increase in purchases of property and equipment in the year ended December 31, 2004 is the result of the construction and renovation of our planned manufacturing plant in Bothell, Washington. In 2005, we anticipate our capital expenditures will decrease somewhat from 2004 levels, as a majority of our manufacturing plant construction and renovation has been completed.

Net cash provided by financing activities totaled \$59.6 million, \$12.8 million and \$12.8 million in the years ended December 31, 2004, 2003 and 2002, respectively. In March 2004, we raised net proceeds of approximately \$29.7 million from the sale of 4,200,000 shares of common stock in our initial public offering. In connection with the initial public offering, all of our outstanding shares of redeemable convertible preferred stock and all of our outstanding convertible promissory notes, including interest accrued thereon through the closing date of the offering, were converted into 6,781,814 and 1,357,357 shares of our common stock, respectively. In November 2004, we raised net proceeds of approximately \$27.5 million from the sale of 2,990,000 shares of our convertible preferred stock.

We have financed the acquisition of property and equipment through financing arrangements with General Electric Capital Corporation, Oxford Finance Corporation and Phoenix Leasing Incorporated. At December 31, 2004, we had two financing arrangements. Under the first arrangement, with General Electric Capital Corporation, we may borrow up to \$3.0 million, subject to credit approval. At December 31, 2004, we have \$1.8 million available under the outstanding arrangement, which expires in July 2005. Under the second arrangement, with Oxford Finance Corporation, we may borrow up to \$3.0 million, subject to credit approval. At December 31, 2004, we have \$2.2 million available under the outstanding arrangement, which expires in December 2005. Outstanding borrowings under the current and previous financing arrangements were \$4.2 million and \$1.8 million at years ended December 31, 2004 and 2003, respectively. Outstanding borrowings require monthly principal and interest payments and mature at various dates through 2008. Interest rates applicable to the outstanding borrowings at December 31, 2004 ranged from 7.91% to 11.61%. The weighted average interest rates for borrowings outstanding during the years ended December 31, 2004, 2002 and 2003 were 8.99%, 10.27% and 11.09%, respectively. Borrowings are secured by the acquired assets that have a net book value of \$5.8 million at December 31, 2004. Under all agreements, we are required to comply with certain nonfinancial covenants.

We have entered into agreements to develop bead and antibody technology that required significant cash expenditures, including an agreement with Dynal under which we agreed to make payments totaling \$3.0 million upon the accomplishment of bead development activities. Additionally, we have two agreements with Lonza under which we agreed to make payments to develop and produce cGMP-grade antibodies totaling \$6.7 million. As of December 31, 2004, we have paid the entire \$3.0 million to Dynal and \$5.0 million to Lonza. We anticipate that the remaining payments to Lonza will be made in 2005. Under the terms of the agreement with Dynal, should we not buy a minimum of \$250,000 of beads in the first 12 months after the development phase ends and \$500,000 of beads annually thereafter over the remaining term of the agreement, Dynal shall have the right to terminate the agreement. As of December 31, 2004, the development phase, as defined in the Dynal agreement, has not yet been completed. Under our license agreement with Genetics Institute, we must spend no less than \$500,000 annually on research and development activities related to product development until the first commercial sale of a product.

The following summarizes our long-term contractual obligations as of December 31, 2004 (in thousands):

Contractual obligations	Total	PAYMENTS DUE BY PERIOD			
		Less than 1 year	1 to 3 years	3 to 5 years	After 5 years
Operating leases	\$ 7,594	\$ 1,644	\$ 2,562	\$ 2,285	\$ 1,103
Equipment financing	4,272	1,556	2,411	305	—
Development and supply agreements	1,743	1,743	—	—	—
Total ⁽¹⁾	\$13,609	\$ 4,943	\$ 4,973	\$ 2,590	\$ 1,103

(1) Does not include commitments for purchases of beads under the Dynal agreement or product development spending under the Genetics Institute license agreement, as described above.

Based on the current status of our product development and collaboration plans, we believe that our current cash, cash equivalents and investments will be adequate to satisfy our capital needs through at least the end of the second quarter of 2006. We will likely seek additional financing prior to that time to, among other things, support our continuing product development, manufacturing and clinical trials for Phase II or Phase III clinical trials in future periods. Furthermore, we expect to require additional funding before we are able to generate revenue, if at all, from our potential products. Additional financing may not be available on favorable terms, if at all. If we are unable to raise additional funds when we need them, we may have to delay, reduce or eliminate some or all of our development programs or our clinical trials. We also may have to license our technologies to others, including technologies that we would prefer to develop internally, to raise capital.

Recent Accounting Pronouncements

In March 2004, the EITF reached a consensus on EITF 03-1, "The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments." EITF 03-1 provides guidance for determining when an investment is considered impaired, whether that impairment is other than temporary, and the measurement of an impairment loss. EITF 03-1 also includes accounting considerations subsequent to the recognition of an other-than-temporary impairment and requires certain disclosures about unrealized losses that have not been recognized as other-than-temporary. The effective date for the recognition and measurement guidance of EITF 03-1 has been delayed until certain implementation issues are addressed. Final implementation guidance is expected to be issued in 2005. The disclosure requirements of EITF 03-1 remain in effect. We have complied with the disclosure requirements, and the adoption of the remaining portions of EITF 03-1 is not expected to have a material impact on our results of operations or financial condition.

In December 2004, the FASB issued SFAS 123R, *Share-Based Payment*. SFAS 123R establishes standards for the accounting for transactions in which an entity receives employee services in exchange for the entity's equity instruments or liabilities that are based on the fair value of the entity's equity instruments or that may be settled by the issuance of those equity instruments. SFAS 123R eliminates the ability to account for share-based compensation using APB 25 and generally requires that such transactions be accounted for using a fair value method. The provisions of this statement are effective for financial statements issued for fiscal periods beginning after June 15, 2005 and will become effective for us beginning with the third quarter of 2005. The impact that the adoption of this statement will have on our financial position and results of operations will be determined by share-based payments granted in future periods, as well as the fair value model and assumptions we will choose, which have not been finalized yet.

Subsequent Events

As a result of the plan to focus most of our clinical development resources on our planned Phase II/III trial in CLL and planned Phase I/II trial in patents with HIV, on March 22, 2005, we reduced our workforce by approximately 24%, to 81 employees. The Company will record a charge in the first quarter of 2005 of approximately \$300,000, consisting of severance, benefits and outplacement services.

Important Factors That May Affect Our Business, Results of Operations and Stock Price

You should carefully consider the risks described below, together with all of the other information included in this annual report on Form 10-K and the information incorporated by reference herein. If we do not effectively address the risks we face, our business will suffer and we may never achieve or sustain profitability. See "Management's Discussion and Analysis of Financial Condition and Results of Operations."

This annual report on Form 10-K also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of factors that are described below and elsewhere in this annual report on Form 10-K.

WE EXPECT TO CONTINUE TO INCUR SUBSTANTIAL LOSSES, AND WE MAY NEVER ACHIEVE PROFITABILITY.

We are a development stage company with limited operating history. We have incurred significant operating losses since we began operations in 1996, including net losses of approximately \$39.6 million for the year ended December 31, 2004, and we may never become profitable. As of December 31, 2004, we had a deficit accumulated during the development stage of approximately \$126.2 million. These losses have resulted principally from costs incurred in our research and development programs and from our general and administrative expenses. We also expect to incur significant costs to renovate our leased facility for the manufacture of Xcellerated T Cells for our planned clinical trials and, if we receive FDA approval, for initial commercialization activities. To date, we have derived no revenues from product sales or royalties. We do not expect to have any significant product sales or royalty revenue for a number of years. Our operating losses have been increasing during the past several years and will continue to increase significantly in the next several years as we expand our research and development, participate in clinical trial activities, acquire or license technologies, scale up and improve our manufacturing operations, seek regulatory approvals and, if we receive FDA approval, commercialize our products. We also may be required to recognize additional losses based upon changes in the fair value of our derivative liability, which resulted from the dividend make-whole payment feature of our convertible preferred stock. These losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity and working capital. Because of the numerous risks and uncertainties associated with our product development efforts, we are unable to predict when we may become profitable, if at all. If we are unable to achieve and then maintain profitability, the market value of our common stock and convertible preferred stock will likely decline.

WE WILL NEED TO RAISE SUBSTANTIAL ADDITIONAL CAPITAL TO FUND OUR OPERATIONS, AND OUR FAILURE TO OBTAIN FUNDING WHEN NEEDED MAY FORCE US TO DELAY, REDUCE OR ELIMINATE OUR PRODUCT DEVELOPMENT PROGRAMS OR COLLABORATION EFFORTS.

Developing products and conducting clinical trials for the treatment of cancer and infectious diseases require substantial amounts of capital. To date, we have raised capital through private equity financings, an initial public offering, a public offering of convertible preferred stock, the sale of convertible promissory notes and equipment leases. Currently, we anticipate that our cash, cash equivalents and investments will be adequate to satisfy our capital needs through at least the end of the second quarter of 2006. If we are unable to obtain additional funding in a timely fashion, we may never conduct required clinical trials to demonstrate safety and clinical efficacy of Xcellerated T Cells, and we may never obtain FDA approval or commercialize any of our products. We will need to raise additional capital to, among other things:

- fund our clinical trials;
- expand our research and development activities;
- scale up and improve our manufacturing operations;
- finance our general and administrative expenses;
- acquire or license technologies;
- prepare, file, prosecute, maintain, enforce and defend our patent and other proprietary rights;
- pursue regulatory approval and commercialization of Xcellerated T Cells and any other products that we may develop; and
- develop and implement sales, marketing and distribution capabilities.

Our future funding requirements will depend on many factors, including, among other things:

- the progress, expansion and cost of our clinical trials and research and development activities;
- any future decisions we may make about the scope and prioritization of the programs we pursue;
- the development of new product candidates or uses for our Xcellerate Technology;
- changes in regulatory policies or laws that affect our operations; and
- competing technological and market developments.

If we raise additional funds by issuing securities, further dilution to stockholders may result and new investors could have rights superior to our current stockholders. In addition, debt financing, if available, may include restrictive covenants. If adequate funds are not available to us, we may have to liquidate some or all of our assets or delay, reduce the scope of or eliminate some portion or all of our development programs or clinical trials. We also may have to license to other companies our products or technologies that we would prefer to develop and commercialize ourselves.

DUE TO OUR LIMITED RESOURCES AND ACCESS TO CAPITAL, WE MUST PRIORITIZE OUR DEVELOPMENT PROGRAMS AND MAY CHOOSE TO PURSUE PROGRAMS THAT NEVER RECEIVE REGULATORY APPROVAL OR PROVE TO BE PROFITABLE.

Because we have limited resources and access to capital to fund our operations, our management must make significant prioritization decisions on which programs to pursue and how much of our resources to allocate to each program. We are currently focusing our research and

development efforts on the use of Xcellerated T Cells to treat CLL and HIV. As a result of our plan to limit clinical development primarily to the planned Phase II/III in CLL and planned Phase I/II trial in HIV, we reduced our workforce by approximately 24%, to 81 employees on March 22, 2005. We would need to expand our workforce if these two clinical trials are successful or if we decide to conduct other clinical trials in the future. If we advance or expand our clinical trials in the future, we cannot be sure that we will be able to hire employees with the skills and experience desirable or necessary to support such clinical development. Our management has broad discretion to suspend, scale down or discontinue any of these programs or to initiate new programs to treat other clinical indications. Xcellerated T Cells may never prove to be safe and clinically effective to treat any of these indications, and the market for these indications may never prove to be profitable even if we obtain regulatory approval for these indications. Accordingly, we cannot assure you that the programs we decide to pursue will lead to regulatory approval or will prove to be profitable.

OUR ABILITY TO INITIATE A PHASE II/III TRIAL IN PATIENTS WITH CLL ON OUR PROPOSED PROTOCOL AND TIMELINE IS UNCERTAIN AND HIGHLY DEPENDENT ON THE FDA.

We cannot be sure that the FDA will ultimately let us proceed with the proposed design of our Phase II/III clinical trial protocol for Xcellerated T Cells in patients with CLL, who have been previously treated with chemotherapy and have failed treatment with Campath, an FDA-approved drug used to treat CLL. In February 2005, the FDA requested that we withdraw our Phase II/III clinical trial protocol and resubmit the protocol as a draft to enable further discussion. The FDA may conclude that we have not adequately addressed the issues they raised in our initial meeting on September 23, 2004 or in subsequent telephone conversation or they may propose additional modifications to address new concerns they have with our protocol. The FDA may recommend that we conduct an additional clinical trial to address their concerns, which would cause significant delays in the initiation of our Phase II/III clinical trial, or make the clinical trial too costly to pursue for this indication. Even if the FDA does let us proceed with our Phase II/III clinical trial, there is no guarantee that we will receive approval from the FDA upon completion of such clinical trial. Our clinical development plan for CLL is premised upon the continued existence of an unmet medical need in this population. The FDA may require that we conduct larger, controlled studies in more patients, particularly if the FDA approves another drug or biologic to treat Campath-refractory CLL.

Our ability to initiate any clinical trial will also depend on our ability to address comments received from the FDA related to chemistry, manufacturing and controls issues for the Xcellerated T Cells. We plan to provide further information and have further discussions with the FDA concerning these issues. We cannot be sure that the FDA will accept our proposals.

IF WE PROCEED WITH OUR CURRENTLY PROPOSED PHASE II/III TRIAL OF XCELLERATED T CELLS IN PATIENTS WITH CLL, EVEN IF THE TRIAL MEETS ITS PRESPECIFIED ENDPOINTS IT MAY NOT BE SUFFICIENT TO SUPPORT APPROVAL BY THE FDA.

We have submitted a draft Phase II/III protocol to the FDA for the use of Xcellerated T Cells in patients with CLL. We may choose to proceed with this trial, assuming the FDA does not place the proposed trial on clinical hold, even if we have not addressed all of the concerns raised by the FDA. If we proceed with the trial on this basis, it may not ultimately meet FDA approvability standards and we may be forced to conduct an additional Phase III study in patients with CLL. The FDA's advice on the design of our proposed Phase II/III trial has itself changed over time, and we cannot assure you that, even if we conduct the study according to the FDA's current design preferences, that if successful, the FDA will approve our product for this indication.

To date, Xcellerated T Cells have been shown in CLL patients to decrease lymph nodes and spleen size, but not leukemic blood counts. We cannot be sure that the FDA will accept two of these three major measurements of tumor response as sufficient to support product approval. In addition, although the FDA has accepted tumor response as a valid clinical endpoint in disease indications where there is an unmet clinical need such as CLL, we cannot be sure that the FDA will not require us to demonstrate patient survival in a pre-approval trial rather than a post-approval confirming trial that we plan to do. The Phase II/III clinical trial we plan to conduct is not randomized or powered statistically to demonstrate patient survival. To address decreases in leukemic counts in the blood in order to achieve all three major measurements of tumor response, we are planning to enroll CLL patients in our proposed Phase II/III clinical trial who have been recently treated with Campath, a drug that leads to decreases in leukemic counts in the blood. We have not previously tested the effects of using Xcellerated T Cells after use of Campath and there may be unforeseen side effects when patients receive Xcellerated T Cells after use of Campath. We cannot be sure that patients' leukemic counts will not rise again after the use of Campath or that we will observe a similar safety profile and treatment effects of our Xcellerated T Cells in CLL patients who have received Campath as we have observed in our previous clinical trials.

IF WE ARE UNABLE TO PROTECT OUR PROPRIETARY RIGHTS, WE MAY NOT BE ABLE TO COMPETE EFFECTIVELY.

Our success depends in part on obtaining, maintaining and enforcing our patents and in-licensed and proprietary rights throughout the world. We believe we own, or have rights under licenses to, issued patents and pending patent applications that are necessary to commercialize Xcellerated T Cells. However, the patents on which we rely may be challenged and invalidated, and our patent applications may not result in issued patents. Moreover, our patents and patent applications may not be sufficiently broad to prevent others from practicing our technologies or developing competing products. We also face the risk that others may independently develop similar or alternative technologies or may design around our proprietary and patented technologies.

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date in the United States. Furthermore, the application and enforcement of patent laws and regulations in foreign countries is even more uncertain, particularly where, as here, patent rights are co-owned with others, thus requiring their consent to ensure exclusivity in the marketplace. Accordingly, we cannot assure you that we will be able to effectively file, protect or defend our proprietary rights in the United States or in foreign jurisdictions on a consistent basis.

Third parties may successfully challenge the validity of our patents. We will only be able to protect our technologies from unauthorized use by third parties to the extent that valid and enforceable patents or other proprietary rights cover them. Because the issuance of a patent is not conclusive of its validity or enforceability, we cannot assure you how much protection, if any, will be given to our patents if we attempt to enforce them or if others challenge their validity in court. It is possible that a competitor may successfully challenge our patents or that a challenge will result in limiting the coverage of our patents. If the outcome of litigation is adverse to us, third parties may be able to use our technologies without payment to us.

In addition, it is possible that others may infringe upon our patents or successfully avoid them through design innovation. We may initiate litigation to police unauthorized use of any of our proprietary rights, whether or not related to our Xcellerated T Cells. However, the cost of litigation to uphold the validity of our patents and to prevent infringement could be substantial, particularly where patent rights are co-owned with others, thus requiring their participation in the litigation, and the litigation will consume time and other resources. Some of our competitors may be better able to sustain the costs of complex patent litigation because they have substantially greater resources. Moreover, if a court decides that our patents are not valid, we will not have the right to stop others from using our inventions. There is also the risk that, even if the validity of our patents were upheld, a court may refuse to stop others on the ground that their activities do not infringe upon our patents. Because protecting our intellectual property is difficult and expensive, we may be unable to prevent misappropriation of our proprietary rights.

We also rely on certain proprietary trade secrets and know-how, especially where we believe patent protection is not appropriate or obtainable. Trade secrets and know-how, however, are difficult to protect. We have taken measures to protect our unpatented trade secrets and know-how, including the use of confidentiality and invention assignment agreements with our employees, consultants and some of our contractors. It is possible, however, that these persons may unintentionally or willingly breach the agreements or that our competitors may independently develop or otherwise discover our trade secrets and know-how.

THE CLINICAL AND COMMERCIAL UTILITY OF OUR XCELLERATE TECHNOLOGY IS UNCERTAIN AND MAY NEVER BE REALIZED.

Our Xcellerate Technology is based on a novel approach to treat cancer and infectious diseases and is in an early stage of development. Our clinical trials and independent clinical trials using an earlier version of our technology, to date, have involved small numbers of patients, which, unless otherwise stated, were not designed to produce statistically significant results as to efficacy. In addition, these trials have neither been randomized nor blinded to ensure the results are due to the effect of Xcellerated T Cells. Some of the data regarding our Xcellerate Technology were derived from independent clinical trials, including physician-sponsored trials, which we do not control. In addition, data from these independent clinical trials were derived using T cells activated with an earlier version of our proprietary technology. Success in early clinical trials neither ensures that large-scale trials will be successful nor predicts final results. Acceptable results in early trials may not be repeated in later trials. In addition, we may not be able to treat patients if we cannot collect a sufficient quantity of T cells that meet our minimum specifications to enable us to produce Xcellerated T Cells. Also, some patients may be unable to tolerate the required procedures for blood collection and administration of Xcellerated T Cells. Finally, we only have limited experience in treating patients with multiple doses of Xcellerated T Cells, which may be required to achieve optimal therapeutic effects.

Although we have observed few serious side effects in patients infused with Xcellerated T Cells in clinical trials conducted to date, we may not ultimately be able to provide the FDA with satisfactory data to support a claim of clinical safety and efficacy sufficient to enable the FDA to approve Xcellerated T Cells for commercialization. This may be because later clinical trials may fail to reproduce favorable data we may have obtained in earlier clinical trials, because the FDA may disagree with how we interpret the data from these clinical trials or because the FDA may not accept these therapeutic effects as valid endpoints in pivotal trials necessary for market approval. For example, although our studies to date have indicated that our Xcellerate Technology can lead to increased T cell and lymphocyte counts, the FDA will not accept increased T cell and lymphocyte counts as a valid endpoint in pivotal studies necessary for market approval. Instead, we would be required to show that Xcellerated T Cells lead to a significant clinical benefit. We will also need to demonstrate that Xcellerated T Cells are safe. We do not have data on possible harmful long-term effects of Xcellerated T Cells and will not have any data on long-term effects in the near future. We also have limited data on the safety and efficacy of Xcellerated T Cells to treat patients with very weakened immune systems, such as patients with HIV. For these and other reasons, the clinical effectiveness and commerciality of our Xcellerate Technology is uncertain and may never be realized.

WE MAY FAIL TO OBTAIN OR MAY EXPERIENCE DELAYS IN OBTAINING REGULATORY APPROVALS TO MARKET XCELLERATED T CELLS, WHICH WILL SIGNIFICANTLY HARM OUR BUSINESS.

We do not have the necessary approvals to market or sell Xcellerated T Cells in the United States or any foreign market. Before marketing Xcellerated T Cells, we must successfully complete extensive preclinical studies and clinical trials and rigorous regulatory approval procedures. We cannot assure you that we will obtain the necessary regulatory approvals to commercialize Xcellerated T Cells.

Conducting clinical trials is uncertain and expensive and often takes many years to complete. The results from preclinical testing and early clinical trials are often not predictive of results obtained in later clinical trials. In conducting clinical trials, we may fail to establish the effectiveness of Xcellerated T Cells for the targeted indication or we may discover unforeseen side effects. Moreover, clinical trials may require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit. Patients participating in the trials may die before completion of the trial or suffer adverse medical effects unrelated to treatment with Xcellerated T Cells. Many patients who enroll in clinical trials, particularly for treatment of hematological malignancies, have received prior therapies, including therapies that may have significantly compromised their health, and their immune system particularly. As we expand our trials to include larger number of patients and face more competition for these patients, we are likely to enroll more patients that have been previously treated with multiple other therapies than in our earlier, smaller clinical trials, which may reduce the effectiveness of our therapy in these patients or increase the number of patients who cannot complete the clinical trial due to death or adverse medical effects unrelated to treatment with Xcellerated T Cells. These factors could lead to delays, termination or failure of our clinical trials. A number of companies in the biotechnology industry have suffered significant setbacks in every stage of clinical trials, even in advanced clinical trials after positive results in earlier trials. In addition, we have developed a custom bioreactor system in our manufacturing process, and we will not be able to obtain FDA approval to commercialize Xcellerated T Cells without the FDA's acceptance of our manufacturing process using this bioreactor system.

To date, the FDA has approved only a few cell-based therapies for commercialization. The FDA recently formed a new division that will regulate biologic products, such as Xcellerated T Cells. The processes and requirements associated with this new division may cause delays and additional costs in obtaining regulatory approvals for our products. Because our Xcellerate Technology is novel, and cell-based therapies are relatively new, regulatory agencies may lack experience in evaluating product candidates like Xcellerated T Cells. This inexperience may lengthen the regulatory review process, increase our development costs and delay or prevent commercialization of Xcellerated T Cells.

In addition, the following factors may impede or delay our ability to obtain timely regulatory approvals, if at all:

- our limited experience in filing and pursuing the applications necessary to gain regulatory approvals;
- any failure to satisfy efficacy, safety or quality standards;
- any difficulty identifying, recruiting, enrolling and retaining a sufficient number of qualified patients for our clinical trials;
- a decision by us or regulators to suspend or terminate our clinical trials if the participating patients are being exposed to unacceptable health risks;
- regulatory inspections of our clinical trials or manufacturing facilities, which may, among other things, require us to undertake corrective action or suspend or terminate our clinical trials if investigators find us not to be in compliance with applicable regulatory requirements;
- our ability to produce sufficient quantities of Xcellerated T Cells to complete our clinical trials;
- varying interpretations of the data generated from our clinical trials; and
- changes in governmental regulations or administrative actions.

Any delays in, or termination of, our clinical trials could materially and adversely affect our development and collaboration timelines, which may cause our stock price to decline. If we do not complete clinical trials for Xcellerated T Cells and obtain regulatory approvals, we will not be able to commercialize Xcellerated T Cells and we may not be able to recover any of the substantial costs we have invested in the development of Xcellerated T Cells.

WE HAVE LIMITED MANUFACTURING EXPERIENCE AND MAY NOT BE ABLE TO MANUFACTURE XCELLERATED T CELLS ON A LARGE SCALE OR IN A COST-EFFECTIVE MANNER.

Until the end of March 2005, we will have manufactured Xcellerated T Cells for research and development and our clinical activities in one manufacturing facility in Seattle, Washington. We have not demonstrated the ability to manufacture Xcellerated T Cells beyond quantities sufficient for research and development and limited clinical activities. We have no experience manufacturing Xcellerated T Cells at the capacity that will be necessary to support large clinical trials or commercial sales. We are now in the process of relocating our manufacturing activities to our leased property in Bothell, Washington, which we have recently renovated for the manufacture of Xcellerated T Cells for our planned clinical trials and, if we receive FDA approval, initial commercialization. However, we may encounter difficulties in obtaining the approvals for validating and operating this manufacturing facility. On March 22, 2005, we reduced our workforce by approximately

24%, to 81 employees, and we cannot be sure that the smaller staff will not delay or restrict our planned transfer of manufacturing operations to our new facility. We may also be unable to hire the qualified personnel that we may later require to accommodate the expansion of our operations and manufacturing capabilities. Relocation of our manufacturing activities to a new facility during or after a pivotal clinical trial, will require that we demonstrate to the FDA similarity of the Xcellerated T Cells manufactured in the new facility to the Xcellerated T Cells manufactured in the prior facility to obtain FDA approval. If we cannot adequately demonstrate similarity to the FDA, we could be required to repeat clinical trials, which would be expensive and substantially delay regulatory approval.

Because our Xcellerate Technology is a patient-specific, cell-based product, the manufacture of Xcellerated T Cells is more complicated than the manufacture of most pharmaceuticals. Our present manufacturing process may not meet our initial expectations as to reproducibility, yield, purity or other measurements of performance. In addition, we are using a custom bioreactor system in our manufacturing process and only have limited manufacturing experience using this bioreactor system to activate and expand T cells. Because this new manufacturing process is unproven, we may never successfully utilize our custom bioreactor system to commercialize our products. In addition, because some of our prior clinical trials were conducted using a prior version of the manufacturing system, which did not use the custom bioreactor, we may have to show comparability of the Xcellerated T Cells manufactured with the different versions of the manufacturing systems we have used. To show comparability, we may be required to conduct additional clinical trials. If we make additional modifications in our manufacturing process in the future, we may also have to show comparability of newer versions of the manufacturing process. We are currently negotiating a manufacturing and supply agreement with Wave Biotech LLC, the manufacturer of our bioreactor system. If we are unable to successfully negotiate this contract or are unable to procure a suitable alternative manufacturer in a timely manner, we could face a setback in the development of our manufacturing process. For these and other reasons, we may not be able to manufacture Xcellerated T Cells on a large scale or in a cost-effective manner.

We are the only manufacturer of Xcellerated T Cells. Although we are considering third-party manufacturing options, we expect that we will conduct most of our manufacturing in our own facility for the next several years. Furthermore, because we are the only manufacturer of Xcellerated T Cells and we currently use only one manufacturing facility, any damage to or destruction of our manufacturing facility or our equipment, prolonged power outage, contamination of our facility or shutdown by the FDA or other regulatory authority could significantly impair or curtail our ability to produce Xcellerated T Cells. In addition, we store our patients' cells in freezers at our manufacturing facility. If these cells are damaged at our facility, including by the loss or malfunction of these freezers or our back-up power systems, we would need to collect replacement patient cells, which would delay our patients' treatments. If we are unable to collect replacement cells from our patients, we could incur liability and our business could suffer.

OUR CLINICAL TRIALS MAY TAKE LONGER TO COMPLETE THAN WE PROJECT OR THEY MAY NOT BE COMPLETED AT ALL.

The timing of the commencement, continuation and completion of clinical trials may be subject to significant delays relating to various causes, including scheduling conflicts with participating clinicians and clinical institutions, and difficulties in identifying and enrolling patients who meet trial eligibility criteria. 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 trial, the existence of competing clinical trials and the availability of alternative or new treatments. For example, the proposed design of our planned Phase II/III clinical trial in CLL requires us to enroll patients with CLL who have been previously treated with chemotherapy and have failed treatment with Campath, an FDA-approved drug used to treat CLL. The size of this patient population is relatively small and we anticipate we will encounter difficulties in identifying and enrolling an adequate number of such patients. In addition, patients who enroll in this clinical trial will have received prior therapies, including therapies that may have significantly compromised their health, and their immune system particularly, which may reduce the effectiveness of our therapy in these patients or increase the number of patients who cannot complete the clinical trial due to death or adverse medical effects unrelated to treatment with Xcellerated T Cells. These factors could lead to delays, termination or failure of our clinical trials.

We depend on medical institutions to conduct our clinical trials and to the extent they fail to enroll patients for our clinical trials or are delayed for a significant time in achieving full enrollment, we may be affected by increased costs, program delays or both, which may harm our business. In addition, we may be required to conduct clinical trials in foreign countries to increase patient enrollment in the future, which may subject us to further delays and expenses as a result of increased drug shipment costs, additional regulatory requirements and the engagement of foreign clinical research organizations, as well as expose us to risks associated with foreign currency transactions insofar as we might desire to use U.S. dollars to make contract payments denominated in the foreign currency where the trial is being conducted.

CLINICAL TRIALS ARE EXPENSIVE, TIME CONSUMING AND THEIR OUTCOME IS UNCERTAIN.

Before we can obtain regulatory approval for the commercial sale of any product candidate that we wish to develop, we are required to complete preclinical development and extensive clinical trials in humans to demonstrate its safety and efficacy. Each of these trials requires the investment of substantial expense and time. We currently have ongoing Phase II clinical trials in multiple myeloma and non-Hodgkin's lymphoma and Phase I/II clinical trial in CLL. We expect to commence additional trials in the future. There are numerous factors that could delay each of these clinical trials or prevent us from completing these trials successfully.

Ongoing and future clinical trials of our product candidates may not show sufficient safety or efficacy to obtain requisite regulatory approvals. We still only have limited efficacy data of Xcellerated T Cells from our Phase I/II and Phase II trials. Phase I and Phase II clinical trials are not primarily designed to test the efficacy but rather to test safety, and to understand the drug candidate's side effects at various doses and schedules. Furthermore, success in preclinical and early clinical trials does not ensure that later large-scale trials will be successful nor does it predict final results. Acceptable results in early trials may not be repeated in later trials. We believe that any clinical trial designed to test the efficacy of Xcellerated T Cells, whether Phase II or Phase III, will likely involve a large number of patients to achieve statistical significance and will be expensive. We may conduct lengthy and expensive clinical trials of Xcellerated T Cells, only to learn that it is not an effective treatment. A number of companies in the biotechnology industry have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials. In addition, clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. Negative or inconclusive results or adverse medical events during a clinical trial could cause it to be redone or terminated. In addition, failure to construct appropriate clinical trial protocols could result in the test or control group experiencing a disproportionate number of adverse events and could cause a clinical trial to be redone or terminated. The length of time necessary to complete clinical trials and to submit an application for marketing approval for a final decision by the FDA or another regulatory authority may also vary significantly based on the type, complexity and novelty of the product involved, as well as other factors.

THE GOVERNMENT AND OTHER THIRD-PARTY PAYORS MAY CONTROL THE PRICING AND PROFITABILITY OF OUR PRODUCTS.

Our ability to commercialize Xcellerated T Cells successfully will depend in part on the extent to which governmental authorities, private health insurers and other organizations establish appropriate reimbursement levels for the cost of Xcellerated T Cells and related treatments. Increasing emphasis on managed care in the United States will continue to put pressure on the pricing of healthcare products. In addition, governmental authorities may establish pricing and reimbursement levels for some disease indications but not others, which may reduce the demand for Xcellerated T Cells and our profitability. Pricing and profitability of healthcare products are also subject to governmental control in some foreign markets. Cost control initiatives could:

- result in lower prices for Xcellerated T Cells or any future products or their exclusion from reimbursement programs;
- reduce any future revenues we may receive from collaborators;
- discourage physicians from delivering Xcellerated T Cells to patients in connection with clinical trials or future treatments; and
- limit off-label use of Xcellerated T Cells.

WE RELY ON THIRD PARTIES TO CONDUCT SOME OF THE CLINICAL TRIALS FOR XCELLERATED T CELLS, AND THEIR FAILURE TO TIMELY AND SUCCESSFULLY PERFORM THEIR OBLIGATIONS TO US, OR THEIR DEFECTIVE PERFORMANCE, COULD SIGNIFICANTLY HARM OUR PRODUCT DEVELOPMENT PROGRAMS AND OUR BUSINESS.

Because we rely on academic institutions, site management organizations and clinical research organizations to conduct, supervise or monitor some or all aspects of clinical trials involving our Xcellerate Technology, we have limited control over the timing and other aspects of these clinical trials. If these third parties do not successfully carry out their duties under their agreements with us, fail to inform us if these trials fail to comply with clinical trial protocols or fail to meet expected deadlines, this may adversely affect our clinical trials and we may not be able to obtain regulatory approvals.

A third party on whom we rely to conduct clinical trials for Xcellerated T Cells could conduct those clinical trials defectively. This could lead to patients experiencing harmful side effects or could prevent us from proving that Xcellerated T Cells are effective, which may result in:

- our failure to obtain or maintain regulatory approval;
- physicians not using or recommending our products; and
- significant product liability.

XCELLERATED T CELLS MAY NEVER ACHIEVE MARKET ACCEPTANCE EVEN IF WE OBTAIN REGULATORY APPROVALS.

We do not expect to receive regulatory approvals for the commercial sale of any products derived from our Xcellerate Technology for several years, if at all. Even if we do receive regulatory approvals, the future commercial success of Xcellerated T Cells will depend, among other things, on its acceptance by physicians, patients, healthcare payors and other members of the medical community as a therapeutic and cost-effective alternative to commercially available products. Because only a few cell-based therapy products have been commercialized, we do not know to what extent cell-based immunotherapy products will be accepted as therapeutic alternatives. If we fail to gain market acceptance, we may not be able to earn sufficient revenues to continue our business. Market acceptance of and demand for any product that we may develop will depend on many factors, including:

- our ability to provide acceptable evidence of safety and efficacy;

- convenience and ease of administration;
- prevalence and severity of adverse side effects;
- availability of alternative and competing treatments;
- cost effectiveness;
- effectiveness of our marketing and distribution strategy and the pricing of any product that we may develop;
- publicity concerning our products or competitive products; and
- our ability to obtain sufficient third-party coverage or reimbursement.

If Xcellerated T Cells do not become widely accepted by physicians and patients, it is unlikely that we will ever become profitable.

EVEN IF WE OBTAIN REGULATORY APPROVALS FOR XCELLERATED T CELLS, THOSE APPROVALS AND ONGOING REGULATION OF OUR PRODUCTS MAY LIMIT HOW WE MANUFACTURE AND MARKET OUR PRODUCTS, WHICH COULD PREVENT US FROM REALIZING THE FULL BENEFIT OF OUR EFFORTS.

If we obtain regulatory approvals, Xcellerated T Cells, our Xcellerate Technology and our manufacturing facilities will be subject to continual review, including periodic inspections, by the FDA and other U.S. and foreign regulatory authorities. In addition, regulatory authorities may impose significant restrictions on the indicated uses or marketing of Xcellerated T Cells or other products that we may develop. These and other factors may significantly restrict our ability to successfully commercialize Xcellerated T Cells and our Xcellerate Technology.

We and many of our vendors and suppliers are required to comply with current Good Manufacturing Practices, or cGMP, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation. Furthermore, our manufacturing facilities must be approved by regulatory agencies before these facilities can be used to manufacture Xcellerated T Cells, and they will also be subject to additional regulatory inspections. Any material changes we may make to our manufacturing process may require approvals by the FDA and state or foreign regulatory authorities. Failure to comply with FDA or other applicable regulatory requirements may result in criminal prosecution, civil penalties, recall or seizure of products, partial or total suspension of production or withdrawal of a product from the market.

We must also report adverse events that occur when our products are used. The discovery of previously unknown problems with Xcellerated T Cells or our manufacturing facilities may result in restrictions or sanctions on our products or manufacturing facilities, including withdrawal of our products from the market. Regulatory agencies may also require us to reformulate our products, conduct additional clinical trials, make changes in the labeling of our product or obtain re-approvals. This may cause our reputation in the market place to suffer or subject us to lawsuits, including class action suits.

WE RELY ON THIRD PARTIES TO ADMINISTER XCELLERATED T CELLS TO PATIENTS, AND OUR BUSINESS COULD BE HARMED IF THESE THIRD PARTIES ADMINISTER XCELLERATED T CELLS INCORRECTLY.

We rely on the expertise of physicians, nurses and other associated medical personnel to administer Xcellerated T Cells to patients. Although our Xcellerate Technology employs mostly standard medical procedures, if these medical personnel are not properly trained to administer, or are negligent in the administration of, Xcellerated T Cells, the therapeutic effect of Xcellerated T Cells may be diminished or the patient may suffer critical injury.

In addition, third-party medical personnel must thaw Xcellerated T Cells received from us. If this thawing is not performed correctly, the patient may suffer critical injury. While we intend to provide training materials and adequate resources to these third-party medical personnel, the thawing of Xcellerated T Cells will occur outside our supervision and may not be administered properly. If, due to a third-party error, people believe that Xcellerated T Cells are ineffective or harmful, the desire to use Xcellerated T Cells may decline, which will negatively impact our ability to generate revenue. We may also face significant liability even though we may not be responsible for the actions of these third parties.

THERE ARE RISKS INHERENT IN OUR BUSINESS THAT MAY SUBJECT US TO POTENTIAL PRODUCT LIABILITY SUITS AND OTHER CLAIMS, WHICH MAY REQUIRE US TO ENGAGE IN EXPENSIVE AND TIME-CONSUMING LITIGATION OR PAY SUBSTANTIAL DAMAGES AND MAY HARM OUR REPUTATION AND REDUCE THE DEMAND FOR OUR PRODUCT.

Our business exposes us to product liability risks, which are inherent in the testing, manufacturing, marketing and sale of biopharmaceutical products. We will face an even greater risk of product liability if we commercialize Xcellerated T Cells. An individual may bring a product liability claim against us if Xcellerated T Cells cause, or merely appear to have caused, an injury. In addition, we are licensing our Xcellerate Technology in the field of HIV retroviral gene therapy to our collaborative partner, Fresenius. We may incur liability and be exposed to claims for products manufactured by Fresenius.

Certain aspects of how Xcellerated T Cells are processed and administered may increase our exposure to liability. Our Xcellerate Technology requires us to activate a patient's T cells *ex vivo*, or outside of the body, using blood collected from the patient. Third-party physicians or other medical personnel initially collect a patient's blood through a process called leukapheresis, which may pose risks, such as bleeding and infection. The blood that we collect from our patients may contain infectious agents that may infect medical personnel or others with whom the blood comes in contact. Medical personnel administer Xcellerated T Cells to patients intravenously in an outpatient procedure. This procedure poses risks to the patient similar to those occurring with infusions of other frozen cell products, such as stem cells, including blood clots, infection and mild to severe allergic reactions.

It is possible that we or third parties may misidentify Xcellerated T Cells and deliver them to the wrong patient. If these misidentified Xcellerated T Cells are administered to the wrong patient, the patient could suffer irreversible injury or death.

The discovery of unforeseen side effects of Xcellerated T Cells could also lead to lawsuits against us. Regardless of merit or eventual outcome, product liability or other claims may, among other things, result in:

- injury to our reputation and decreased demand for Xcellerated T Cells;
- withdrawal of clinical trial volunteers;
- costs of related litigation; and
- substantial monetary awards to plaintiffs.

We currently have clinical trial insurance that covers our clinical trials up to \$5.0 million per occurrence with a \$5.0 million aggregate limit, and we intend to obtain product liability coverage in the future. However, due to factors outside of our control, including the risks discussed above as well as conditions in the relevant insurance markets, we may not be able to renew or obtain such coverage on acceptable terms, if at all. Furthermore, even if we secure coverage, we may not be able to obtain policy limits adequate to satisfy any liability that may arise. If a successful product liability or other claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover these claims and our business operations could suffer.

IF XCELLERATED T CELLS OR COMPONENTS OF OUR XCELLERATE TECHNOLOGY ALONE OR IN COMBINATION WITH COMPLEMENTARY TREATMENTS CAUSE UNFORESEEN HARMFUL SIDE EFFECTS, PHYSICIANS MAY NOT USE OUR PRODUCTS AND/OR WE MAY INCUR SIGNIFICANT PRODUCT LIABILITY, WHICH WILL ADVERSELY AFFECT OUR ABILITY TO OPERATE OUR BUSINESS.

Xcellerated T Cells or components of our Xcellerate Technology may cause unforeseen harmful side effects. For example, a patient receiving Xcellerated T Cells could have a severe allergic reaction or could develop an autoimmune condition. While we employ procedures to substantially remove the antibodies and beads used to generate Xcellerated T Cells, it is possible that residual antibodies or beads may be infused into patients and cause harmful effects.

In addition, we have not conducted studies on the long-term effects associated with the different types of media that we use to grow and freeze cells as part of our Xcellerate Technology. These media contain substances that have proved harmful if used in certain quantities. While we believe that we use sufficiently small quantities of these substances, harmful effects may still arise from our use of these media. As we continue to develop our Xcellerate Technology, we may encounter harmful side effects that we did not previously observe in our prior studies and clinical trials.

We believe Xcellerated T Cells may be used in combination with complementary treatments, including cancer vaccines, monoclonal antibodies, genes, cytokines or chemotherapy, and one or more of these other therapies could cause harmful side effects that could be attributed to Xcellerated T Cells. Any or all of these harmful side effects may occur at various stages of our product development, including the research stage, the development stage, the clinical stage or the commercial stage of our products. If people believe Xcellerated T Cells or any component of our Xcellerate Technology alone or in combination with complementary treatments causes harmful side effects, we may incur significant damages from product liability claims, which will adversely affect our ability to operate our business.

WE RELY ON A LIMITED NUMBER OF MANUFACTURERS AND SUPPLIERS FOR SOME OF THE KEY COMPONENTS OF OUR XCELLERATE TECHNOLOGY. THE LOSS OF THESE SUPPLIERS, OR THEIR FAILURE TO PROVIDE US WITH ADEQUATE QUANTITIES OF THESE KEY COMPONENTS WHEN NEEDED, COULD DELAY OUR CLINICAL TRIALS AND PREVENT OR DELAY COMMERCIALIZATION OF XCELLERATED T CELLS.

We rely on third party suppliers for some of the key components used to manufacture Xcellerated T Cells. We rely on Lonza to develop and manufacture the antibodies that we use in our Xcellerate Technology. Either party may terminate our agreements with Lonza for breach or insolvency of the other party or if Lonza is unable to perform its obligations for scientific or technical reasons. Our current agreements with Lonza provide for manufacturing development and validation, and the creation and submission of materials required to obtain regulatory

approval of the antibody manufacturing process. We are using the antibodies supplied by Lonza under the agreements to manufacture the Xcellerated T Cells used in our clinical trials. We are currently negotiating an agreement with Lonza to manufacture the antibodies for commercial use. If we are unable to negotiate this contract with Lonza or are unable to procure a suitable alternative manufacturer in a timely manner and on favorable terms, if at all, we may incur significant costs and be unable to continue developing our Xcellerate Technology. We are aware of few companies with the ability to manufacture commercial-grade antibodies.

Our Xcellerate Technology also depends in part on the successful attachment of the antibodies to magnetic beads. We currently use magnetic beads developed and manufactured by Dynal in Oslo, Norway. Dynal has the right to terminate the agreement if we do not purchase a minimum quantity of beads. Either party may terminate the agreement as of August 2009 for any reason, or earlier for the material breach or insolvency of the other party. If the agreement is not terminated by August 2009, either party can elect to extend the term of the agreement for an additional 5 years. Otherwise, it will automatically renew on a year to year basis. We are contractually obligated to obtain our beads from Dynal unless Dynal is unable to fill our orders or certain other circumstances arise. If Dynal terminates our contract or if Dynal discontinues manufacturing our beads for any reason, we may be unable to find a suitable alternative manufacturer in a timely manner, or at all, which would delay our clinical trials and delay or prevent commercialization of Xcellerated T Cells.

Our manufacturing process currently uses a commercially available tissue culture media that is available from only one manufacturer, Cambrex Bio Science Walkersville, Inc. We currently have a supply agreement with Cambrex with a term of ten years. We may terminate the agreement after the initial term for any reason by providing at least six months' notice, and Cambrex may terminate the agreement after the initial term for any reason by providing at least twelve months' notice. Otherwise, it will automatically renew on a year to year basis. If Cambrex is unwilling or unable to supply us with this media, we would need to use an alternative tissue culture media, which may delay our clinical trials and harm our business.

In addition, we currently use a custom bioreactor to manufacture Xcellerated T Cells that is available from only one manufacturer, Wave Biotech LLC. There are a limited number of manufacturers that are capable of manufacturing custom bioreactors. If Wave Biotech is unwilling or unable to manufacture or supply us with custom bioreactors, we may be unable to find a suitable alternative in a timely manner, or at all, which would delay our clinical trials and delay or prevent commercialization of Xcellerated T Cells. We do not have agreements with Wave Biotech which obligate them to provide us with custom bioreactors.

We have qualified and validated commercially available disposable bags and tubing sets in our manufacturing process from only one manufacturer, Baxter International, Inc. If Baxter is unwilling or unable to supply us with the disposables, we would need to find an alternative manufacturer and qualify and validate alternative disposables, which may delay our clinical trials and harm our business. We do not have agreements with Baxter which obligate them to provide us with any products for future clinical trials or future commercial sales.

Although these and other suppliers have produced our components with acceptable quality, quantity and cost in the past, they may be unable or unwilling to timely meet our future demands. They may also increase the prices they charge us. Obtaining similar components from other suppliers and validating these components may be difficult and expensive. If we have to switch to a replacement supplier, we could face additional regulatory delays, which could interrupt the manufacture and delivery of our product for an extended period. In addition, because Lonza and Dynal are located outside the United States, we are subject to foreign import laws and customs regulations, which complicate, and could delay, shipment of components to us and delay the development and production of Xcellerated T Cells. Any delay in the development or production of Xcellerated T Cells may impact our ability to generate revenue and cause our stock price to decline.

IF WE OR ANY OF OUR THIRD-PARTY MANUFACTURERS DO NOT MAINTAIN HIGH STANDARDS OF MANUFACTURING, OUR ABILITY TO DEVELOP AND COMMERCIALIZE XCELLERATED T CELLS COULD BE DELAYED OR CURTAILED.

We and any third parties that we may use in the future to manufacture our products must continuously adhere to cGMP regulations enforced by the FDA through its facilities inspection program. If our facilities or the facilities of these third parties do not pass a pre-approval plant inspection, the FDA will not grant market approval for Xcellerated T Cells. In complying with cGMP, we and any third-party manufacturers must expend significant time, money and effort in production, record-keeping and quality control to assure that each component of our Xcellerate Technology meets applicable specifications and other requirements. We or any of these third-party manufacturers may also be subject to comparable or more stringent regulations of foreign regulatory authorities. If we or any of our third-party manufacturers fail to comply with these requirements, we may be subject to regulatory action, which could delay or curtail our ability to develop and commercialize Xcellerated T Cells. If our component part manufacturers and suppliers fail to provide components of sufficient quality, our clinical trials or commercialization of Xcellerated T Cells could be delayed or halted and we could face product liability claims.

IF OUR PRINCIPAL STOCKHOLDERS, EXECUTIVE OFFICERS AND DIRECTORS CHOOSE TO ACT TOGETHER, THEY MAY BE ABLE TO CONTROL OUR MANAGEMENT AND OPERATIONS, ACTING IN THEIR BEST INTERESTS AND NOT NECESSARILY THOSE OF OTHER STOCKHOLDERS.

Our executive officers, directors and principal stockholders, and entities affiliated with them, beneficially own in the aggregate approximately 61% of our common stock, and approximately 53% of our common and convertible preferred stock taken together on an

as-converted to common stock basis. This significant concentration of share ownership may adversely affect the trading price of our common stock because investors often perceive disadvantages in owning stock in companies with controlling stockholders. These stockholders, acting together, have the ability to exert substantial influence over all matters requiring approval by our stockholders, including the election and removal of directors and any proposed merger, consolidation or sale of all or substantially all of our assets. In addition, they could dictate the management of our business and affairs. This concentration of ownership could have the effect of delaying, deferring or preventing a change in control of us or impeding a merger, consolidation, takeover or other business combination that could be favorable to you. Since the convertible preferred stock has very limited voting rights prior to conversion, owners of our convertible preferred stock will have little or no ability to control matters requiring approval of our stockholders.

OUR LEASED FACILITIES ARE AT RISK OF DAMAGE BY EARTHQUAKES, AND ANY DAMAGE TO OUR FACILITIES WILL HARM OUR CLINICAL TRIALS AND DEVELOPMENT PROGRAMS.

We currently rely on the availability and condition of our leased Seattle, Washington facility to conduct research and development and until March 31, 2005 for the manufacture of Xcellerated T Cells. This facility is located in a seismic zone, and there is the possibility of an earthquake which, depending on its magnitude, could be disruptive to our operations. Our leased facility in Bothell, Washington, where we are now locating our manufacturing activities, is also in a seismic area. We currently have no insurance against damage caused by earthquakes.

IF THIRD PARTY CARRIERS FAIL TO SHIP PATIENT SAMPLES AND OUR PRODUCTS IN A PROPER AND TIMELY MANNER, THE TREATMENT OF PATIENTS COULD BE DELAYED OR PREVENTED, OUR REPUTATION MAY SUFFER AND WE MAY INCUR LIABILITY.

We depend on third-party carriers to deliver patient-specific blood cells to us and to deliver Xcellerated T Cells back to patients in a careful and timely manner. Our Xcellerate Technology currently requires that we process each patient's leukapheresis blood sample within 48 hours of collection. Xcellerated T Cells must currently be shipped in a frozen storage shipping container and received by the patient within six days from leaving our manufacturing facility. If the shipping containers fail to maintain the necessary temperature, Xcellerated T Cells could be damaged. If third-party carriers fail to timely deliver the leukapheresis blood sample to us or fail to timely ship Xcellerated T Cells to the clinic, or if they damage or contaminate them during shipment, the treatment of patients could be delayed or discontinued, our reputation may suffer and we may incur liability. In addition, as we expand our clinical trial sites, we may need to make modifications to the shipping process to ship internationally, such as requiring third parties to freeze the patient's white blood cells prior to shipment to us for processing, which may reduce our control over the production of Xcellerated T Cells. Furthermore, shipping blood products internationally will subject us to foreign import laws and customs regulations, which complicate, and could delay, shipment of components to and from us and delay the development, production and infusion of Xcellerated T Cells.

WE USE HAZARDOUS MATERIALS AND MUST COMPLY WITH ENVIRONMENTAL, HEALTH AND SAFETY LAWS AND REGULATIONS, WHICH CAN BE EXPENSIVE AND RESTRICT HOW WE DO BUSINESS.

Our research and development and manufacturing processes involve the controlled storage, use and disposal of hazardous materials, including biological hazardous materials. We are subject to federal, state and local regulations governing the use, manufacture, storage, handling and disposal of materials and waste products. Although we believe that our safety procedures for handling and disposing of these hazardous materials comply with the standards prescribed by law and regulation, we cannot completely eliminate the risk of accidental contamination or injury from hazardous materials. In the event of an accident, we could be held liable for any damages that result, and any liability could exceed the limits or fall outside the coverage of our insurance. We may not be able to obtain insurance on acceptable terms, if at all. We could incur significant costs to comply with current or future environmental laws and regulations.

Our current commercial property insurance provides coverage up to \$25,000 for pollution clean-up or removal and up to \$25,000 for biological agency clean-up or removal. Additionally our business income coverage provides for up to \$250,000 for extra expenses for pollution clean-up or removal to enable us to re-establish operations after a hazardous event.

IN SOME CIRCUMSTANCES WE PLAN TO RELY ON COLLABORATORS TO COMMERCIALIZE XCELLERATED T CELLS. IF OUR CURRENT COLLABORATORS DO NOT PERFORM AS EXPECTED OR IF FUTURE COLLABORATORS DO NOT COMMIT ADEQUATE RESOURCES TO THEIR COLLABORATION WITH US, OUR PRODUCT DEVELOPMENT AND POTENTIAL FOR PROFITABILITY MAY SUFFER.

We have entered into alliances with third-party collaborators to develop and market Xcellerated T Cells for diseases and markets that we are not pursuing on our own. In addition, our strategy includes substantial reliance on additional strategic collaborations for research, development, manufacturing, marketing and other commercialization activities relating to Xcellerated T Cells. If our collaborators do not prioritize and commit substantial resources to these collaborations, or if we are unable to secure successful future collaborations, we may be unable to commercialize Xcellerated T Cells for important diseases and in important markets, which would limit our ability to generate revenue and become profitable. Furthermore, disputes may arise between us and our existing or future collaborators, which could result in delays in the development and commercialization of Xcellerated T Cells.

For example, we have licensed our Xcellerate Technology and some related improvements, on an exclusive basis in the field of HIV retroviral gene therapy to Fresenius, for research, development and commercialization in Europe, with a right of first negotiation under some circumstances to expand their territory to include North America. Our agreement with Fresenius requires us to license our Xcellerate Technology, including methods for manufacturing Xcellerated T Cells, to Fresenius. This agreement also requires us to supply all proprietary magnetic beads, or Xcyte Dynabeads, used to manufacture Xcellerated T Cells ordered by Fresenius to support its development and commercialization efforts. If we do not supply the Xcyte Dynabeads, Fresenius has the right to manufacture such Xcyte Dynabeads on its own or through a third party, until such time that we are able to supply the quantity of Xcyte Dynabeads ordered by Fresenius. The agreement terminates upon the last to expire of the licensed patents and is subject to earlier termination by Fresenius at any time if Fresenius determines it cannot develop a commercially viable product or complete a required manufacturing audit. The agreement may be terminated by Xcyte if Fresenius does not meet certain development and commercialization milestones and by either party for the material breach or insolvency of the other party. At Fresenius' expense, we are required to expend significant resources to transfer technology to Fresenius and assist them in developing and manufacturing products using our Xcellerate Technology. Even so, Fresenius may not have sufficient resources to fund, or may decide not to proceed with, development of our Xcellerate Technology. In this event, we may terminate the Fresenius agreement, but we may not have sufficient capital resources to develop the use of Xcellerate Technology in the field of HIV retroviral gene therapy in Europe or North America on our own.

WE MAY BE UNABLE TO ESTABLISH SALES, MARKETING AND DISTRIBUTION CAPABILITIES NECESSARY TO SUCCESSFULLY COMMERCIALIZE OUR PRODUCTS.

We currently have only limited marketing capabilities and no direct or third-party sales or distribution capabilities. We currently plan to develop an internal sales force to serve certain North American markets and pursue strategic partnerships to obtain development and marketing support for territories outside North America. However, we may be unable to establish marketing, sales and distribution capabilities necessary to commercialize and gain market acceptance for our potential products. In addition, developing a sales force, or entering into co-promotion agreements with third parties, is expensive and time-consuming and could delay any product launch. Co-promotion or other marketing arrangements with third parties to commercialize potential products may also not be successful and could significantly limit the revenues we derive from Xcellerated T Cells.

WE FACE COMPETITION IN OUR INDUSTRY, AND MANY OF OUR COMPETITORS HAVE SUBSTANTIALLY GREATER EXPERIENCE AND RESOURCES THAN WE HAVE.

Even if our Xcellerate Technology proves successful, we might not be able to remain competitive because of the rapid pace of technological development in the biotechnology field. We are currently aware of several companies developing *ex vivo* cell-based immunotherapy products as a method of treating cancer and infectious diseases. These competitors include Antigenics, Inc., CancerVax Corporation, Cell Genesys, Inc., CellExSys, Inc. (recently sold to Chromos Molecular Systems, Inc.), Dendreon Corporation, Faville, Inc., Genitope Corporation, IDM, S.A., Kirin Pharmaceutical and Therion Biologics Corporation. Many of our competitors have greater financial and other resources, larger research and development staffs and more experienced capabilities in researching, developing and testing products than we do. Many of these companies also have more experience in conducting clinical trials, obtaining FDA and other regulatory approvals and manufacturing, marketing and distributing therapeutic products. Smaller companies may successfully compete with us by establishing collaborative relationships with larger pharmaceutical companies or academic institutions. In addition, large pharmaceutical companies or other companies with greater resources or experience than us may choose to forgo *ex vivo* cell-based immunotherapy opportunities that would have otherwise been complementary to our product development and collaboration plans. Our competitors may succeed in developing, obtaining patent protection for or commercializing their products more rapidly than us. A competing company developing, or acquiring rights to, a more effective therapeutic product for the same diseases targeted by us, or one that offers significantly lower costs of treatment, could render our products noncompetitive or obsolete.

IN THE FUTURE, WE WILL NEED TO GROW SIGNIFICANTLY IF WE ARE GOING TO EXPAND OUR RESEARCH AND CLINICAL ACTIVITIES, AND WE MAY BE UNABLE TO MANAGE THAT GROWTH OR HIRE QUALIFIED NEW PERSONNEL.

We will need to add a significant number of new personnel and expand our capabilities in order to successfully pursue our research, development and commercialization efforts and secure collaborations to market and distribute our products. This growth may strain our existing managerial, operational, financial and other resources. We will also need to add personnel in our research and development and manufacturing departments if we expand our clinical trial and research capabilities. On March 22, 2005, we reduced our workforce by approximately 24%, to 81 employees. This reduction in workforce may have an adverse effect on our ability to hire new personnel in the future when we need it to expand our capabilities. Our failure to manage this recent reduction in workforce effectively, or to effectively manage our growth in the future if we need to expand our operations again, could delay or curtail our product development and commercialization efforts and harm our business.

IF WE LOSE KEY MANAGEMENT OR SCIENTIFIC PERSONNEL, OUR BUSINESS COULD SUFFER.

Our success depends, to a significant extent, on the efforts and abilities of Ronald J. Berenson, M.D., our President and Chief Executive Officer, Robert L. Kirkman, M.D., our Chief Business Officer and Vice President, Stewart Craig, Ph.D., our Chief Operating Officer and Vice President, Mark Frohlich, M.D., our Medical Director and Vice President, and other members of our senior management and our scientific personnel. We do not have employment agreements with Dr. Berenson, Dr. Craig or several other members of our senior management. Additionally, any employment agreement that we may enter into will not ensure the retention of the employee. Since the pool of employees with relevant experience in immunology and biotechnology is small, replacing any of our senior management or scientific personnel would likely be costly and time-consuming. Our recent workforce reductions and the size of our company could make it more difficult to hire new or additional senior management or scientific personnel. Although we maintain key person life insurance on Dr. Berenson, we do not maintain key person life insurance on any of our other officers, employees or consultants. The loss of the services of one or more of our key employees could delay or curtail our research and development and product development efforts.

WE MAY UNDERTAKE ACQUISITIONS IN THE FUTURE, AND ANY DIFFICULTIES FROM INTEGRATING THESE ACQUISITIONS COULD DAMAGE OUR ABILITY TO ATTAIN OR MAINTAIN PROFITABILITY.

We may acquire additional businesses, products or product candidates that complement or augment our existing business. Integrating any newly acquired business or product could be expensive and time-consuming. We may not be able to integrate any acquired business or product successfully or operate any acquired business profitably. Moreover, we may need to raise additional funds through public or private debt or equity financing to make acquisitions, which may result in dilution to stockholders and the incurrence of indebtedness that may include restrictive covenants.

CHANGES IN THE VALUE OF THE BRITISH POUND AND EURO RELATIVE TO THE US DOLLAR MAY ADVERSELY AFFECT US.

We do not engage in foreign currency hedging; however, we have entered into certain contracts denominated in foreign currencies and therefore we are exposed to currency exchange risks.

Under our agreements with Lonza to purchase antibodies, we must make payments denominated in British pounds. As a result, from time to time, we are exposed to currency exchange risks related to the British pound. Accordingly, if the British pound strengthens against the U.S. dollar, our payments to Lonza will increase in U.S. dollar terms. We have paid a total of \$5.0 million to Lonza under our agreements with them as of December 31, 2004. Assuming development and supply services are completed as scheduled under our agreements with Lonza, our remaining payments will be approximately \$1.7 million through the end of 2005.

The terms of our license agreement with Fresenius include potential royalties on net sales as well as potential milestone payments to us denominated in Euro. As a result, we are exposed to currency exchange risks related to the Euro. If the Euro weakens against the U.S. dollar, payments received from Fresenius will decrease in U.S. dollar terms.

IF WE DO NOT ACHIEVE OUR PROJECTED DEVELOPMENT GOALS IN THE TIME FRAMES WE ANNOUNCE AND EXPECT, THE COMMERCIALIZATION OF OUR PRODUCTS MAY BE DELAYED AND, AS A RESULT, OUR STOCK PRICE MAY DECLINE.

From time to time, we estimate the timing of the accomplishment of various scientific, clinical, regulatory and other product development goals, which we sometimes refer to as milestones. These milestones may include the commencement or completion of scientific studies and clinical trials and the submission of regulatory filings. From time to time, we may publicly announce the expected timing of some of these milestones. All of these milestones will be based on a variety of assumptions. The actual timing of these milestones can vary dramatically compared to our estimates, in some cases for reasons beyond our control. If we do not meet these milestones as publicly announced, the commercialization of our products may be delayed and, as a result, our stock price may decline.

IF THE USE OF OUR TECHNOLOGIES CONFLICTS WITH THE RIGHTS OF OTHERS, WE COULD BE SUBJECT TO EXPENSIVE LITIGATION OR BE REQUIRED TO OBTAIN LICENSES FROM OTHERS TO DEVELOP OR MARKET XCELLERATED T CELLS.

Our competitors or others may have or acquire patent rights that they could enforce against us. If they do so, we may be required to alter our Xcellerate Technology, pay licensing fees or cease activities. If our Xcellerate Technology conflicts with patent rights of others, third parties could bring legal action against us or our licensees, suppliers, customers or potential collaborators, claiming damages and seeking to enjoin manufacturing and marketing of the affected products. If these legal actions are successful, in addition to any potential liability for damages, we might have to obtain a license in order to continue to manufacture or market the affected products. A required license under the related patent may not be available on acceptable terms, if at all.

We may be unaware that the use of our technology conflicts with pending or issued patents. Because patent applications can take many years to issue, there may be currently pending applications, unknown to us, that may later result in issued patents upon which our Xcellerate Technology or Xcellerated T Cells may infringe. There could also be existing patents of which we are unaware upon which our Xcellerate

Technology or Xcellerated T Cells may infringe. In addition, if third parties file patent applications or obtain patents claiming technology also claimed by us in pending applications, we may have to participate in interference proceedings in the U.S. Patent and Trademark Office to determine priority of invention. If third parties file oppositions in foreign countries, we may also have to participate in opposition proceedings in foreign tribunals to defend the patentability of the filed foreign patent applications. We may have to participate in interference proceedings involving our issued patents or our pending applications.

If a third party claims that we infringe upon its proprietary rights, any of the following may occur:

- we may become involved in time-consuming and expensive litigation, even if the claim is without merit;
- we may become liable for substantial damages for past infringement if a court decides that our technology infringes upon a competitor's patent;
- a court may prohibit us from selling or licensing our product without a license from the patent holder, which may not be available on commercially acceptable terms, if at all, or which may require us to pay substantial royalties or grant cross licenses to our patents; and
- we may have to redesign our technology or clinical candidate so that it does not infringe upon others' patent rights, which may not be possible or could require substantial funds or time.

If any of these events occurs, our business will suffer and the market price of our common stock will likely decline.

OUR RIGHTS TO USE ANTIBODIES AND TECHNOLOGIES LICENSED TO US BY THIRD PARTIES ARE NOT WITHIN OUR CONTROL, AND WE MAY NOT BE ABLE TO IMPLEMENT OUR XCELLERATE TECHNOLOGY WITHOUT THESE ANTIBODIES AND TECHNOLOGIES.

We have licensed patents and other rights which are necessary to our Xcellerate Technology and Xcellerated T Cells. Our business will significantly suffer if these licenses terminate, if the licensors fail to abide by the terms of the license or fail to prevent infringement by third parties or if the licensed patents or other rights are found to be invalid.

Our Xcellerate Technology uses two monoclonal antibodies that we license from third parties. We rely on our non-exclusive license from the Fred Hutchinson Cancer Research Center in Seattle, Washington to use the monoclonal antibody that binds to the CD3 molecule and our exclusive license from Diaclone S.A., or Diaclone, in Besancon, France to use the monoclonal antibody that binds to the CD28 molecule. These antibodies are necessary components of our Xcellerate Technology. Our rights to use these antibodies depend on the licensors abiding by the terms of those licenses and not terminating them. Our license agreement with the Fred Hutchinson Research Center is effective for 15 years following the first commercial sale of a product based on the license and may be terminated earlier by either party for material breach. Our license agreement with Diaclone is effective for 15 years from the date of the first FDA approval, or its foreign equivalent, of a therapeutic product containing a bead coated with the licensed antibody and may be terminated earlier by either party for material breach. With regard to our agreement with Diaclone, at the end of the relevant 15-year period, we will have a perpetual, irrevocable, fully-paid royalty-free, exclusive license. Except for certain circumstances which would permit us to obtain the monoclonal antibody from third parties or manufacture it ourselves, our agreement with Diaclone obligates us to purchase the monoclonal antibody from them until we begin preparing for Phase III clinical trials of a product covered by this license.

In addition, we have in-licensed several T cell activation patents and patent applications from the Genetics Institute, a subsidiary of Wyeth, Inc. The technology underlying these patents is a critical part of our Xcellerate Technology. Under our agreement, we have the right to enforce the licensed patents. The license from Genetics Institute terminates upon the end of the enforceable term of the last licensed patent or the license agreements under which Genetics Institute has sublicensed rights to XcYTE, and may also be terminated earlier by either party for material breach. Of the five in-licensed U.S. patents presently issued related to this technology, two patents expire in 2016, two others expire in 2019, and the remaining patent expires in 2020.

If we violate the terms of our licenses, or otherwise lose our rights to these antibodies, patents or patent applications, we may be unable to continue development of our Xcellerate Technology. Our licensors or others may dispute the scope of our rights under any of these licenses. Additionally, the licensors under these licenses might breach the terms of their respective agreements or fail to assist in the prevention of infringement of the licensed patents by third parties. Loss of any of these licenses for any reason could materially harm our financial condition and operating results.

WE WILL SOON BE REQUIRED TO COMPLY WITH SECTION 404 OF THE SARBANES-OXLEY ACT OF 2002 REGARDING INTERNAL CONTROL ATTESTATION AND ANY INABILITY TO DO SO MAY NEGATIVELY IMPACT THE REPORT ON OUR FINANCIAL STATEMENTS.

We are in the process of implementing the requirements of Section 404 of the Sarbanes-Oxley Act of 2002 which requires our management to assess the effectiveness of our internal controls over financial reporting and include an assertion in our annual report as to the effectiveness of our controls beginning on either December 31, 2005 or December 31, 2006, depending on the value of our common stock as of June 30, 2005. Subsequently, our independent auditors will be required to attest to whether our assessment of the effectiveness of

our internal control over financial reporting is fairly stated in all material respects and separately report on whether it believes we maintained, in all material respects, effective internal control over financial reporting as of December 31, 2005 or December 31, 2006, as applicable. We are beginning our assessment of the effectiveness of our internal controls. We expect to comply with the reporting disclosure requirements of Section 404 by our year ending December 31, 2005 or December 31, 2006, as applicable, including remediation of any deficiencies identified in our existing internal controls. However, if we are not able to remediate any identified deficiencies in a timely fashion or otherwise comply with the Section 404 disclosure requirements for the year ending December 31, 2005 or December 31, 2006, as applicable, we will not be able to give assurance regarding the effectiveness of our internal controls and the report on our financial statements provided by our independent auditors may be negatively impacted.

LEGISLATIVE ACTIONS, POTENTIAL NEW ACCOUNTING PRONOUNCEMENTS AND HIGHER INSURANCE COSTS ARE LIKELY TO IMPACT OUR FUTURE FINANCIAL POSITION OR RESULTS OF OPERATIONS.

Future changes in financial accounting standards may cause adverse, unexpected revenue fluctuations and affect our financial position or results of operations. New pronouncements and varying interpretations of pronouncements have occurred with frequency in the past and may occur again in the future and as a result we may be required to make changes in our accounting policies. Compliance with new regulations regarding corporate governance and public disclosure may result in additional expenses. Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, new SEC regulations and Nasdaq National Market rules, are creating uncertainty for companies such as ours and insurance costs are increasing as a result of this uncertainty and other factors. As a result, we intend to invest all reasonably necessary resources to comply with evolving standards, and this investment may result in increased general and administrative expenses and a diversion of management time and attention from science and business activities to compliance activities. For example, we will incur substantial costs and expend significant resources to comply with the new regulations promulgated under Section 404 of the Sarbanes-Oxley Act of 2002.

OUR COMMON AND CONVERTIBLE PREFERRED STOCK MAY EXPERIENCE EXTREME PRICE AND VOLUME FLUCTUATIONS, WHICH COULD LEAD TO COSTLY LITIGATION FOR US AND MAKE AN INVESTMENT IN US LESS APPEALING.

The market price of our common and convertible preferred stock may fluctuate substantially due to a variety of factors, including:

- results of our clinical trials;
- announcements of technological innovations or new products or services by us or our competitors;
- media reports and publications about immunotherapy;
- announcements concerning our competitors or the biotechnology industry in general;
- new regulatory pronouncements and changes in regulatory guidelines;
- general and industry-specific economic conditions;
- additions to or departures of our key personnel;
- changes in financial estimates or recommendations by securities analysts;
- variations in our quarterly results;
- announcements about our collaborators or licensors; and
- changes in accounting principles.

The market prices of the securities of biotechnology companies, particularly companies like ours without consistent product revenues and earnings, have been highly volatile and are likely to remain highly volatile in the future. This volatility has often been unrelated to the operating performance of particular companies. In the past, companies that experience volatility in the market price of their securities have often faced securities class action litigation. Moreover, market prices for stocks of biotechnology-related and technology companies frequently reach levels that bear no relationship to the operating performance of these companies. These market prices generally are not sustainable and are highly volatile. Whether or not meritorious, litigation brought against us could result in substantial costs, divert our management's attention and resources and harm our financial condition and results of operations.

OUR AMENDED AND RESTATED CERTIFICATE OF INCORPORATION AND BYLAWS MAY DELAY OR PREVENT A CHANGE IN OUR MANAGEMENT.

Our amended and restated certificate of incorporation and bylaws contain provisions that could delay or prevent a change in our board of directors and management teams. Some of these provisions:

- authorize the issuance of preferred stock that can be created and issued by the board of directors without prior stockholder approval, commonly referred to as "blank check" preferred stock, with rights senior to those of our common stock; and
- provide for a classified board of directors.

These provisions could make it more difficult for our stockholders to replace members of our board of directors. Because our board of directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt to replace our current management team.

WE MAY BE UNABLE TO MAINTAIN OUR LISTING ON NASDAQ, WHICH COULD CAUSE OUR STOCK PRICE TO FALL AND DECREASE THE LIQUIDITY OF OUR STOCK.

Our common stock and preferred stock trades on the Nasdaq National Market, which has certain compliance requirements for continued listing, including a requirement that our common stock and preferred stock each have a minimum bid price of \$1.00 per share. If the minimum closing bid price per share is less than \$1.00 for a period of 30 consecutive business days, our shares may be delisted following a 180 day notice period during which the minimum closing bid price must be \$1.00 or above per share for a period of 10 consecutive business days, if we do not file an appeal. Although the bid price per share of our common stock and preferred stock has never fallen below Nasdaq's minimum bid price of \$1.00 per share, the bid price per share of our common stock was \$1.40 as of March 21, 2005, and has declined to that point over the past year and may continue to decline.

If our shares are delisted and any appeal we might file receives an unfavorable determination by Nasdaq, our common stock or preferred stock, as applicable, would be removed from listing on the Nasdaq National Market, and we would seek to have the applicable shares listed for trading on the Nasdaq SmallCap Market. We cannot assure you that we would be able to obtain listing for our shares on the Nasdaq SmallCap Market or that we will be able on an ongoing basis to meet the maintenance requirements thereof. If our common stock is delisted, our preferred stock would also be delisted unless the preferred stock meets the minimum listing requirements applicable to our common stock.

If our shares were to be delisted from trading on the Nasdaq National Market, in order to obtain relisting on the Nasdaq National Market, we would need to satisfy certain quantitative designation criteria which we may not meet.

If our shares were to be delisted from trading on the Nasdaq National Market and were neither relisted thereon nor listed for trading on the Nasdaq SmallCap Market, trading, if any, in our shares may continue to be conducted on the OTC Bulletin Board or in a non-Nasdaq over-the-counter market, such as the "pink sheets." Delisting of our shares would result in limited release of the market price of those shares and limited analyst coverage and could restrict investors' interest in our securities. Also, a delisting could materially adversely affect the trading market and prices for our shares and our ability to issue additional securities or to secure additional financing. In addition, if our shares were not listed and the trading price of our shares was less than \$5 per share, our shares could be subject to Rule 15c-2 under the Securities Exchange Act of 1934 which, among other things, requires that broker/dealers satisfy special sales practice requirements, including making individualized written suitability determinations and receiving a purchaser's written consent prior to any transaction. In such case, our securities could also be deemed to be a "penny stock" under the Securities Enforcement and Penny Stock Reform Act of 1990, which would require additional disclosure in connection with trades in those shares, including the delivery of a disclosure schedule explaining the nature and risks of the penny stock market. Such requirements could severely limit the liquidity of our securities.

WE MAY HAVE LIMITED ABILITY TO PAY CASH DIVIDENDS ON THE CONVERTIBLE PREFERRED STOCK.

Delaware law may limit our ability to pay cash dividends on the convertible preferred stock. Under Delaware law, cash dividends on our capital stock may only be paid from "surplus" or, if there is no "surplus," from the corporation's net profits for the current or preceding fiscal year. Delaware law defines "surplus" as the amount by which the total assets of a corporation, after subtracting its total liabilities, exceed the corporation's capital, as determined by its board of directors. Since we are not profitable, our ability to pay cash dividends will require the availability of adequate surplus. Even if adequate surplus is available to pay cash dividends on the convertible preferred stock, we may not have sufficient cash to pay dividends on the convertible preferred stock. We currently intend to pay cash dividends on the convertible preferred stock.

THE FUTURE SALE OF OUR COMMON AND CONVERTIBLE PREFERRED STOCK, AND FUTURE ISSUANCES OF OUR COMMON STOCK UPON PAYMENT OF MAKE-WHOLE DIVIDENDS, IF ANY, COULD NEGATIVELY AFFECT OUR STOCK PRICE.

If our common or convertible preferred stockholders sell substantial amounts of our stock in the public market, or the market perceives that such sales may occur, the market price of our common and convertible preferred stock could fall. In addition, if we exercise our right to pay

make-whole dividends in common stock rather than in cash upon conversion of our convertible preferred stock to common stock, then the sale of such shares of common stock or the perception that such sales may occur could cause the market price of our common stock to fall. In addition, the issuance of common stock to convertible preferred stockholders upon conversion of the convertible preferred stock will cause immediate and possibly substantial dilution to the common stockholders. After our convertible preferred stock offering, according to the terms of our investors rights agreement, the holders of approximately 9.0 million shares of our common stock and warrants had rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. Furthermore, if we were to include in a company-initiated registration statement shares held by those holders pursuant to the exercise of their registration rights, those sales could impair our ability to raise needed capital by depressing the price at which we could sell our common stock.

In addition, we will need to raise substantial additional capital in the future to fund our operations. If we raise additional funds by issuing equity securities, our stock price may decline and our existing stockholders may experience significant dilution.

ANTI-TAKEOVER PROVISIONS COULD MAKE IT MORE DIFFICULT FOR A THIRD PARTY TO ACQUIRE US.

Our Board of Directors has the authority to issue up to 2,010,000 shares of preferred stock and to determine the price, rights, preferences, privileges and restrictions, including voting rights, of those shares without any further vote or action by the stockholders. The rights of the holders of common stock may be subject to, and may be adversely affected by, the rights of the holders of any preferred stock that may be issued in the future. The issuance of preferred stock may have the effect of delaying, deferring or preventing a change of control of Xcyte Therapies without further action by the stockholders and may adversely affect the voting and other rights of the holders of common stock. Further, certain provisions of our charter documents, including provisions eliminating the ability of stockholders to take action by written consent and limiting the ability of stockholders to raise matters at a meeting of stockholders without giving advance notice, may have the effect of delaying or preventing changes in control or management of Xcyte Therapies, which could have an adverse effect on the market price of our stock. In addition, our charter documents provide for a classified board, which may make it more difficult for a third party to gain control of our Board of Directors. Similarly, state anti-takeover laws in Washington related to corporate takeovers may prevent or delay a change of control of Xcyte Therapies.

IF WE EXCHANGE THE CONVERTIBLE PREFERRED STOCK FOR DEBENTURES, THE EXCHANGE WILL BE TAXABLE BUT WE WILL NOT PROVIDE ANY CASH TO PAY ANY TAX LIABILITY THAT ANY CONVERTIBLE PREFERRED STOCKHOLDER MAY INCUR.

An exchange of convertible preferred stock for debentures, as well as any dividend make-whole or interest make-whole payments paid in our common stock, will be taxable events for U.S. federal income tax purposes, which may result in tax liability for the holder of convertible preferred stock without any corresponding receipt of cash by the holder. In addition, the debentures may be treated as having original issue discount, a portion of which would generally be required to be included in the holder's gross income even though the cash to which such income is attributable would not be received until maturity or redemption of the debenture. We will not distribute any cash to you to pay these potential tax liabilities.

IF WE AUTOMATICALLY CONVERT THE CONVERTIBLE PREFERRED STOCK, THERE IS A SUBSTANTIAL RISK OF FLUCTUATION IN THE PRICE OF OUR COMMON STOCK FROM THE DATE WE ELECT TO AUTOMATICALLY CONVERT TO THE CONVERSION DATE.

We may elect to automatically convert the convertible preferred stock on or prior to maturity if our common stock price has exceeded 150% of the conversion price for at least 20 trading days during a 30-day trading period ending within five trading days prior to the notice of automatic conversion. You should be aware that there is a risk of fluctuation in the price of our common stock between the time when we may first elect to automatically convert the preferred and the automatic conversion date.

WE DO NOT INTEND TO PAY CASH DIVIDENDS ON OUR COMMON STOCK IN THE FORESEEABLE FUTURE.

We do not anticipate paying cash dividends on our common stock in the foreseeable future. Any payment of cash dividends will depend on our financial condition, results of operations, capital requirements and other factors and will be at the discretion of our board of directors. Accordingly, investors will have to rely on capital appreciation, if any, to earn a return on their investment in our common stock. Furthermore, we may in the future become subject to contractual restrictions on, or prohibitions against, the payment of dividends.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

Our short-term investments as of December 31, 2004 consisted of \$17.3 million in corporate bonds, \$14.1 million in federal agency obligations, and \$2.0 million in municipal bonds with contractual maturities of one year or less. Due to the short-term nature of our investments, we believe that our exposure to market interest rate fluctuations is minimal. The corporate bonds in which we invest are rated "A" or better

by both Moody's and Standard and Poor's. Our cash and cash equivalents are held primarily in commercial paper and highly liquid money market accounts. A hypothetical 10% change in short-term interest rates from those in effect at December 31, 2004 would not have a significant impact on our financial position or our expected results of operations. We do not currently hold any derivative financial instruments.

Because interest rates on our equipment financing obligations are fixed at the beginning of the repayment term, exposure to changes in interest rates is limited to new financings.

Foreign Currency Risk

We do not engage in foreign currency hedging; however, we have entered into certain contracts denominated in foreign currencies and therefore, we are subject to currency exchange risks.

For antibody development and supply services provided by Lonza, we must make payments denominated in British pounds. As a result, from time to time, we are exposed to currency exchange risks related to the British pound. If the British pound strengthens against the U.S. dollar, our payments to Lonza will increase in U.S. dollar terms. Assuming development and supply services are completed as scheduled under our agreements with Lonza, our remaining payments will be approximately \$1.7 million through the end of 2005. A hypothetical 10% change in the British pound from the rate in effect at December 31, 2004 would not have a significant impact on our financial position or our expected results of operations.

The terms of our license agreement with Fresenius include the receipt of potential royalties on net sales as well as potential milestone payments to us denominated in Euro. As a result, we are exposed to currency exchange risks related to the Euro. If the Euro weakens against the U.S. dollar, payments received from Fresenius will decrease in U.S. dollar terms. A hypothetical 10% change in the Euro from the rate in effect at December 31, 2004 would not have a significant impact on our financial position or our expected results of operations.

Derivatives Valuation Risk

The terms of our November 2004 convertible preferred stock offering include a dividend make-whole payment feature. This feature is considered to be an embedded derivative and was valued on the balance sheet at \$4.0 million on October 29, 2004 (the commitment date). The carrying value of this derivative was reduced by \$1.7 million, during the period from November 3, 2004 through December 31, 2004, based on the fair value of common stock issued as dividend make-whole payments pursuant to voluntary holder conversions during this period. At December 31, 2004, the estimated fair value of the derivative liability was valued at \$3.0 million, resulting in the recognition of \$727,000 as other expense for the year ended December 31, 2004. As the fair value of this derivative may fluctuate significantly from period to period, the resulting change in valuation may have a significant impact on our results of operations.

[Table of Contents](#)

48 XCYTE THERAPIES, 2005
ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA
INDEX TO FINANCIAL STATEMENTS

PART II ITEM 8

	PAGE
Report of Independent Registered Public Accounting Firm	49
Balance Sheets	50
Statements of Operations	51
Statements of Changes in Stockholders' Equity (Deficit)	52
Statements of Cash Flows	54
Notes to Financial Statements	55

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors
Xcyte Therapies, Inc.

We have audited the accompanying balance sheets of Xcyte Therapies, Inc. (a development stage company) (the Company) as of December 31, 2003 and 2004, and the related statements of operations, stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2004 and for the period from inception (January 5, 1996) to December 31, 2004. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (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. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Xcyte Therapies, Inc. (a development stage company) at December 31, 2003 and 2004, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2004 and for the period from inception (January 5, 1996) to December 31, 2004, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

Seattle, Washington
March 30, 2005

XCYTE THERAPIES, INC.
(a development stage company)
BALANCE SHEETS

DECEMBER 31,	2003	2004
(in thousands, except share and per share data)		
Assets		
Current assets:		
Cash and cash equivalents	\$ 2,241	\$ 13,897
Short-term investments	11,299	33,421
Prepaid expenses and other current assets	519	1,021
Total current assets	14,059	48,339
Property and equipment, net	2,767	6,208
Deposits and other assets	1,672	1,056
Total assets	\$ 18,498	\$ 55,603
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	\$ 954	\$ 1,707
Accrued compensation and related benefits	405	665
Other accrued liabilities	856	417
Derivative liability	—	3,020
Current portion of deferred revenue	—	47
Convertible promissory notes	11,652	—
Current portion of equipment financings	845	1,556
Total current liabilities	14,712	7,412
Deferred revenue, less current portion	—	762
Equipment financings, less current portion	993	2,678
Other liabilities	562	631
Commitments and contingencies		
Redeemable convertible preferred stock, Issued and outstanding— 6,781,814 shares as of December 31, 2003; none as of December 31, 2004	64,604	—
Redeemable convertible preferred stock warrants	2,467	—
Stockholders' equity (deficit):		
Preferred stock, \$0.001 par value per share		
Authorized—42,000,000 shares as of December 31, 2003; 5,000,000 shares as of December 31, 2004		
Designated redeemable and convertible—41,909,976 shares as of December 31, 2003; none as of December 31, 2004		
Designated 6% convertible exchangeable—none as of December 31, 2003; 2,990,000 as of December 31, 2004		
Issued and outstanding—none as of December 31, 2003; 2,079,813 as of December 31, 2004 Aggregate preference in liquidation—\$20,999 at December 31, 2004	—	2
Common stock, par value \$0.001 per share		
Authorized—70,000,000 shares as of December 31, 2003; 100,000,000 shares as of December 31, 2004		
Issued and outstanding—1,546,624 and 19,498,256 shares as of December 31, 2003 and 2004, respectively	2	19
Additional paid-in capital	24,532	171,708
Deferred stock compensation	(2,774)	(1,417)
Accumulated other comprehensive loss	(5)	(9)
Deficit accumulated during the development stage	(86,595)	(126,183)
Total stockholders' equity (deficit)	(64,840)	44,120
Total liabilities and stockholders' equity (deficit)	\$ 18,498	\$ 55,603

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

XCYTE THERAPIES, INC.
(a development stage company)
STATEMENTS OF OPERATIONS

Year ended December 31,	2002	2003	2004	Period from inception (January 5, 1996) to December 31, 2004
(in thousands, except per share data)				
Revenue:				
License fee	\$ —	\$ —	\$ 35	\$ 135
Collaborative agreement	—	170	27	197
Government grant	—	—	—	144
Total revenue	—	170	62	476
Operating expenses:				
Research and development	14,663	13,685	19,698	86,523
General and administrative	4,979	4,322	6,876	28,327
Total operating expenses	19,642	18,007	26,574	114,850
Loss from operations	(19,642)	(17,837)	(26,512)	(114,374)
Other income (expense):				
Interest income	467	149	421	3,893
Interest expense	(267)	(768)	(12,770)	(14,780)
Change in valuation of derivative	—	—	(727)	(727)
Loss on sale of equipment	(11)	(1)	—	(195)
Other income (expense), net	189	(620)	(13,076)	(11,809)
Net loss	(19,453)	(18,457)	(39,588)	(126,183)
Accretion of preferred stock	(8,001)	—	(8,973)	(25,385)
Net loss applicable to common stockholders	\$ (27,454)	\$ (18,457)	\$ (48,561)	\$ (151,568)
Basic and diluted net loss per common share	\$ (19.34)	\$ (12.40)	\$ (3.90)	
Shares used in computation of basic and diluted net loss per common share	1,419,755	1,488,218	12,440,381	

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

XCYTE THERAPIES, INC.

(a development stage company)

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)

	PREFERRED STOCK		COMMON STOCK		ADDITIONAL PAID-IN CAPITAL	DEFERRED STOCK COMPENSATION	ACCUMULATED OTHER COMPREHENSIVE INCOME (LOSS)	DEFICIT ACCUMULATED DURING THE DEVELOPMENT STAGE	TOTAL
	Shares	Amount	Shares	Amount					
(in thousands, except share data)									
Common stock issued upon incorporation	—	\$ —	613,564	\$ 1	\$ 2	\$ —	\$ —	\$ —	\$ 3
Deferred stock-based compensation	—	—	—	—	7	(7)	—	—	—
Amortization of deferred compensation	—	—	—	—	—	2	—	—	2
Common stock issued August 1996 for technology license, valued at \$0.0055 per share	—	—	36,110	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	(551)	(551)
Balance at December 31, 1996	—	—	649,674	1	9	(5)	—	(551)	(546)
Common stock repurchases	—	—	(115,454)	—	(1)	—	—	—	(1)
Common stock issued August 1997 in acquisition, valued at \$0.61 per share	—	—	545,434	—	330	—	—	—	330
Deferred stock-based compensation	—	—	—	—	9	(9)	—	—	—
Amortization of deferred compensation	—	—	—	—	—	4	—	—	4
Common stock issued January 1997 for technology license, valued at \$0.0055 per share	—	—	74,033	—	1	—	—	—	1
Stock options exercised	—	—	2,317	—	1	—	—	—	1
Net loss	—	—	—	—	—	—	—	(3,288)	(3,288)
Balance at December 31, 1997	—	—	1,156,004	1	349	(10)	—	(3,839)	(3,499)
Repurchase of founder's stock	—	—	(16,098)	—	—	—	—	—	—
Stock options exercised	—	—	45	—	—	—	—	—	—
Deferred stock-based compensation	—	—	—	—	8	(8)	—	—	—
Amortization of deferred compensation	—	—	—	—	—	6	—	—	6
Net loss	—	—	—	—	—	—	—	(5,446)	(5,446)
Balance at December 31, 1998	—	—	1,139,951	1	357	(12)	—	(9,285)	(8,939)
Common stock returned for technology license termination	—	—	(72,726)	—	—	—	—	—	—
Common stock issued June 1999 for technology license, valued at \$0.55 per share	—	—	3,636	—	2	—	—	—	2
Deferred stock-based compensation	—	—	—	—	720	(720)	—	—	—
Amortization of deferred compensation	—	—	—	—	—	93	—	—	93
Stock options exercised	—	—	9,769	—	5	—	—	—	5
Change in unrealized loss on investments	—	—	—	—	—	—	(18)	—	(18)
Net loss	—	—	—	—	—	—	—	(6,947)	(6,947)
Comprehensive loss	—	—	—	—	—	—	—	—	(6,965)
Balance at December 31, 1999	—	—	1,080,630	1	1,084	(639)	(18)	(16,232)	(15,804)
Common stock issued December 2000 for technology license, valued at \$27.28 per share	—	—	27,272	—	744	—	—	—	744
Issuance of common stock warrants	—	—	—	—	2,716	—	—	—	2,716
Deferred stock-based compensation	—	—	—	—	1,988	(1,988)	—	—	—
Amortization of deferred compensation	—	—	—	—	—	770	—	—	770
Remeasurement and issuance of stock options in exchange for consulting services	—	—	—	—	112	—	—	—	112
Stock options exercised	—	—	128,922	—	228	—	—	—	228
Change in unrealized loss on investments	—	—	—	—	—	—	18	—	18
Net loss	—	—	—	—	—	—	—	(12,941)	(12,941)
Comprehensive loss	—	—	—	—	—	—	—	—	(12,923)
Balance at December 31, 2000	—	—	1,236,824	1	6,872	(1,857)	—	(29,173)	(24,157)
Common stock repurchased	—	—	(2,424)	—	(2)	—	—	—	(2)
Warrants issued November 2001 and beneficial conversion in preferred stock	—	—	—	—	13,060	—	—	—	13,060
Deferred stock-based compensation	—	—	—	—	1,652	(1,652)	—	—	—
Amortization of deferred compensation	—	—	—	—	—	1,445	—	—	1,445
Remeasurement and issuance of stock options in exchange for consulting services	—	—	—	—	1,122	—	—	—	1,122
Stock options and warrants exercised	—	—	117,807	—	195	—	—	—	195
Accretion of redeemable convertible preferred stock	—	—	—	—	(8,411)	—	—	—	(8,411)
Net loss and comprehensive loss	—	—	—	—	—	—	—	(19,512)	(19,512)
Balance at December 31, 2001	—	\$ —	1,352,207	\$ 1	\$ 14,488	\$ (2,064)	\$ —	\$ (48,685)	\$ (36,260)

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

XCYTE THERAPIES, INC.
(a development stage company)

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT) (continued)

	PREFERRED STOCK		COMMON STOCK		ADDITIONAL PAID-IN CAPITAL	DEFERRED STOCK COMPENSATION	ACCUMULATED OTHER COMPREHENSIVE INCOME (LOSS)	DEFICIT ACCUMULATED DURING THE DEVELOPMENT STAGE	TOTAL
	Shares	Amount	Shares	Amount					
(in thousands, except share data)									
Balance at December 31, 2001	—	\$ —	1,352,207	\$ 1	\$ 14,488	\$ (2,064)	\$ —	\$ (48,685)	\$(36,260)
Common stock issued May 2002 for technology license, valued at \$10.67 per share	—	—	63,636	—	679	—	—	—	679
Warrants issued February and March 2002 and beneficial conversion in preferred stock	—	—	—	—	12,325	—	—	—	12,325
Deferred stock-based compensation	—	—	—	—	3,188	(3,188)	—	—	—
Amortization of deferred compensation, net of reversal of \$867 for terminated employees	—	—	—	—	(867)	3,372	—	—	2,505
Remeasurement and issuance of stock options in exchange for consulting services	—	—	—	—	65	—	—	—	65
Stock options and warrants exercised	—	—	108,024	1	10	—	—	—	11
Accretion of redeemable convertible preferred stock	—	—	—	—	(8,001)	—	—	—	(8,001)
Change in unrealized gain on investments	—	—	—	—	—	—	4	—	4
Net loss	—	—	—	—	—	—	—	(19,453)	(19,453)
Comprehensive loss									(19,449)
Balance at December 31, 2002	—	—	1,523,867	2	21,887	(1,880)	4	(68,138)	(48,125)
Deferred stock-based compensation	—	—	—	—	2,423	(2,423)	—	—	—
Amortization of deferred compensation, net of reversal of \$222 for terminated employees	—	—	—	—	(222)	1,529	—	—	1,307
Remeasurement and issuance of stock options in exchange for consulting services	—	—	—	—	360	—	—	—	360
Stock options and warrants exercised	—	—	22,757	—	84	—	—	—	84
Change in unrealized gain on investments	—	—	—	—	—	—	(9)	—	(9)
Net loss	—	—	—	—	—	—	—	(18,457)	(18,457)
Comprehensive loss									(18,466)
Balance at December 31, 2003	—	—	1,546,624	2	24,532	(2,774)	(5)	(86,595)	(64,840)
Issuance of common stock at \$8.00 per share, net of issuance costs	—	—	4,200,000	4	29,696	—	—	—	29,700
Conversion of preferred stock and warrants into common stock and warrants	—	—	6,781,814	6	76,037	—	—	—	76,043
Accretion of redeemable convertible preferred stock	—	—	—	—	(8,973)	—	—	—	(8,973)
Conversion of promissory notes and accrued interest into common stock	—	—	1,357,357	1	13,029	—	—	—	13,030
Recognition of beneficial conversion on convertible promissory notes	—	—	—	—	11,276	—	—	—	11,276
Issuance of convertible preferred stock at \$10.00 per share, net of issuance costs	2,990,000	3	—	—	23,469	—	—	—	23,472
Conversions of preferred stock into common stock	(910,187)	(1)	3,873,124	4	(3)	—	—	—	—
Make-whole payment upon conversion of preferred stock	—	—	793,054	1	1,722	—	—	—	1,723
Deferred stock-based compensation	—	—	—	—	810	(810)	—	—	—
Amortization of deferred compensation, net of reversal of \$30 for terminated employees	—	—	—	—	(30)	2,167	—	—	2,137
Remeasurement and issuance of stock options in exchange for consulting services	—	—	—	—	65	—	—	—	65
Issuance of common stock in connection with employee stock purchase plan	—	—	5,108	—	10	—	—	—	10
Stock options and warrants exercised	—	—	941,175	1	68	—	—	—	69
Change in unrealized loss on investments	—	—	—	—	—	—	(4)	—	(4)
Net loss	—	—	—	—	—	—	—	(39,588)	(39,588)
Comprehensive loss									(39,592)
Balance at December 31, 2004	2,079,813	\$ 2	19,498,256	\$ 19	\$ 171,708	\$ (1,417)	\$ (9)	\$ (126,183)	\$ 44,120

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

XCYTE THERAPIES, INC.
(a development stage company)
STATEMENTS OF CASH FLOWS

	YEARS ENDED DECEMBER 31,			PERIOD FROM INCEPTION (JANUARY 5, 1996) TO DECEMBER 31, 2004
	2002	2003	2004	
(in thousands)				
Cash flows from operating activities				
Net loss	\$ (19,453)	\$ (18,457)	\$ (39,588)	\$ (126,183)
Adjustments to reconcile net loss to net cash used in operating activities:				
Non-cash research and development expense for technology licenses	679	—	—	1,716
Amortization of investment premiums, net	217	89	300	606
Non-cash stock compensation expense	2,570	1,667	2,202	9,993
Non-cash interest expense	55	365	12,559	13,062
Non-cash rent expense	34	34	34	136
Change in valuation of derivative	—	—	727	727
Depreciation and amortization	823	840	1,006	5,697
Loss on sale of property and equipment	11	1	—	195
Changes in assets and liabilities:				
(Increase) decrease in prepaid expenses and other current assets	(298)	140	(536)	(1,207)
(Increase) decrease in deposits and other assets	63	(825)	582	(699)
Increase (decrease) in accounts payable	(428)	359	753	1,707
Increase in accrued liabilities	568	301	875	2,698
Net cash used in operating activities	(15,159)	(15,486)	(21,086)	(91,552)
Cash flows from investing activities				
Purchases of property and equipment	(1,144)	(995)	(4,447)	(11,364)
Proceeds from sale of property and equipment	—	—	—	64
Net cash acquired in acquisition	—	—	—	437
Purchases of investments available-for-sale	(26,975)	(30,543)	(79,982)	(143,316)
Purchases of investments held-to-maturity	—	—	—	(17,732)
Proceeds from maturities of investments available-for-sale	13,146	32,761	57,555	121,866
Proceeds from maturities of investments held-to-maturity	—	—	—	5,145
Net cash provided by (used in) investing activities	(14,973)	1,223	(26,874)	(44,900)
Cash flows from financing activities				
Net proceeds from issuances of preferred stock	12,313	—	27,488	103,042
Net proceeds from issuances of common stock	—	—	29,700	29,700
Net proceeds from issuances of convertible promissory notes	—	12,660	—	12,660
Common stock repurchased	—	—	—	(3)
Proceeds from stock options and warrants exercised	11	83	69	591
Proceeds from issuances of common stock in connection with employee stock purchase plan	—	—	10	10
Proceeds from equipment financings	1,304	913	3,629	9,681
Principal payments on equipment financings	(866)	(880)	(1,280)	(5,332)
Net cash provided by financing activities	12,762	12,776	59,616	150,349
Net increase (decrease) in cash and cash equivalents	(17,370)	(1,487)	11,656	13,897
Cash and cash equivalents at beginning of period	21,098	3,728	2,241	—
Cash and cash equivalents at end of period	\$ 3,728	\$ 2,241	\$ 13,897	\$ 13,897
Supplemental cash flow information				
Interest paid	\$ 212	\$ 212	\$ 276	\$ 1,617
Non-cash investing and financing activities				
Common stock issued for acquisition	\$ —	\$ —	\$ —	\$ 330
Preferred stock issued for acquisition	\$ —	\$ —	\$ —	\$ 579
Preferred stock warrants issued for acquisition	\$ —	\$ —	\$ —	\$ 330
Preferred stock warrants issued in connection with equipment financing	\$ 56	\$ 14	\$ —	\$ 298
Preferred stock warrants issued in connection with lease	\$ —	\$ —	\$ —	\$ 340
Preferred stock warrants issued in preferred stock financing	\$ —	\$ —	\$ —	\$ 48
Issuance of common stock warrants and beneficial conversion in preferred stock	\$ 12,325	\$ —	\$ —	\$ 25,385
Accretion of preferred stock	\$ (8,001)	\$ —	\$ (8,973)	\$ (25,385)
Conversion of redeemable convertible preferred stock and warrants into common stock and warrants	\$ —	\$ —	\$ 76,043	\$ 76,043
Conversion of promissory notes and accrued interest into common stock	\$ —	\$ —	\$ 13,065	\$ 13,065
Common stock issued in satisfaction of make-whole payments upon conversion of preferred stock	\$ —	\$ —	\$ 1,723	\$ 1,723
Property and equipment costs accrued	\$ 24	\$ 148	\$ 300	\$ 300

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

XCYTE THERAPIES, INC.
(a development stage company)**NOTES TO FINANCIAL STATEMENTS****1. ORGANIZATION AND SIGNIFICANT ACCOUNTING POLICIES****Organization**

Xcyte Therapies, Inc. (the Company), a development stage enterprise, operates in one business segment, developing products based on T cell activation to treat cancer, infectious diseases and other medical conditions associated with compromised immune systems. As a development stage enterprise, substantially all efforts of the Company have been devoted to performing research and experimentation, conducting clinical trials, developing and acquiring intellectual properties, raising capital and recruiting and training personnel.

Cash, cash equivalents and investments

Cash equivalents include highly liquid investments with a maturity on the date of purchase of three months or less. The Company's cash equivalents consist of money market securities. While cash and cash equivalents held by financial institutions may at times exceed federally insured limits, management believes that no material credit or market risk exposure exists due to the high quality of the institutions. The Company has not experienced any losses on such accounts.

All investment securities are classified as available-for-sale and are carried at fair value. Unrealized gains and losses are reported in a separate component of stockholders' equity. Amortization, accretion, interest and dividends, realized gains and losses and declines in value judged to be other-than-temporary on available-for-sale securities are included in interest income. The cost of securities sold is based on the specific-identification method. Investments in securities with maturities of less than one year or which management intends to use to fund current operations are classified as short-term investments.

The Company evaluates whether an investment is other-than-temporarily impaired. This evaluation is dependent on the specific facts and circumstances. Factors that are considered in determining whether an other-than-temporary decline in value has occurred include: the market value of the security in relation to its cost basis; the financial condition of the issuer; and the intent and ability to retain the investment for a sufficient period of time to allow for recovery in the market value of the investment.

Property and equipment

Property and equipment is stated at cost and is depreciated using the straight-line method over the assets' useful lives, which are six years for equipment and furniture and fixtures and three years for computer equipment. Leasehold improvements are amortized over the lesser of their estimated useful lives or the term of the lease.

Impairment of long-lived assets

In accordance with the provisions of Statement of Financial Accounting Standards No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* (SFAS 144), the Company reviews long-lived assets, including property and equipment, for impairment whenever events or changes in business circumstances indicate that the carrying amounts of the assets may not be fully recoverable. An impairment loss will be recognized when estimated undiscounted future cash flows expected to result from the use of an asset and its eventual disposition are less than its carrying amount. In that event, a loss is recognized based on the amount by which the carrying value exceeds the fair value of the long-lived asset.

Revenue recognition

To date, the Company has generated no revenues from sales of products. Revenues relate to fees received for licensed technology, cost reimbursement contracts and a Small Business Innovation Research (SBIR) grant awarded to the Company by the National Institutes of Health. Revenue associated with up-front license fees and research and development funding payments are recognized ratably over the relevant periods specified in the agreement, generally the period the Company is obligated to perform services. Revenue under research and development cost-reimbursement agreements is recognized as the related costs are incurred. Revenue related to grant agreements is recognized as related research and development expenses are incurred.

Other comprehensive income (loss)

Other comprehensive income (loss) includes certain non-owner changes in equity that are excluded from net income (loss). The Company's only other comprehensive income (loss) is unrealized gain (loss) on investments.

Research and development expenses

Research and development expenses are charged to expense as incurred and include, but are not limited to, personnel costs, lab supplies, depreciation, amortization and other indirect costs directly related to the Company's research and development activities.

Segments

The Company has adopted Statement of Financial Accounting Standards No. 131, *Disclosure about Segments of an Enterprise and Related Information* (SFAS 131), and related disclosures about its products, services, geographic areas and major customers. The Company has determined that it operates in only one segment.

Stock-based compensation

The Company has adopted the disclosure-only provisions of Statement of Financial Accounting Standards No. 123, *Accounting for Stock-Based Compensation* (SFAS 123), as amended by SFAS No. 148, *Accounting for Stock-Based Compensation—Transition and Disclosure*, and applies Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* (APB 25), and related interpretations in accounting for stock options. Accordingly, employee stock-based compensation expense is recognized based on the intrinsic value of the option at the date of grant.

As required under SFAS No. 123, the pro forma effects of stock-based compensation on net loss are estimated at the date of grant using the Black-Scholes option-pricing model. 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. 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, the existing models do not, in management's opinion, necessarily provide a reliable single measure of the fair value of the Company's employee stock options.

The fair value of these options was estimated at the date of grant using the Black-Scholes option-pricing model with the following weighted average assumptions for the years ended December 31, 2002, 2003 and 2004: risk-free interest rate of 5.0% for all periods; a dividend yield of 0% for all periods; expected volatility of 80% for all periods; and weighted average expected lives of the options of 4 years for all periods. The estimated weighted average fair value of stock options granted during 2002, 2003 and 2004 was \$12.55, \$13.76, and \$3.21 per share of common stock, respectively.

For purposes of pro forma disclosures, the estimated fair value of the options is amortized to expense over the vesting period of the related options. The Company's pro forma information follows (in thousands, other than per share information):

YEAR ENDED DECEMBER 31,	2002	2003	2004
Net loss applicable to common stockholders, as reported	\$(27,454)	\$(18,457)	\$(48,561)
Add: Employee stock-based compensation, as reported	2,505	1,307	2,137
Deduct: Stock-based compensation determined under the fair value method	(2,879)	(1,612)	(2,972)
Pro forma net loss	\$(27,828)	\$(18,762)	\$(49,396)
Basic and diluted pro forma net loss per share	\$ (19.60)	\$ (12.61)	\$ (3.97)

Stock options granted to non-employees are recorded using the fair value approach in accordance with SFAS 123 and Emerging Issues Task Force Consensus (EITF) Issue No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services* (EITF 96-18). The options to non-employees are subject to periodic revaluation over their vesting terms.

Deferred stock compensation includes amounts recorded when the exercise price of an option is lower than the fair value of the underlying common stock on the date of grant. Deferred stock-based compensation is amortized over the vesting period of the underlying option using the graded-vesting method.

Income taxes

The Company accounts for income taxes utilizing the liability method in accordance with Statement of Financial Accounting Standards No. 109, *Accounting for Income Taxes* (SFAS 109). Deferred tax assets or liabilities are recorded for all temporary differences between financial and tax reporting. A valuation allowance is recorded when it is more likely than not that the deferred tax asset will not be recovered.

Net loss per share

Basic net loss per share is computed by dividing net loss applicable to common stockholders by the weighted average number of common shares outstanding for the period. Common stock equivalents, including convertible preferred stock, redeemable convertible preferred stock, stock options and warrants are excluded from the computation of diluted loss per share as their effect is anti-dilutive. For the periods presented, there is no difference between the basic and diluted net loss per share.

Financial instruments

Financial instruments, including cash and cash equivalents and payables, are recorded at cost, which approximates fair value based on the short-term maturities of these instruments. The fair value of investments is determined based on quoted market prices. Refer to Note 2 for further information on the fair value of investments. Based on the borrowing rates currently available to the Company for loans with similar terms, management believes that the carrying value of equipment financing arrangements approximates fair value.

Derivative financial instruments

The terms of our November 2004 convertible preferred stock offering include a dividend make-whole payment feature. This feature is considered to be an embedded derivative and is recorded at fair value in accordance with Statement of Financial Accounting Standards No. 133, *Accounting for Derivative Instruments* (SFAS 133). The derivative liability is reduced for make-whole payments triggered upon conversion of the preferred stock as well as dividends declared by the Company, if any, on the convertible preferred stock. The changes in the fair value of the derivative financial instrument are included in other income (expense) in each reporting period.

Use of estimates

The preparation of financial statements in conformity with generally accepted accounting principles in the United States requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

Recent accounting pronouncements

In March 2004, the EITF reached a consensus on EITF 03-1, *"The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments."* EITF 03-1 provides guidance for determining when an investment is considered impaired, whether that impairment is other than temporary, and the measurement of an impairment loss. EITF 03-1 also includes accounting considerations subsequent to the recognition of an other-than-temporary impairment and requires certain disclosures about unrealized losses that have not been recognized as other-than-temporary. The effective date for the recognition and measurement guidance of EITF 03-1 has been delayed until certain implementation issues are addressed. Final implementation guidance is expected to be issued in 2005. The disclosure requirements of EITF 03-1 remain in effect. The Company has complied with the disclosure requirements, and the adoption of the remaining portions of EITF 03-1 is not expected to have a material impact on the Company's results of operations or financial condition.

In December 2004, the FASB issued SFAS 123R, *Share-Based Payment*. SFAS 123R establishes standards for the accounting for transactions in which an entity receives employee services in exchange for the entity's equity instruments or liabilities that are based on the fair value of the entity's equity instruments or that may be settled by the issuance of those equity instruments. SFAS 123R eliminates the ability to account for share-based compensation using APB 25 and generally requires that such transactions be accounted for using a fair value method. The provisions of this statement are effective for financial statements issued for fiscal periods beginning after June 15, 2005 and will become effective for the Company beginning with the third quarter of 2005. The impact that the adoption of this statement will have on the Company's financial position and results of operations will be determined by share-based payments granted in future periods, as well as the fair value model and assumptions the Company will choose, which have not been finalized yet.

2. INVESTMENTS

A summary of investments follows (in thousands):

December 31, 2003

	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair value
Federal agency obligations	\$ 770	\$ —	\$ —	\$ 770
Corporate bonds	9,680	1	(6)	9,675
Municipal bonds	854	—	—	854
Total	\$ 11,304	\$ 1	\$ (6)	\$ 11,299

December 31, 2004

	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair value
Federal agency obligations	\$ 14,111	\$ 1	\$ (11)	\$ 14,101
Corporate bonds	17,318	15	(12)	17,321
Municipal bonds	2,001	—	(2)	1,999
Total	\$ 33,430	\$ 16	\$ (25)	\$ 33,421

The Company has realized no gains or losses upon the sale of available-for-sale securities during the years ended December 31, 2002, 2003 and 2004 as no investments were sold prior to maturity. The Company has evaluated the nature of the investments, the duration of the impairments (all less than 1 year) and concluded that the impairments are not other-than-temporary. All investments held at December 31, 2003 and December 31, 2004 have contractual maturities within one year.

3. PROPERTY AND EQUIPMENT

Property and equipment consists of the following (in thousands):

December 31,	2003	2004
Equipment	\$ 3,794	\$ 5,649
Furniture and fixtures	218	494
Leasehold improvements	825	930
Computer equipment	946	1,273
Construction in process	164	2,047
Property and equipment, gross	5,947	10,393
Less accumulated amortization and depreciation	(3,180)	(4,185)
Property and equipment, net	\$ 2,767	\$ 6,208

Depreciation expense totaled \$823,000, \$840,000 and \$1.0 million during the years ended December 31, 2002, 2003 and 2004, respectively.

Interest cost incurred totaled \$12.8 million during the year ended December 31, 2004, of which \$78,000 was capitalized to construction in process. No interest cost was capitalized during the years ended December 31, 2002 and 2003.

4. EMPLOYEE NOTE RECEIVABLE

During the year ended December 31, 2001, the Company made a \$50,000 secured loan to an employee in connection with an individual employment agreement. The loan bears interest at an annual rate of 8.24% and is repayable in equal quarterly installments over four years. The note balance of \$24,000 and \$14,000 at December 31, 2003 and 2004, respectively, has been classified in deposits and other assets. Interest earned on the note has been immaterial to date.

5. SIGNIFICANT AGREEMENTS

Technology licenses

In 1998, the Company entered into a license agreement with Genetics Institute, under which the Company was granted a license under Genetics Institute's rights to several patents and patent applications in exchange for the payment of upfront license fees totaling approximately \$53,000, for the issuance of 26,522 shares of Series B preferred stock and warrants to purchase 35,363 shares of Series B preferred stock at \$6.05 per share. The fees were charged to research and development expenses when paid. The Company, or sublicensee, is required to spend no less than \$500,000 annually on research and development activities related to product development until the first commercial sale of a product.

In 1999, the Company entered into a license and supply agreement with Diaclone S.A., in which the Company was granted a license to make, use and sell certain products created with a specific antibody. In consideration for the license, the Company paid and charged to research and development expense a \$75,000 nonrefundable fee.

In addition, the Company entered into a license agreement with the Fred Hutchinson Cancer Research Center in 1999, in which the Company was granted a license to make, use and sell a specific antibody for certain therapeutic and research purposes. In consideration for the license, the Company paid nonrefundable license fees of \$50,000. The Company also agreed to issue 27,272 shares of common stock,

valued at \$744,000, to the Fred Hutchinson Cancer Research Center. The Company charged research and development expense for all nonrefundable fees paid and the value of the common stock issued.

During the year ended December 31, 2002, the Company entered into a license agreement with the Trustees of the University of Pennsylvania, whereby the Company was granted the right to use certain intellectual property in exchange for payment of nonrefundable license fees of \$150,000. The Company also agreed to issue 63,636 shares of common stock, valued at \$679,000, to the Trustees of the University of Pennsylvania. The Company charged research and development expense for all nonrefundable fees paid and the value of common stock issued. In October 2003, the Company terminated the license agreement, effective December 30, 2003.

All license agreements require the payment of royalties by the Company based on sales and services. No royalty payments have been required or paid through December 31, 2004.

Manufacturing and supply contracts

The Company entered into a development and supply agreement with Dynal S.A. during the year ended December 31, 1999, agreeing to make nonrefundable payments totaling \$3.0 million for certain development activities conducted by Dynal. As of December 31, 2004, the Company had made payments totaling the full \$3.0 million under the agreement, which were charged to research and development expense. Under the terms of the supply agreement, should the Company not buy a minimum \$250,000 of beads in the first 12 months after the development phase ends and \$500,000 of beads annually thereafter over the remaining term of the agreement, Dynal shall have the right to terminate the agreement. As of December 31, 2004, the development phase, as defined in the Dynal agreement, has not yet been completed. Either party may terminate the agreement as of August 2009 for any reason, or earlier on account of the material breach or insolvency of the other party. If the agreement is not terminated by August 2009, either party can elect to extend the terms of the agreement for an additional five years. Otherwise, it will automatically renew on a year to year basis. In March 2004, the Company amended the agreement to allow Dynal to sell a research-grade version of the Company's antibody-coated beads. As of December 31, 2004, no such sales had occurred.

During the year ended December 31, 2000, the Company entered into development and supply agreements with Lonza Biologics PLC (Lonza) for the development and production of cGMP-grade antibodies. In 2004, the Company amended its agreements with Lonza. Under the terms of the agreements, the Company is obligated to make payments in British pounds. Exchange rate gains and losses have been insignificant to date. The Company paid approximately \$1.6 million, \$1.3 million and \$94,000 under the agreements during the years ended December 31, 2002, 2003 and 2004, respectively, all of which were charged to research and development expense. At December 31, 2004, Lonza was in the process of completing certain development phases as defined under the agreements. Remaining payments under the agreements will be approximately \$1.7 million during the year ended December 31, 2005, assuming development phases progress as intended under the agreements.

Corporate collaborations

In November 2003, the Company licensed to Fresenius Biotechnology GmbH, a wholly-owned subsidiary of Fresenius AG, the Company's Xcellerate Technology on an exclusive basis in the field of HIV retroviral gene therapy, for development and commercialization in Europe with an option under certain circumstances to expand their rights to North America. The agreement with Fresenius requires the Company to transfer its Xcellerate Technology, including manufacturing capability, to Fresenius and supply all antibody-coated beads required by Fresenius to support its development and commercialization efforts. Fresenius had previously agreed to reimburse the Company for its expenses in transferring the technology and to pay the Company for the antibody-coated beads on a cost-plus basis. For the years ended December 31, 2003 and 2004, the Company has recognized revenue of \$170,000 and \$27,000, respectively, related to the reimbursement of its actual costs. The terms of the agreement include potential royalties on net sales as well as potential milestone payments to the Company less applicable sublicense fees payable by Xcyte to third parties for each product developed. For the year ended December 31, 2004, the Company has recognized \$35,000 as revenue related to upfront payments received. These payments have been deferred and are being amortized to revenue over the estimated service period of 18 years. Fresenius' obligation to pay the Company royalties under this agreement terminates on a country-by-country basis upon the later of the last to expire of the licensed patents or fifteen years after the first commercial sale of a product in the country. The agreement is also subject to earlier termination by Fresenius at any time if Fresenius determines it cannot develop a commercially viable product or complete a required manufacturing audit; by Xcyte if Fresenius does not meet development milestones; and by either party for the material breach or insolvency of the other party.

6. REDEEMABLE CONVERTIBLE PREFERRED STOCK AND WARRANTS

Redeemable convertible preferred stock

Prior to the Company's initial public offering in March 2004, the Company had issued various series of redeemable convertible preferred stock. A summary of redeemable convertible preferred stock outstanding as of December 31, 2003 is as follows (in thousands, except share data):

DECEMBER 31, 2003

	Shares designated	Issued and outstanding shares	Aggregate redemption and liquidation preference	Carrying value
Series A	7,300,080	1,255,870	\$ 6,562	\$ 6,660
Series B	4,097,580	709,647	4,293	4,293
Series C	7,212,316	1,306,470	12,000	11,976
Series D	10,300,000	1,838,139	28,105	25,263
Series E	6,500,000	863,648	13,205	8,411
Series F	6,500,000	808,040	12,355	8,001
	41,909,976	6,781,814	\$ 76,520	\$ 64,604

From inception through December 31, 1999, the Company issued 1,151,664 shares of Series A preferred stock at \$5.23 per share for proceeds of \$6.0 million; 683,125 shares of Series B preferred stock at \$6.05 per share for proceeds of \$4.1 million; and 1,306,470 shares of Series C preferred stock at \$9.19 per share for proceeds of \$12.0 million. The Company also issued an additional 95,690 shares of Series A preferred stock in conjunction with a business acquisition. The value of the Series A preferred stock of \$579,000 was included in the determination of the purchase price of the acquired business. The Company also issued 26,522 shares of Series B preferred stock to acquire technology licenses. These shares were valued at \$6.05 per share for an aggregate amount of \$160,000. There were no significant costs associated with the Series A, B and C private placements.

During the year ended December 31, 2000, the Company completed a private placement of 1,838,139 shares at \$15.29 per share of Series D redeemable preferred stock for \$28.0 million, net of offering costs of \$117,000. In connection with the offering, holders of the Series D preferred stock received warrants to purchase 205,858 shares of common stock at an exercise price of \$1.65 per share. The warrants were valued at \$2.7 million using the Black-Scholes option-pricing model. Of the total net proceeds of \$28.0 million, \$2.7 million was recorded in paid-in capital and \$25.3 million was recorded as redeemable convertible preferred stock.

During the year ended December 31, 2001, the Company completed a private placement of 863,648 shares at \$15.29 per share of Series E redeemable preferred stock for \$13.1 million, net of offering costs of \$145,000. In connection with the offering, holders of the Series E preferred stock received warrants to purchase 470,205 shares of common stock at an exercise price of \$0.055 per share. The net proceeds from the Series E preferred stock offering were allocated based on the relative fair values of the warrants, using the Black-Scholes option-pricing model, and the preferred stock. The Company assigned \$4.6 million to the value of the warrants and \$8.4 million to the value of the preferred stock. After allocating a portion of the proceeds to the common stock warrants, the effective conversion price of the preferred stock was at a discount to the price of the common stock into which the preferred stock was convertible. The discount associated with the beneficial conversion feature was limited to the proceeds allocated to the preferred stock, or \$8.4 million. Accordingly, the preferred stock was initially recorded at zero. The Company recognized the amortization of the discount associated with the beneficial conversion of \$8.4 million as a charge to additional paid-in capital (also shown as a deduction to arrive at net loss applicable to common stockholders) and a credit to preferred stock immediately upon issuance since the preferred stock could be converted into common stock at any time, at the holder's option. The remaining discount of \$4.6 million was amortized in March 2004, when the preferred stock was converted into common stock upon the closing of the Company's initial public offering.

During the year ended December 31, 2002, the Company completed a private placement of 808,040 shares at \$15.29 per share of Series F redeemable preferred stock for \$12.3 million, net of offering costs of \$30,000. In connection with the offering, holders of the Series F preferred stock received warrants to purchase 439,932 shares of common stock at an exercise price of \$0.055 per share. The net proceeds from the Series F preferred stock offering were allocated based on the relative fair values of the warrants, using the Black-Scholes option-pricing model, and the preferred stock. The Company assigned \$4.3 million to the value of the warrants and \$8.0 million to the value of the preferred stock. After allocating a portion of the proceeds to the common stock warrants, the effective conversion price of the preferred stock was at a discount to the price of the common stock into which the preferred stock was convertible. The discount associated with the beneficial conversion was limited to the proceeds allocated to the preferred stock, or \$8.0 million. Accordingly, the preferred stock was initially recorded at zero. The Company recognized the amortization of the discount associated with the beneficial conversion of \$8.0 million.

as a charge to additional paid-in capital (also shown as a deduction to arrive at net loss applicable to common stockholders) and a credit to preferred stock immediately upon issuance since the preferred stock could be converted into common stock at any time, at the holder's option. The remaining discount of \$4.3 million was amortized in March 2004, when the preferred stock was converted into common stock upon the closing of the Company's initial public offering.

In connection with the initial public offering in March 2004, all of the outstanding shares of the Company's redeemable convertible preferred stock were converted into 6,781,814 shares of common stock.

Redeemable convertible preferred stock warrants

From inception through December 31, 1999, warrants were issued to purchase 66,983 shares of Series A preferred stock in connection with a business acquisition at an exercise price of \$5.23 per share. The value of the warrants of \$330,000 was included in the determination of the purchase price of the business. In addition, warrants to purchase 12,937 shares of Series A preferred stock at \$5.23 per share and warrants to purchase 2,238 shares of Series C preferred stock at \$9.19 per share were issued in connection with equipment financing. The estimated fair value of the warrants issued of \$64,000 and \$15,000, respectively, was recorded as an additional financing cost and was amortized over the term of the loan as interest expense. The warrants to purchase 12,937 shares of Series A preferred stock were exercised in March 2003 through a net exercise, resulting in the issuance of 8,516 shares of Series A preferred stock. In addition, the Company issued warrants to purchase 35,363 shares of Series B preferred stock as partial consideration for a technology license. The warrants were issued at an exercise price of \$6.05 per share, and the estimated fair value of the warrants of \$131,000 was charged to research and development expense.

During the years ended December 31, 2000 and 2001, the Company issued warrants to purchase 2,612 of Series C preferred stock at an exercise price of \$9.19, and 4,316 of Series D preferred stock at an exercise price of \$15.29, respectively in connection with equipment financing. The estimated fair value of the warrants issued of \$36,000 for Series C and \$113,000 for Series D was recorded as additional financing cost and is being amortized over the term of the loan as interest expense using the effective interest method.

During the years ended December 31, 2002 and 2003, the Company issued warrants to purchase 4,316 and 1,143 of Series F stock at an exercise price of \$15.29 and \$15.29, respectively in connection with equipment financing. The estimated fair value of the warrants issued of \$56,000 and \$14,000 was recorded as additional financing cost and is being amortized over the term of the loan as interest expense using the effective interest method.

During the year ended December 31, 2000, the Company issued a warrant for the purchase of 14,545 shares of Series D preferred stock at an exercise price of \$15.29 per share, in connection with a lease for a manufacturing facility. The estimated fair value of the warrant of \$340,000 was recorded as deferred rent and is being recognized as additional rent expense over the initial term of the lease.

During the year ended December 31, 2001, the Company issued a warrant for the purchase of 1,818 shares of Series E preferred stock at an exercise price of \$15.29 per share for services provided in connection with the private placement of Series E redeemable preferred stock. The estimated fair value of the warrants of \$48,000 was included in offering costs of the placement.

Concurrent with the closing of the initial public offering in March 2004, 86,727 preferred stock warrants that expired upon the closing of a public offering were converted into common stock through cashless exercises, resulting in the issuance of 23,233 shares of common stock. The remaining 46,607 preferred stock warrants that did not expire upon the closing of a public offering were converted into 46,607 common stock warrants upon the closing of the initial public offering. The Company has valued the warrants issued during the years ended December 31, 2002, 2003 and 2004 using the Black-Scholes option-pricing model with the following assumptions: no dividend yields; life of 7 years to 10 years; risk-free interest rate of 5.0%; and volatility of 80%.

7. PREFERRED STOCK

Convertible exchangeable preferred stock

On November 3, 2004, the Company completed a public offering of 2,990,000 shares of its 6% convertible exchangeable preferred stock (the Preferred Stock) at \$10.00 per share, including the shares sold to the underwriters pursuant to the over-allotment option granted in connection with the offering. Net proceeds from the offering, after deducting underwriting discounts and offering-related expenses, totaled \$27.5 million.

Dividends on the Preferred Stock will be cumulative from the date of original issue at the annual rate of 6% of the liquidation preference of the Preferred Stock, payable quarterly on the first day of February, May, August and November, commencing February 1, 2005. Any dividends must be declared by the Company's board of directors and must come from funds that are legally available for dividend payments. The Preferred Stock has a liquidation preference of \$10 per share, plus accrued and unpaid dividends. In January 2005, the Company's

board of directors declared a quarterly dividend in the amount of \$0.1467 per share of Preferred Stock, which was paid on February 1, 2005, to the holders of record as of the close of business on January 21, 2005. This quarterly dividend distribution totaled \$300,000.

The Preferred Stock is convertible at the option of the holder at any time into the Company's common stock at a conversion rate of approximately 4.2553 shares of common stock for each share of Preferred Stock, based on an initial conversion price of \$2.35. The initial conversion price is subject to adjustment in certain events. The Company reserved 12,723,404 shares of common stock for issuance upon conversion. At December 31, 2004, holders had voluntarily converted 910,187 shares of Preferred Stock into 3,873,124 shares of common stock.

The Company may automatically convert the Preferred Stock into common stock if the closing price of the Company's common stock has exceeded \$3.53, which is 150% of the conversion price of the Preferred Stock, for at least 20 trading days during any 30-day trading period, ending within five trading days prior to notice of automatic conversion.

If the Company elects to automatically convert, or the holder elects to voluntarily convert, some or all of the Preferred Stock into common stock prior to November 3, 2007, the Company will make an additional payment on the Preferred Stock equal to the aggregate amount of dividends that would have been payable on the Preferred Stock through and including November 3, 2007, less any dividends already paid on the Preferred Stock. This additional payment is payable in cash or, at the Company's option, in shares of the Company's common stock, or a combination of cash and shares of common stock. At December 31, 2004, the Company had issued 793,054 shares of common stock to converting holders in satisfaction of this additional payment.

In accordance with SFAS 133, the Company is required to separate and account for, as an embedded derivative, the dividend make-whole payment feature of the Preferred Stock offering. As an embedded derivative instrument, the dividend make-whole payment feature must be measured at fair value and reflected as a liability. Changes in the fair value of the derivative are recognized in earnings as a component of other income (expense). The Company determined the fair value of the dividend make-whole payment feature to be \$4.0 million at October 29, 2004 (the commitment date). This amount was allocated from the proceeds of the Preferred Stock to the derivative liability. The carrying value of this derivative was reduced by \$1.7 million during the period from November 3, 2004 through December 31, 2004, based on the fair value of common stock issued as dividend make-whole payments pursuant to voluntary holder conversions during this period. At December 31, 2004, the derivative liability was valued at \$3.0 million, resulting in the recognition of \$727,000 as other expense for the year ended December 31, 2004.

The Company may elect to redeem the Preferred Stock at declining redemption prices on or after November 6, 2007.

The Preferred Stock is exchangeable, in whole but not in part, at the option of the Company on any dividend payment date beginning on November 1, 2005 (the "Exchange Date") for the Company's 6% Convertible Subordinated Debentures ("Debentures") at the rate of \$10 principal amount of Debentures for each share of Preferred Stock. The Debentures, if issued, will mature 25 years after the Exchange Date and have terms substantially similar to those of the Preferred Stock.

The Preferred Stock has no maturity date and no voting rights prior to conversion into common stock, except under limited circumstances.

8. STOCK PLANS

1996 Stock Option Plan

Under the Company's Amended and Restated 1996 Stock Option Plan (1996 Plan), 1,163,636 shares of common stock have been reserved for grants to employees, directors and consultants as of December 31, 2004. In September 2003, the 1996 Plan was amended to increase common stock reserved for grants to 1,163,636 shares and certain outstanding stock options were modified to accelerate vesting for employees with a five-year vesting schedule to a four-year schedule. There was no immediate accounting impact to this change. However, if employees benefit from the change, the appropriate stock compensation charge will be recorded in the period in which there was a benefit to the employee(s) based upon the measurement of the intrinsic value of the related stock options on the date of modification. As of December 31, 2004, no additional stock compensation charges have been recognized as a result of this modification. The term of the 1996 Plan is 10 years unless terminated earlier by the Board of Directors. Options granted under the 1996 Plan may be designated as incentive or nonqualified at the discretion of the 1996 Plan administrator. The vesting period, exercise price and expiration period of options are also established at the discretion of the 1996 Plan administrator. Vesting periods are typically four or five years, and incentive stock options are exercisable at no less than the fair market value at the date of grant, and nonqualified stock options are exercisable at prices determined by the 1996 Plan administrator. In no event shall the term of any incentive stock option exceed 10 years.

Shares issued upon exercise of options that are unvested are restricted and subject to repurchase by the Company at the original exercise price upon termination of employment, and such restrictions lapse over the original vesting schedule. During the year ended December 31,

2000, the Board of Directors amended the 1996 Plan to allow options granted to certain executives to become exercisable immediately. Three executives elected to early exercise stock options for 93,426 shares of restricted common stock in the year ended December 31, 2000. During the year ended December 31, 2001, the Company repurchased 2,424 shares of restricted stock. The shares were repurchased in an amount equal to the original purchase price of the shares. At December 31, 2004, there were a total of 12,946 shares of restricted common stock outstanding and subject to repurchase.

2003 Stock Plan

The 2003 Stock Plan (2003 Plan) provides for the grant of incentive stock options and stock purchase rights to employees (including employee directors) and non-statutory stock options to employees, directors and consultants. A total of 636,363 shares of common stock have been reserved for issuance under the 2003 Plan as of December 31, 2004. In January and March 2005, the Board of Directors increased the number of shares reserved for issuance under the 2003 Plan by 400,000 shares and 200,000 shares, respectively. In addition, the number of shares reserved for issuance under the 2003 Plan will be subject to an automatic annual increase on the first day of each fiscal year beginning in 2005 and ending in 2010 equal to the lesser of 109,090 shares, 4% of the number of outstanding shares of common stock on the last day of the immediately preceding fiscal year or such lesser number of shares as the Board of Directors determines. With respect to options granted under the 2003 Plan, the term of options may not exceed 10 years. In no event may an employee receive awards for more than 1 million shares under the 2003 Plan in any fiscal year.

2003 Directors' Stock Option Plan

A total of 90,909 shares of common stock have been reserved for issuance under the Amended and Restated 2003 Directors' Stock Option Plan (2003 Directors' Plan) as of December 31, 2004. In January 2005, the Board of Directors increased the number of shares reserved for issuance under the 2003 Directors' Plan by 350,000 shares. Under the 2003 Directors' Plan, each non-employee director who first becomes a non-employee director after the effective date of the plan will receive an automatic initial grant of an option to purchase 10,000 shares of common stock upon becoming a member of the Board of Directors. On the date of each annual meeting of stockholders, each non-employee director will be granted an option to purchase 10,000 shares of common stock if, on such a date, the director has served on the Board of Directors for at least six months. Additionally, the chairman of each committee of the Board of Directors and each member of the audit committee will receive an additional annual option grant to purchase 2,500 shares of common stock. The 2003 Directors' Plan provides that each option granted to a non-employee director shall vest in equal monthly installments over two years. All options granted under the 2003 Directors' Plan have a term of 10 years and an exercise price equal to the fair market value on the date of the grant.

A summary of stock option activity and related information follows:

YEARS ENDED DECEMBER 31,	2002		2003		2004	
	Options	Weighted average exercise price	Options	Weighted average exercise price	Options	Weighted average exercise price
Outstanding at beginning of period	341,858	\$ 2.92	610,489	\$ 4.24	717,615	\$ 4.48
Granted with an exercise price equal to the fair value of common stock	126,853	5.50	—	—	718,407	3.50
Granted with an exercise price less than the fair value of common stock	229,641	5.50	225,470	5.45	80,452	5.50
Canceled	(86,641)	4.29	(95,587)	5.34	(10,009)	5.59
Exercised	(1,222)	1.98	(22,757)	3.69	(44,940)	1.26
Outstanding at end of period	610,489	\$ 4.24	717,615	\$ 4.48	1,461,525	\$ 4.15

The following summarizes information about stock options outstanding and exercisable at December 31, 2004:

Range of exercise price	Number of options	Outstanding weighted average remaining contractual life (years)	Weighted average exercise price	EXERCISABLE	
				Number of options	Weighted average exercise price
\$0.55 – \$1.65	78,876	4.07	\$ 0.83	78,876	\$ 0.83
\$2.09 – \$2.75	498,627	9.49	2.17	51,407	2.30
\$3.36 – \$5.10	99,532	9.62	4.19	5,836	4.46
\$5.50 – \$6.54	784,490	8.21	5.73	304,741	5.58
	1,461,525	8.52	\$ 4.15	440,860	\$ 4.33

The number of options exercisable at December 31, 2002, 2003 and 2004 was 227,892, 328,831 and 440,860, respectively. The weighted average exercise price of options vested and exercisable at December 31, 2002, 2003 and 2004 was \$2.53, \$3.36 and \$4.33, respectively.

During the years ended December 31, 2002, 2003 and 2004, the Company granted options to purchase a total of 6,363, 10,908 and 11,630 shares of common stock, respectively, to consultants and Scientific Advisory Board members for services to be performed through April 2008. In accordance with SFAS 123 and EITF 96-18, options granted to consultants and Scientific Advisory Board members are recorded at fair value based on an option-pricing model and periodically revalued over the related service periods. The Company recorded stock compensation of \$65,000, \$360,000 and \$65,000 during the years ended December 31, 2002, 2003 and 2004, respectively, related to consulting services.

During the years ended December 31, 2002, 2003 and 2004, in connection with the grant of certain options to employees, the Company recorded deferred stock compensation of \$3.2 million, \$2.4 million and \$810,000, respectively, representing the difference between the exercise price and the subsequently determined fair value of the Company's common stock on the date such stock options were granted. The deferred compensation relates to options granted prior to the Company's completion of its initial public offering in March 2004. The subsequently determined fair value of the Company's common stock ranged from \$5.50 to \$21.01 during the year ended December 31, 2002, ranged from \$5.50 to \$18.59 during the year ended December 31, 2003 and ranged from \$8.00 to \$15.57 during the period from January 1, 2004 to March 16, 2004 (the effective date of the Company's initial public offering Registration Statement on Form S-1). All options granted subsequent to the Company's completion of its initial public offering have been granted with an exercise price equal to the fair value of the underlying common stock on the date of grant. Deferred stock compensation is being amortized on a graded vesting method. During the years ended December 31, 2002, 2003 and 2004, the Company recorded non-cash deferred stock compensation expense related to employees of \$2.5 million, \$1.3 million and \$2.1 million, respectively.

2003 Employee Stock Purchase Plan

A total of 109,090 shares of common stock have been reserved for issuance under the 2003 Employee Stock Purchase Plan (2003 Employee Plan). The number of shares reserved for issuance under the 2003 Employee Plan will be increased on the first day of each of the fiscal years in 2005 to 2010 by the lesser of 54,545 shares, 1% of the number of outstanding shares of common stock on the last day of the immediately preceding fiscal year or such lesser number of shares as the Board of Directors determines. Unless terminated earlier by the Board of Directors, the 2003 Employee Plan will terminate in September 2023. In 2004, 5,108 shares were issued under the 2003 Employee Plan at \$1.93 per share.

9. COMMON STOCK

Initial public offering

On March 19, 2004, the Company completed an initial public offering, which, after deducting underwriting discounts and offering-related expenses, resulted in net proceeds to the Company of approximately \$29.7 million and issuance by the Company of 4,200,000 shares of common stock. In connection with the initial public offering, all of the outstanding shares of the Company's redeemable convertible preferred stock and all of its outstanding convertible promissory notes, including interest accrued thereon through the closing date of the offering, were converted into 6,781,814 and 1,357,357 shares of common stock, respectively. Concurrent with the initial public offering, certain redeemable convertible preferred stock warrants were converted into common stock through payment of cash and cashless exercises, resulting in the issuance of 896,235 shares of common stock. In addition, the Company filed an Amended and Restated Certificate of Incorporation to amend the number of authorized shares of common stock to 100,000,000 and the authorized shares of preferred stock to 5,000,000.

Stock split

On March 4, 2004, the Company effected a 2 for 11 reverse stock split of the outstanding common and preferred stock and stock options and warrants. All share and per share amounts reflect the reverse stock split.

Common stock reserved for future issuance at December 31, 2004 is as follows:

DESCRIPTION	
1996 Stock Option Plan	
Options granted and outstanding	948,369
Options reserved for future grant	5,422
2003 Stock Plan	
Options granted and outstanding	503,156
Options reserved for future grant	133,207
2003 Directors Stock Option Plan	
Options granted and outstanding	10,000
Options reserved for future grant	80,909
2003 Employee Stock Purchase Plan	103,982
Convertible preferred stock	8,850,280
Make-whole dividend payments of common stock on convertible preferred stock	1,871,831
Common stock warrants	46,607
	12,553,763

Milestone pool

Pursuant to a business acquisition prior to January 1, 1999, the Company reserved 287,698 shares of common stock (Milestone Pool) for the Company's possible acquisition of new technology from the scientific founders of the acquired business. During the year ended December 31, 2001, the Milestone Pool was terminated. In exchange for the termination of all rights to the remaining Milestone Pool shares, these scientific founders entered in consulting agreements and were granted options to purchase a total of 68,178 shares of the Company's common stock. The options vest in equal monthly installments over the four-year consulting term and will be periodically revalued and recognized as expense over the related service period based on the estimated fair value of the options using an options-pricing model. During the years ended December 31, 2002, 2003 and 2004, the Company recorded stock-based compensation of \$30,000, \$132,000 and \$24,000, respectively.

Common stock warrants

The Company has issued warrants to purchase shares of common stock, to private investors in connection with the issuance of preferred stock. During the year ended December 31, 2003, the Company issued warrants to purchase 13,635 shares of common stock in connection with a consulting arrangement. Concurrent with the Company's initial public offering in March 2004, all 907,316 outstanding common stock warrants existing immediately prior to the closing of the offering were converted into common stock through payment of cash and cashless exercises, resulting in the issuance of 873,002 shares of common stock. Also concurrent with the initial public offering, certain preferred stock warrants that did not expire at the closing of the offering were automatically converted into common stock warrants. At December 31, 2004, warrants to purchase 46,607 shares of common stock remain outstanding with a weighted average exercise price of \$7.94 per share. These warrants expire at various dates from July 2006 to February 2009.

9. INCOME TAXES

At December 31, 2004, the Company had operating loss carryforwards of approximately \$97.5 million and research and development tax credit carryforwards of \$3.9 million for federal income tax reporting purposes. The net operating losses and tax credits will expire beginning in 2011 if not previously utilized. In certain circumstances, as specified under Section 382 of the Internal Revenue Code of 1986, as amended, due to ownership changes, the Company's ability to utilize its net operating loss carryforwards may be limited.

Deferred income taxes reflect the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. The significant components of deferred taxes are as follows (in thousands):

DECEMBER 31,	2003	2004
Deferred tax assets:		
Net operating loss carryforwards	\$ 25,147	\$ 33,151
Research and development tax credit	3,195	3,947
License agreements	242	479
Other	309	444
	<u>28,893</u>	<u>38,021</u>
Less valuation allowance	(28,743)	(37,826)
Net deferred tax assets	150	195
Deferred tax liabilities:		
Depreciation	(150)	(195)
Net deferred taxes	<u>\$ —</u>	<u>\$ —</u>

A valuation allowance has been recorded for deferred tax assets because realization is primarily dependent on generating sufficient taxable income prior to the expiration of net operating loss carryforwards. The valuation allowance for deferred tax assets increased \$6.1 million and \$9.1 million during the years ended December 31, 2003 and 2004, respectively, principally due to net operating losses recorded during those periods. There have been no offsets or other deductions to the valuation allowance in any period since the Company's inception.

10. CONVERTIBLE PROMISSORY NOTES

In October 2003, the Company issued Convertible Promissory Notes (the Notes) for \$12.7 million, with interest on the unpaid principal amount of the Notes accruing annually at a rate of 6 percent. The Notes (including accrued and unpaid interest) automatically converted into 1,357,357 shares of the Company's common stock upon the closing of the Company's initial public offering.

In connection with the issuance of the Notes, the holders of the Notes received warrants to purchase 207,977 shares of the Company's Series F preferred stock at \$15.29 per share, exercisable after the maturity date of the Notes, through 2008. As the Company's initial public offering occurred prior to the maturity date of the Notes and the closing of the next private financing, the warrants expired. The Company had allocated \$1.4 million of the proceeds to the warrants based on the relative fair values of the Notes and warrants (using the Black-Scholes option pricing model). The resulting \$1.4 million discount on the Notes was being amortized to interest expense over the term of the Notes. Through March 19, 2004 (the conversion date of the Notes), \$614,000 of the discount had been amortized to interest expense (\$299,000 during the year ended December 31, 2004). The unamortized discount of \$769,000 existing on the day of conversion was recognized as interest expense immediately upon conversion of the Notes.

Upon the Company's consummation of its initial public offering, and the Notes conversion to common stock, the Company also recognized \$11.3 million in additional interest expense, which represents the beneficial conversion feature of the Notes. This interest expense is in addition to the interest expense recognized associated with the unamortized discount existing on the date of conversion.

11. LONG-TERM OBLIGATIONS AND LEASE OBLIGATIONS

The Company has commitments for noncancelable operating leases for a manufacturing facility, building space and office equipment. The building lease includes rent escalation clauses (3% annually) and has two five-year renewal options. The manufacturing facility lease contains annual rent escalations of 4.5% and an option to renew the lease for two additional five-year periods. In addition to base rent, the Company is required to pay a pro rata share of the operating costs related to the manufacturing facility and building leased space. The Company was required to provide security under the manufacturing lease agreement totaling \$435,000 in the form of cash and issued a preferred stock warrant to the lessor.

The Company has financed the acquisition of laboratory and scientific equipment, furniture and fixtures, computer equipment and leasehold improvements through financing arrangements with various third parties. In connection with the financings, the Company has issued preferred stock warrants to the third parties. At December 31, 2004, the Company had two financing arrangements. Under the first arrangement, the Company may borrow up to \$3.0 million, subject to credit approval. At December 31, 2004, the Company has \$1.8 million available to it under this outstanding arrangement, which expires in July 2005. This agreement contains a subjective acceleration clause, whereby the events of default includes a material adverse change in the Company's financial condition that would materially impair the ability of the Company to perform its material obligations under the agreement, as determined solely, reasonably and in good faith by the

lender. Under the second arrangement, the Company may borrow up to \$3.0 million, subject to credit approval. At December 31, 2004, the Company has \$2.2 million available to it under the outstanding arrangement, which expires in December 2005. Outstanding borrowings under the current and previous financing arrangements were \$1.8 million and \$4.2 million at years ended December 31, 2003 and 2004, respectively. Outstanding borrowings require monthly principal and interest payments and mature at various dates through 2008. Interest rates applicable to the outstanding borrowings at December 31, 2004 range from 7.91% to 11.61%. The weighted average interest rates for borrowings outstanding during the years ended December 31, 2002, 2003 and 2004 were 11.09%, 10.27% and 8.99%, respectively. Borrowings are secured by the acquired assets that have a net book value of \$5.8 million at December 31, 2004. Under all agreements, the Company is required to comply with certain non financial covenants.

Future minimum payments under operating leases and equipment financing arrangements at December 31, 2004 are as follows (in thousands):

	EQUIPMENT FINANCINGS ARRANGEMENTS	OPERATING LEASES
Year ended December 31,		
2005	\$ 1,556	\$ 1,644
2006	1,441	1,471
2007	970	1,091
2008	305	1,126
2009	—	1,159
Thereafter	—	1,103
	<u>4,272</u>	<u>\$ 7,594</u>
Less unamortized discount		(39)
Less current portion		<u>(1,556)</u>
Long-term equipment obligations	<u>\$ 2,677</u>	

Rent expense totaled \$1.6 million, \$1.6 million and \$1.7 million during the years ended December 31, 2002, 2003 and 2004, respectively.

12. Net loss per share

The calculation of basic and diluted loss per share is shown on the table below (in thousands, except share and per share data).

Year ended December 31,	2002	2003	2004
Net loss	\$ (19,453)	\$ (18,457)	\$ (39,588)
Accretion of preferred stock	(8,001)	—	(8,973)
Net loss applicable to common stockholders	<u>\$ (27,454)</u>	<u>\$ (18,457)</u>	<u>\$ (48,561)</u>
Weighted average common shares	1,476,716	1,527,775	12,462,677
Weighted average common shares subject to repurchase	(56,961)	(39,557)	(22,296)
Weighted average number of shares used for basic and diluted per share amounts	<u>1,419,755</u>	<u>1,488,218</u>	<u>12,440,381</u>
Basic and diluted net loss per common share	<u>\$ (19.34)</u>	<u>\$ (12.40)</u>	<u>\$ (3.90)</u>

The Company has excluded all convertible exchangeable preferred stock, redeemable convertible preferred stock, redeemable convertible preferred stock warrants, convertible promissory notes, common stock warrants and outstanding stock options from the calculation of diluted net loss per common share because all securities are antidilutive for the periods presented. The total number of shares excluded from the calculations of diluted net loss per common share was 8,422,596, 9,880,023 and 10,358,400 for the years ended December 31, 2002, 2003 and 2004, respectively.

13. SUBSEQUENT EVENT

Restructuring

As a result of the Company's plan to limit clinical development primarily to the planned Phase II/III trial in CLL and planned Phase I/II trial in HIV, the Company reduced its workforce by approximately 24%, to 81 employees on March 22, 2005. The Company will record a charge in the first quarter of 2005 of approximately \$300,000, consisting of severance, benefits and outplacement services.

14. QUARTERLY FINANCIAL DATA (UNAUDITED)

The following table contains selected unaudited statement of operations information for each of the quarters in 2003 and 2004. The Company believes that the following information reflects all adjustments, consisting of only normal recurring adjustments, necessary for a fair presentation of the information for the periods presented. The operating results for any quarter are not necessarily indicative of results for any future period.

QUARTER ENDED	MARCH 31	JUNE 30	SEPTEMBER 30	DECEMBER 31
(in thousands, except per share data)				
2003				
Revenue	\$ 13	\$ 59	\$ 73	\$ 25
Net loss	\$ (3,843)	\$ (5,346)	\$ (3,975)	\$ (5,293)
Net loss attributable to common stockholders	\$ (3,843)	\$ (5,346)	\$ (3,975)	\$ (5,293)
Basic and diluted net loss per common share	\$ (2.60)	\$ (3.60)	\$ (2.67)	\$ (3.53)
2004				
Revenue	\$ 12	\$ 24	\$ 13	\$ 13
Net loss ⁽¹⁾	\$ (18,284)	\$ (6,086)	\$ (6,830)	\$ (8,388)
Net loss attributable to common stockholders ⁽²⁾	\$ (27,257)	\$ (6,086)	\$ (6,830)	\$ (8,388)
Basic and diluted net loss per common share ^{(1),(2)}	\$ (7.98)	\$ (0.41)	\$ (0.46)	\$ (0.50)

(1) Net loss for the quarter ended March 31, 2004 includes \$12.5 million in noncash interest expense associated with the convertible promissory notes.

(2) Net loss attributable to common stockholders for the quarter ended March 31, 2004 includes \$9.0 million in accretion of preferred stock.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

At the end of the period covered by this report, as part of our quarterly review, we evaluated, under the supervision and with the participation of the Company's management, including our Principal Executive Officer and Principal Financial and Accounting Officer, the effectiveness of the design and operation of our disclosure controls and procedures. Based upon that evaluation, the Principal Executive Officer and the Principal Financial and Accounting Officer concluded that our disclosure controls and procedures are effective to timely alert them to any material information relating to the Company that must be included in our periodic SEC filings. There have been no significant changes in the Company's internal controls or in other factors that could significantly affect internal controls subsequent to their evaluation.

ITEM 9B. OTHER INFORMATION

In December 2004, the compensation committee of our Board of Directors approved base salary increases for our Chief Executive Officer and each of our four other most highly compensated executive officers whose total salary and bonus exceeded \$100,000 (referred to in this report as the Named Executive Officers), where 50% of such increase was retroactive to September 1, 2004 and 50% of such increase was effective March 1, 2005, with the exception of our President and Chief Executive Officer, Dr. Ronald J. Berenson, who received 100% of his increase retroactive to September 1, 2004. As of March 1, 2005, the new salary for each of the Named Executive Officers is: Dr. Berenson: \$300,000; Dr. Stewart Craig: \$263,967; Dr. Robert Kirkman: \$249,600; Dr. Mark Frohlich: \$223,865; and Ms. Kathi L. Cordova: \$206,242. In addition, in December 2004, the compensation committee approved a one-time year-end bonus for Dr. Berenson in the amount of \$75,000.

In December 2004, the compensation committee of our Board of Directors approved option grants to the Named Executive Officers in connection with their 2004 compensation review, which vest over four years. Each of the Named Executive Officers received options in the following amounts: Dr. Berenson: 100,000 shares; Dr. Craig: 40,000 shares; Dr. Kirkman: 40,000 shares; Dr. Frohlich: 20,000 shares; and Ms. Cordova: 20,000 shares.

In January 2005, the Board of Directors approved additional option grants to the Named Executive Officers in connection with their 2004 compensation review, which vest upon the meeting of certain Company milestones, provided that 100% of such options vest upon the four-year anniversary of the date of grant if such milestones are not earlier met. This milestones-based vesting provides that 50% of the shares vest based on certain clinical trial-related goals, 25% of the shares vest based on the consummation of certain corporate transactions, and 25% of the shares vest based on the achievement of FDA-related goals. Each of the Named Executive Officers received options with such vesting parameters in the following amounts: Dr. Berenson: 100,000 shares; Dr. Craig: 40,000 shares; Dr. Kirkman: 40,000 shares; Dr. Frohlich: 20,000 shares; and Ms. Cordova: 20,000 shares.

PART III

The information required by Part III is omitted from this report because the Company will file a definitive proxy statement within 120 days after the end of its fiscal year pursuant to Regulation 14A for its annual meeting of shareholders to be held on June 9, 2005, and the information to be included in the proxy statement is incorporated herein by reference.

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

The information required by this item is incorporated herein by reference from the Company's definitive proxy statement which will be filed within 120 days after the end of the Company's 2004 fiscal year pursuant to Regulation 14A for its annual meeting of shareholders to be held June 17, 2005.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated herein by reference from the Company's definitive proxy statement which will be filed within 120 days after the end of the Company's 2004 fiscal year pursuant to Regulation 14A for its annual meeting of shareholders to be held June 17, 2005.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The information required by this item is incorporated herein by reference from the Company's definitive proxy statement which will be filed within 120 days after the end of the Company's 2004 fiscal year pursuant to Regulation 14A for its annual meeting of shareholders to be held June 17, 2005.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information required by this item is incorporated herein by reference from the Company's definitive proxy statement which will be filed within 120 days after the end of the Company's 2004 fiscal year pursuant to Regulation 14A for its annual meeting of shareholders to be held June 17, 2005.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this item is incorporated herein by reference from the Company's definitive proxy statement which will be filed within 120 days after the end of the Company's 2004 fiscal year pursuant to Regulation 14A for its annual meeting of shareholders to be held June 17, 2005.

Part IV

Item 15. Exhibits and Financial Statement Schedules

(a) Documents filed as part of this report are as follows:

- (1) Financial Statements and Report of Independent Registered Public Accounting Firm
See Index to Financial Statements included under Item 8 in Part II of this Annual Report on Form 10-K.
- (2) Financial Statement Schedules
None required.
- (3) Exhibits
Exhibits are incorporated herein by reference or are filed with this report as indicated below.

EXHIBIT NUMBER	DESCRIPTION
3.1(1)	Amended and Restated Certificate of Incorporation of Xcyte Therapies, Inc.
3.2(1)	Amended and Restated Bylaws of Xcyte Therapies, Inc.
3.3(6)	Preferred Stock Certificate of Designations.
4.1(1)	Form of Common Stock Certificate.
4.2(6)	Preferred Stock Certificate of Designations.
4.3(7)	Indenture.
4.4(4)	Form of Preferred Stock Certificate.
10.1(1)	Form of Indemnification Agreement between Xcyte Therapies, Inc. and each of its officers and directors.
10.2(1)	Convertible Note and Warrant Purchase Agreement dated October 9, 2003.
10.3(1)	Form of Convertible Promissory Note issued in connection with the Convertible Note and Warrant Purchase Agreement dated October 9, 2003.
10.4(1)	Amended and Restated Investor Rights Agreement dated February 5, 2002.
10.5(1)	Amendment to Amended and Restated Investor Rights Agreement dated May 22, 2002.
10.6(1)	Waiver of Preemptive Rights and Amendment to Amended and Restated Investor Rights Agreement dated October 9, 2003.
10.7(1)	Form of Warrant to purchase Common Stock issued by Xcyte Therapies, Inc.
10.8(1)	Form of Warrant to purchase Series F Preferred Stock issued by Xcyte Therapies, Inc. in favor of General Electric Capital Corporation.
10.9(1)	Master Security Agreement between Xcyte Therapies, Inc. and Oxford Finance Corporation dated July 1, 2003.
10.10(1)	Senior Loan and Security Agreement dated July 1, 1999 between Xcyte Therapies, Inc. and Phoenix Leasing Incorporated.
10.11(4)	Master Security Agreement dated May 1, 2000 between Xcyte Therapies, Inc. and General Electric Capital Corporation.
10.12(4)	Amendment No. 1 to Master Security Agreement dated May 1, 2000 between Xcyte Therapies, Inc. and General Electric Capital Corporation.
10.13(4)	Amendment No. 2 to Master Security Agreement dated August 18, 2004 between Xcyte Therapies, Inc. and General Electric Capital Corporation.
10.14(1)	Facility Lease dated June 21, 1999 between Xcyte Therapies, Inc. and Alexandria Real Estate Equities, Inc.
10.15(1)	First Amendment to Lease dated October 23, 2001 to Lease dated June 21, 1999 between Xcyte Therapies, Inc. and Alexandria Real Estate Equities, Inc.
10.16(1)	Second Amendment to Lease dated March 26, 2003 to Lease dated June 21, 1999 between Xcyte Therapies, Inc. and Alexandria Real Estate Equities, Inc.
10.17(1)	Third Amendment to Lease dated November 12, 2003 to Lease dated June 21, 1999 between Xcyte Therapies, Inc. and Alexandria Real Estate Equities, Inc.

EXHIBIT NUMBER	DESCRIPTION
10.18(1)	Facility Lease dated December 7, 2000 between Xcyte Therapies, Inc. and Hibbs/Woodinville Associates, LLC.
10.19(1)	Amended and Restated 1996 Stock Option Plan.
10.20(4)	Form of Notice of Option Grant and Agreement for 1996 Stock Option Plan.
10.21(1)	2003 Stock Plan.
10.22(4)	Form of Notice of Stock Option Grant and Agreement for 2003 Stock Plan.
10.23(1)	2003 Employee Stock Purchase Plan.
10.24(4)	Amended and Restated 2003 Directors' Stock Option Plan.
10.25(4)	Form of Notice of Stock Option Grant and Agreement for 2003 Directors' Stock Option Plan.
10.26(1)†	License and Supply Agreement dated October 15, 1999 between Xcyte Therapies, Inc. and Diaclone S.A., as amended.
10.27(1)†	First Amendment to License and Supply Agreement dated August 15, 2000 between Xcyte Therapies, Inc. and Diaclone S.A., as amended.
10.28(1)†	Development and Supply Agreement dated August 1, 1999 between Xcyte Therapies, Inc. and Dynal S.A.
10.29(2)†	Amendment to Development and Supply Agreement dated March 26, 2004 between Xcyte Therapies, Inc. and Dynal S.A.
10.30(1)†	License Agreement dated July 8, 1998 between Xcyte Therapies, Inc. and Genetics Institute, Inc.
10.31(1)†	First Amendment to License Agreement dated April 10, 2003 between Xcyte Therapies, Inc. and Genetics Institute, Inc.
10.32(1)†	Non-Exclusive License Agreement dated October 20, 1999 between Xcyte Therapies, Inc. and the Fred Hutchinson Cancer Research Center, as amended.
10.33(1)†	Services Agreement dated June 6, 2000 between Xcyte Therapies, Inc. and Lonza Biologics PLC.
10.34(1)†	Amendment No. 1 dated January 10, 2001 to the Services Agreement dated June 6, 2000 between Xcyte Therapies, Inc. and Lonza Biologics PLC.
10.35(1)†	Amendment No. 2 dated April 18, 2001 to the Services Agreement dated June 6, 2000 between Xcyte Therapies, Inc. and Lonza Biologics PLC.
10.36(1)†	Amendment No. 3 dated August 26, 2002 to the Services Agreement dated June 6, 2000 between Xcyte Therapies, Inc. and Lonza Biologics PLC.
10.37(1)†	Amendment No. 4 dated September 30, 2002 to the Services Agreement dated June 6, 2000 between Xcyte Therapies, Inc. and Lonza Biologics PLC.
10.38(1)†	Amendment No. 5 dated August 5, 2003 to the Services Agreement dated June 6, 2000 between Xcyte Therapies, Inc. and Lonza Biologics PLC.
10.39(4)†	Amendment No. 6 dated August 2, 2004 to the Services Agreement dated June 6, 2000 between Xcyte Therapies, Inc. and Lonza Biologics PLC.
10.40(1)†	Services Agreement dated June 6, 2000 between Xcyte Therapies, Inc. and Lonza Biologics PLC.
10.41(1)†	Amendment No. 2 dated August 26, 2002 to the Services Agreement dated June 6, 2000 between Xcyte Therapies, Inc. and Lonza Biologics PLC.
10.42(1)†	Amendment No. 3 dated August 5, 2003 to the Services Agreement dated June 6, 2000 between Xcyte Therapies, Inc. and Lonza Biologics PLC.
10.43(4)†	Amendment No. 4 dated August 2, 2004 to the Services Agreement dated June 6, 2000 between Xcyte Therapies, Inc. and Lonza Biologics PLC.
10.44(1)†	Collaboration Agreement dated November 14, 2003 between Xcyte Therapies, Inc. and Fresenius Biotech GmbH.
10.45(1)	Employment Agreement between Xcyte Therapies, Inc. and Mark Frohlich, M.D. dated as of August 27, 2001.
10.46(1)	Employment Agreement between Xcyte Therapies, Inc. and Joanna Lin Black, J.D. dated as of December 31, 2001.
10.47(1)	Employment Agreement between Xcyte Therapies, Inc. and Robert L. Kirkman dated as of January 15, 2004.
10.48(3)	Employment Agreement between Xcyte Therapies, Inc. and Larry Romel dated as of June 14, 2004.

EXHIBIT NUMBER	DESCRIPTION
10.49(2)	Xcyte Therapies, Inc. Code of Business Conduct and Ethics.
10.50(5)†	Amendment No. 7 dated October 7, 2004 to the Services Agreement dated June 6, 2000 between Xcyte Therapies, Inc. and Lonza Biologics PLC.
10.51(5)†	Amendment No. 5 dated October 7, 2004 to the Services Agreement dated June 6, 2000 between Xcyte Therapies, Inc. and Lonza Biologics PLC.
23.1	Consent of Independent Registered Public Accounting Firm
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a).
31.2	Certification of Principal Financial and Accounting Officer pursuant to Rule 13a-14(a).
32.1	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350.
32.2	Certification of Principal Financial and Accounting Officer pursuant to 18 U.S.C. Section 1350.

-
- (1) Previously filed as an exhibit to registrant's registration statement on Form S-1, File No. 333-109653, originally filed with the Commission on October 10, 2003, as subsequently amended, and incorporated herein by reference.
 - (2) Previously filed as an exhibit to registrant's quarterly report on Form 10-Q filed with the Commission on May 17, 2004.
 - (3) Previously filed as an exhibit to registrant's quarterly report on Form 10-Q filed with the Commission on August 16, 2004.
 - (4) Previously filed as an exhibit to registrant's registration statement on Form S-1, File No. 333-119585, originally filed with the Commission on October 7, 2004, as subsequently amended, and incorporated herein by reference.
 - (5) Previously filed as an exhibit to registrant's current report on Form 8-K filed with the Commission on October 8, 2004.
 - (6) Previously filed as an exhibit to registrant's current report on Form 8-K filed with the Commission on November 5, 2004.
 - (7) Previously filed as an exhibit to registrant's quarterly report on Form 10-Q filed with the Commission on November 15, 2004.
 - † Certain information in these exhibits has been omitted and filed separately with the Commission pursuant to a confidential treatment request under 17 C.F.R. Sections 200.80(b)(4), 200.83 and 230.406.

SIGNATURES

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

XCYTE THERAPIES, INC.

By: /s/ RONALD J. BERENSON

Ronald J. Berenson
President and Chief Executive Officer

Date: March 31, 2005

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

<u>SIGNATURE</u>	<u>TITLE</u>	<u>DATE</u>
By: /s/ RONALD J. BERENSON <hr/> Ronald J. Berenson	President, Chief Executive Officer and Director (Principal Executive Officer)	March 31, 2005
By: /s/ KATHI L. CORDOVA <hr/> Kathi L. Cordova	Senior Vice President of Finance and Treasurer (Principal Financial and Accounting Officer)	March 31, 2005
By: /s/ STEPHEN N. WERTHEIMER, M.M. <hr/> Stephen N. Wertheimer, M.M.	Director	March 31, 2005
By: /s/ JEAN DELEAGE, PH.D. <hr/> Jean Deleage, Ph.D.	Director	March 31, 2005
By: /s/ PETER LANGECKER, M.D., PH.D. <hr/> Peter Langecker, M.D., Ph.D.	Director	March 31, 2005
By: /s/ ROBERT T. NELSEN <hr/> Robert T. Nelsen	Director	March 31, 2005
By: /s/ ROBERT M. WILLIAMS, PH.D. <hr/> Robert M. Williams, Ph.D.	Director	March 31, 2005
By: /s/ DANIEL R. SPIEGELMAN <hr/> Daniel R. Spiegelman	Director	March 31, 2005
By: /s/ CHRISTOPHER S. HENNEY, PH.D. <hr/> Christopher Henney, Ph.D.	Director	March 31, 2005

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statement on (Form S-8 No. 333-113753) of Xcyte Therapies, Inc. and in the related Prospectus of our report dated March 30, 2005, with respect to the financial statements of Xcyte Therapies, Inc. included in this Annual Report (Form 10-K) for the year ended December 31, 2004.

/s/ Ernst & Young LLP

Seattle, Washington
March 31, 2005

CERTIFICATION PURSUANT TO SECTION 302

CERTIFICATION

I, Dr. Ronald J. Berenson, certify that:

1. I have reviewed this annual report on Form 10-K of Xcyte Therapies, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) [Paragraph omitted pursuant to SEC Release 33-8238.];
 - (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):
 - (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 31, 2005

/s/ Dr. Ronald J. Berenson

Dr. Ronald J. Berenson
President, Chief Executive Officer and Director
(Principal Executive Officer)

CERTIFICATION PURSUANT TO SECTION 302

CERTIFICATION

I, Kathi L. Cordova, certify that:

1. I have reviewed this annual report on Form 10-K of Xcyte Therapies, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and we have:
 - (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) [Paragraph omitted pursuant to SEC Release 33-8238.];
 - (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):
 - (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 31, 2005

/s/ Kathi L. Cordova

Kathi L. Cordova
Senior Vice President of Finance and Treasurer
(Principal Financial and Accounting Officer)

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of Xcyte Therapies, Inc. (the "Company") on Form 10-K for the year ended December 31, 2004, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Dr. Ronald J. Berenson, Principal Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Signature: /s/ Dr. Ronald J. Berenson

Dr. Ronald J. Berenson
President, Chief Executive Officer and Director
(Principal Executive Officer)

Dated: March 31, 2005

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of Xcyte Therapies, Inc. (the "Company") on Form 10-K for the year ended December 31, 2004, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Kathi L. Cordova, Principal Financial and Accounting Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Signature: /s/ Kathi L. Cordova

Kathi L. Cordova
Senior Vice President of Finance and Treasurer
(Principal Financial and Accounting Officer)

Dated: March 31, 2005