

XCYTE THERAPIES INC
Form S-1/A
March 16, 2004
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As filed with the Securities and Exchange Commission on March 16, 2004

Registration No. 333-109653

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

AMENDMENT NO. 5

TO

FORM S-1

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

XCYTE THERAPIES, INC.

(Exact name of Registrant as specified in its charter)

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

2834
(Primary Standard Industrial
Classification Code Number)

91-1707622
(I.R.S. Employer
Identification Number)

1124 Columbia Street, Suite 130

Seattle, Washington 98104

(206) 262-6200

(Address, including zip code, and telephone number, including

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(area code, of registrant's principal executive offices)

Ronald J. Berenson, M.D.

President and Chief Executive Officer

Xcyte Therapies, Inc.

1124 Columbia Street, Suite 130

Seattle, Washington 98104

(206) 262-6200

(Name, address, including zip code, and telephone number,
including area code, of agent for service)

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Approximate date of commencement of proposed sale to the public: As soon as practicable after the Registration Statement becomes effective.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. "

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. " _____

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. " _____

If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. " _____

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box. "

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until this registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

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This information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and we are not soliciting offers to buy these securities in any state where the offer or sale is not permitted.

Subject to completion, dated March 16, 2004

PRELIMINARY PROSPECTUS

4,000,000 Shares

**XCYTE THERAPIES, INC.
Common Stock**

\$ per share

-
- Issuer Xcyte Therapies Inc. is offering 4,000,000 shares.
 - This is our initial public offering and no public market currently exists for our shares.
 - We anticipate that the initial public offering price will be \$8.00 per share.
 - Proposed trading symbol: Nasdaq National Market XCYT

This investment involves risk. See Risk Factors beginning on page 10.

	<u>Per Share</u>	<u>Total</u>
Public offering price	\$	\$
Underwriting discount	\$	\$
Proceeds, before expenses, to Xcyte Therapies, Inc.	\$	\$

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The underwriters have a 30-day option to purchase up to 600,000 additional shares of common stock from us to cover over-allotments, if any.

Neither the Securities and Exchange Commission nor any state securities commission has approved of anyone's investment in these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

Piper Jaffray

RBC Capital Markets

Wells Fargo Securities, LLC

JMP Securities

The date of this prospectus is .

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You should rely only on the information contained in this prospectus. We have not, and the underwriters have not, authorized any other person to provide you with different information. This prospectus is not an offer to sell, nor is it seeking an offer to buy, these securities in any state where the offer or sale is not permitted. The information in this prospectus is complete and accurate as of the date on the front cover, but the information may have changed since that date.

Through and including _____, 2004, federal securities laws may require all dealers that effect transactions in our common stock, whether or not participating in this offering, to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

Xcyte™, Xcyte Therapies™, Xcellerate™ and Xcellerated T Cells™ are trademarks of Xcyte Therapies, Inc. All other trademarks appearing in this prospectus are the property of their respective holders.

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PROSPECTUS SUMMARY

This summary highlights selected information appearing elsewhere in this prospectus. While this summary highlights what we consider to be the most important information about us, you should carefully read this prospectus and the registration statement of which this prospectus is a part in their entirety before making an investment decision, especially the risks of investing in our common stock, which we discuss under Risk factors beginning on page 10, and our financial statements and related notes beginning on page F-1.

Unless the context requires otherwise, the words Xcyte, we, company, us and our refer to Xcyte Therapies, Inc.

Our Business

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. 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 plan to submit these findings to the FDA for review in our 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.

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 not been randomized nor double-blinded to ensure that the results are due to the effects of the Xcellerated Technology. Success in early clinical trials does not ensure that large-scale trials will be successful nor does it predict final results. 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 10 of 11 patients evaluated to date. In addition, there was a 50% or greater reduction in spleen size as measured below the rib cage by physical examination in all 10 of the patients with enlarged spleens. We plan to submit these findings to the FDA for review in our annual report.
- **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 32 patients evaluated to date with multiple myeloma following treatment with high-dose chemotherapy and transplantation with the patient's own stem cells, known as autologous stem cell

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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 results on the first 25 patients evaluated for tumor responses in our clinical trial have documented, in

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the majority of patients, a greater than 90% decrease in the tumor marker, which is used to measure disease. We have not yet submitted these data to the FDA and 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 have also recently initiated 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. Based on a September 2003 report of the results of this trial in the peer-reviewed journal, *Blood*, 8 out of these 16 patients with a very poor prognosis were still alive with a median followup of 33 months. These data were derived from an independent clinical trial, which we did not control and which were 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 plan to initiate a Phase II clinical trial in the first half of 2004 in patients with non-Hodgkin's lymphoma who have failed prior therapies.
- ***Kidney cancer.*** In our completed Phase I clinical trial in 25 patients with metastatic kidney cancer, treatment with Xcellerated T Cells and low doses of the T cell activating agent, interleukin-2, or IL-2, led to a median survival of 21 months. The results of this study were published in a peer-reviewed journal, *Clinical Cancer Research*, in September 2003, and have been submitted to the FDA for review. Previous independent clinical studies have demonstrated median survival of patients with metastatic kidney cancer of approximately 12 months.
- ***Prostate cancer.*** In our recently completed Phase I/II clinical trial in prostate cancer, treatment with Xcellerated T Cells led to greater than 50% decreases in the serum tumor marker, prostate specific antigen, or PSA, in 2 out of 19 patients. We have not yet submitted these findings to the FDA. In some independent clinical studies, decreases in PSA levels have been shown to correlate with increased patient survival.
- ***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 were 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. In addition, Fresenius Biotechnology GmbH initiated a Phase I clinical trial under our collaboration to treat HIV patients with genetically-modified T cells produced using our Xcellerate Technology.

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Our Solution

We have developed our proprietary Xcellerate Technology, which consistently activates and grows large numbers of T cells *ex vivo*, or outside of the body, for multiple potential therapeutic applications.

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 a 100-fold to 300-fold increase in T cells during the manufacturing process. These results were published in the peer-reviewed *BioProcessing Journal* in November 2003 and have been submitted to the FDA for review.
- ***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.*** Xcellerated T Cells have been documented to produce a broad spectrum of chemical messengers, including cytokines and other molecules required to generate an effective immune response. We have submitted these findings to the FDA for review.
- ***Broadened T cell diversity.*** We have observed the generation of T cells with a broad diversity of T cell receptors using our Xcellerate Technology and have submitted such findings to the FDA for review. A broad diversity of T cell receptors is important to enable the immune system to recognize and eliminate a wide variety of cancers and infectious diseases.
- ***Favorable side effect profile.*** There have been over 115 infusions of Xcellerated T Cells given to more than 90 patients to date in Xcyte-sponsored clinical trials. We have observed few side effects in most patients. Side effects have generally been minor, consisting primarily of fever, chills and nausea associated with the infusions. To date we have had only two serious adverse events that were judged as possibly or probably related to our technology, both of which resolved following 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.
- ***Complementary to other therapies.*** We believe that Xcellerated T Cells may be complementary to current therapies, such as chemotherapy, radiation and monoclonal antibodies.

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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 outside of the body 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 that our Xcellerate Technology can be applied to a variety of medical conditions, including many types of cancer and infectious diseases.
- ***Ease of administration.*** Xcellerated T Cells are administered in approximately two hours using a routine intravenous procedure in an outpatient clinic.
- ***Reproducible and cost-effective manufacturing.*** We use a 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.

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 and other medical conditions associated with weakened immune systems. We plan to initially develop Xcellerated T Cells to treat life-threatening diseases, such as cancer and HIV, which currently have inadequate treatments. Key elements of our strategy include the following:

- ***Maximize speed to market.***
- ***Expand the therapeutic applications of Xcellerated T Cells.***
- ***Leverage complementary technologies and therapies.***
- ***Retain selected U.S. commercialization rights in cancer.***
- ***Enhance our manufacturing capabilities.***
- ***Expand and enhance our intellectual property.***

Risks Associated With Our Business

We are a development stage company. We are subject to numerous risks and obstacles and we have highlighted the most important of them in Risk factors beginning on page 10. In particular, we have a limited operating history and have incurred losses in each fiscal year since our inception. We incurred net losses of approximately \$18.5 million for the year ended December 31, 2003, and our deficit accumulated during the development stage was approximately \$86.6 million as of December 31, 2003. We have no commercial products for sale, and we anticipate that we will incur substantial and increasing losses over the next several years as we expand our research, development and clinical trial activities, acquire or license technologies, scale up and improve our manufacturing operations, seek regulatory approval and, if we receive FDA approval, commercialize our products. Because of the numerous risks and uncertainties associated with our product development efforts, we are unable to predict whether or when we will achieve profitability. 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 not been randomized nor double-blinded to ensure that the results are due to the effects of the Xcellerate Technology. The results

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reported are preliminary and success in early clinical trials does not ensure that large-scale trials will be successful nor does it predict final results.

Our Corporate Information

We were incorporated in Delaware as MolecuRx, Inc. in January 1996. We changed our name to CDR Therapeutics, Inc. in August 1996 and changed our name to Xcyte Therapies, Inc. in October 1997. Our principal executive offices are located at 1124 Columbia Street, Suite 130, Seattle, Washington 98104, and our telephone number is (206) 262-6200. Our web site address is *www.xcytetherapies.com*. The information contained on our web site is not incorporated by reference into and does not form any part of this prospectus.

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THE OFFERING

Common stock we are offering	4,000,000 shares
Common stock to be outstanding after the offering	14,572,206 shares
Offering price	\$8.00 per share
Use of proceeds	We expect to use the net proceeds from this offering to fund clinical trial activities, manufacturing and preclinical research and development activities and for other general corporate purposes, including capital expenditures, complementary technology acquisition and working capital to fund anticipated operating losses. See Use of proceeds.
Proposed Nasdaq National Market symbol	XCYT

The number of shares of our common stock outstanding after this offering is based on 10,572,206 shares of our common stock outstanding as of January 31, 2004, after giving effect to:

- the conversion of all 6,781,814 shares of our preferred stock outstanding as of January 31, 2004 into 6,781,814 shares of our common stock, which will become effective at the closing of this offering;
- the net exercise of warrants outstanding as of January 31, 2004, which will expire at the closing of this offering, to purchase 907,316 shares of our common stock at a weighted average exercise price of \$0.30 per share, resulting in the issuance of 873,764 shares of common stock, assuming an initial public offering price of \$8 per share;
- the conversion of shares of our preferred stock issuable upon the net exercise of warrants outstanding as of January 31, 2004, which will expire at the closing of this offering, to purchase 66,983 shares of our preferred stock at a weighted average exercise price of \$5.23 per share, resulting in the issuance of 23,233 shares of common stock, assuming an initial public offering price of \$8 per share; and
- the conversion of convertible promissory notes issued in October 2003 for net proceeds of approximately \$12.7 million, into approximately 1,346,771 shares of our common stock, which includes the conversion of approximately \$242,000 in accrued interest as of January 31, 2004.

The number of shares of our common stock outstanding immediately after this offering excludes:

- 46,607 shares of our common stock issuable upon the exercise of warrants outstanding as of January 31, 2004 at a weighted average exercise price of \$7.94 per share;
- 19,744 shares of our preferred stock issuable upon the exercise of warrants outstanding as of January 31, 2004 at a weighted average exercise price of \$14.60 per share, which will expire at the closing of this offering;

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- 798,068 shares of our common stock issuable upon the exercise of stock options outstanding as of January 31, 2004 under our 1996 Stock Option Plan at a weighted average exercise price of \$4.58 per share;
- 198,238 shares of our common stock reserved for future issuance under our 1996 Stock Option Plan; and

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- 636,363 shares of our common stock reserved for future issuance under our 2003 Stock Plan, 109,090 shares of our common stock reserved for future issuance under our 2003 Employee Stock Purchase Plan and 90,909 shares of our common stock reserved for future issuance under our 2003 Directors' Stock Option Plan, as of January 31, 2004.

Unless otherwise indicated, all information in this prospectus assumes the underwriters do not exercise their option to purchase up to 600,000 additional shares of our common stock to cover over-allotments, if any.

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The following summary financial data for the years ended December 31, 1999 through 2003 have been derived from our audited financial statements. This information is only a summary and should be read together with the financial statements and the notes to those statements appearing elsewhere in this prospectus and the information under Selected financial data and Management's discussion and analysis of financial condition and results of operations.

	Years ended December 31,				
	1999	2000	2001	2002	2003
	(in thousands, except per share data)				
Statement of Operations Data					
Total revenue	\$ 16	\$ 98	\$ 30	\$	\$ 170
Operating expenses:					
Research and development	5,471	11,257	14,701	14,663	13,685
General and administrative	1,654	2,403	5,204	4,979	4,322
Total operating expenses	7,125	13,660	19,905	19,642	18,007
Loss from operations	(7,109)	(13,562)	(19,875)	(19,642)	(17,837)
Other income (expense), net	162	621	363	189	(620)
Net loss	(6,947)	(12,941)	(19,512)	(19,453)	(18,457)
Accretion of preferred stock			(8,411)	(8,001)	
Net loss applicable to common stockholders	\$ (6,947)	\$ (12,941)	\$ (27,923)	\$ (27,454)	\$ (18,457)
Basic and diluted net loss per common share	\$ (6.32)	\$ (11.86)	\$ (22.14)	\$ (19.40)	\$ (12.40)
Shares used in basic and diluted net loss per share calculation	1,100	1,091	1,261	1,420	1,488
Pro forma basic and diluted net loss per common share (unaudited) ⁽¹⁾					\$ (2.10)
Shares used in pro forma basic and diluted net loss per common share calculation (unaudited) ⁽¹⁾					8,570

⁽¹⁾ The pro forma basic and diluted net loss per share reflects the weighted effect of the assumed conversion of redeemable convertible preferred stock and convertible promissory notes into common stock. See note 12 to our financial statements for information regarding computation of basic and diluted net loss per share and pro forma basic and diluted net loss per share.

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The following table contains a summary of our balance sheet as of December 31, 2003:

- on an actual basis;
- on a pro forma as adjusted basis to further reflect:
 - the sale of 4,000,000 shares of our common stock we are offering at an assumed initial public offering price of \$8 per share, after deducting underwriting discounts and commissions and estimated offering expenses to be paid by us;
 - the conversion of all 6,781,814 shares of our preferred stock outstanding as of December 31, 2003 into 6,781,814 shares of our common stock, which will become effective at the closing of this offering;
 - the net exercise of warrants outstanding as of December 31, 2003, which will expire at the closing of this offering, to purchase 907,316 shares of our common stock at a weighted average exercise price of \$0.30 per share, resulting in the issuance of 873,764 shares of common stock, assuming an initial public offering price of \$8 per share;
 - the conversion of shares of our preferred stock issuable upon the net exercise of warrants outstanding as of December 31, 2003, which will expire at the closing of this offering, to purchase 66,983 shares of our preferred stock at a weighted average exercise price of \$5.23 per share, resulting in the issuance of 23,233 shares of common stock, assuming an initial public offering price of \$8 per share;
 - reclassification of warrants outstanding at December 31, 2003 to purchase 19,744 shares of our preferred stock at a weighted average exercise price of \$14.60 per share, which will expire at the closing of this offering;
 - the conversion of warrants outstanding as of December 31, 2003 to purchase 46,607 shares of our preferred stock into warrants to purchase 46,607 shares of our common stock, which will become effective at the closing of this offering; and
 - the conversion of the convertible promissory notes we issued in October 2003 for net proceeds of approximately \$12.7 million into approximately 1,339,943 shares of our common stock, which includes the conversion of approximately \$177,000 in accrued interest as of December 31, 2003 and the recognition of approximately \$12.4 million in interest expense associated with the discount on the notes, which will become effective upon the closing of this offering.

As of December 31, 2003	
Actual	Pro forma as adjusted
(unaudited, in thousands)	

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Balance Sheet Data

Cash, cash equivalents and short-term investments	\$ 13,540	\$ 41,950
Working capital	(653)	39,586
Total assets	18,498	46,908
Long-term obligations, less current portion	1,555	1,555
Redeemable convertible preferred stock	64,604	
Redeemable convertible preferred stock warrants	2,467	
Total stockholders' equity (deficit)	(64,840)	42,470

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RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below with all of the other information included in this prospectus before deciding to invest in our common stock. If any of the following risks actually occur, they may materially harm our business and our financial condition and results of operations. In this event, the market price of our common stock could decline and you could lose part or all of your investment. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial may also adversely affect our business.

Risks Related To Our Business

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 \$18.5 million for the year ended December 31, 2003, and we may never become profitable. As of December 31, 2003, we had a deficit accumulated during the development stage of approximately \$86.6 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. 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 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 primarily through private equity financings and equipment leases. If we are unable to timely obtain additional funding, 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;

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- 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.

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Our net cash used in operations has exceeded our cash generated from operations for each year since our inception. For example, we used approximately \$15.5 million in operating activities for the year ended December 31, 2003 and approximately \$15.2 million in 2002. Based on the current status of our product development and collaboration plans, we believe that the net proceeds from this offering, together with our cash, cash equivalents and investments, will be adequate to satisfy our capital needs through at least the end of the second quarter of 2005. However, changes in our business may occur that would consume available capital resources sooner than we expect. As of December 31, 2003, we had cash, cash equivalents and short-term investments of approximately \$13.5 million and current liabilities of approximately \$14.7 million. In October 2003, we issued convertible notes for net proceeds of approximately \$12.7 million. Based on our current financial resources and anticipated expenses and in the event we do not raise any capital from this offering, we believe we have sufficient funding to continue our operations through at least the end of October 2004, unless a majority of the holders of the notes elect to accelerate the maturity date on or after April 30, 2004. These convertible promissory notes have an aggregate principal amount of \$12.7 million and interest accrues annually at a rate of six percent. These convertible promissory notes convert into shares of our common stock at the closing of this offering. Additionally, holders of our preferred stock may redeem their shares at any time for an aggregate redemption price of approximately \$76.5 million based on shares of preferred stock outstanding as of December 31, 2003. The holders of our preferred stock will not have the right to force us to redeem their shares after their shares convert into shares of our common stock, which will occur upon completion of our initial public offering. 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 equity securities, further dilution to stockholders may result and new investors could have rights superior to holders of the shares issued in this offering. 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.

We may decide to pursue development programs for Xcellerated T Cells that may 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, multiple myeloma, non-Hodgkin's lymphoma, kidney cancer, prostate cancer and HIV. 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.

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.

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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 not been randomized and double-blinded to ensure the results are due to the effect of Xcellerate Technology. 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 does not ensure that large-scale trials will be successful nor does it predict 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.

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 to date our studies 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 commercializability of our Xcellerate Technology is uncertain and may never be realized.

We may fail to obtain or may experience delays in obtaining regulatory approval to market Xcellerated T Cells, which will significantly harm our business.

We do not have the necessary approval 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 approval 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. Clinical trials are also often subject to unanticipated delays. In addition, we are currently developing 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. Also, patients participating in the trials may die before completion of the trial or suffer adverse medical effects unrelated to treatment with Xcellerated T Cells. This could delay or lead to termination 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.

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

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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;
- 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 action.

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 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.

We currently manufacture 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 plan to relocate our manufacturing activities to our leased property in Bothell, Washington, which we plan to renovate 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, and designing, constructing, validating and operating, any new manufacturing facility. We may also be unable to hire the qualified personnel that we will require to accommodate the expansion of our operations and manufacturing capabilities. If we relocate our manufacturing activities to a new facility during or after a pivotal clinical trial, we may be unable to obtain regulatory approval unless and until 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. 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.

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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 have recently begun 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 our prior clinical trials were conducted using a prior version of the manufacturing system, we may have to show comparability of the different versions of manufacturing systems we have used. We are currently negotiating a manufacturing and supply agreement with Wave Biotech LLC, the manufacturer of our bioreactor system. If we are unable to negotiate this contract or are unable to

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procure a suitable alternative manufacturer in a timely manner, we would 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.

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.

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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.

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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 US 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.

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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 approval 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.

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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. For example, we have been named as a defendant in connection with a clinical trial using technology similar to ours conducted at the University of Chicago Hospital. This proceeding is currently pending. Because of the nature of the complaint against us, we cannot predict the probability of a favorable or unfavorable outcome or estimate the amount or range of potential loss. Insurance coverage for this claim has been denied to date under our clinical trial insurance policy based on the fact that this trial occurred prior to the date that we licensed our technology and acquired clinical trial insurance. See Business Legal proceedings. In addition, we are licensing our Xcellerate Technology in the field of HIV retroviral gene therapy to Fresenius under our collaboration. 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 enhance 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:

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- 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.

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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 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 Biologics PLC, or 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.

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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 A.S., or 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. 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. We do not have agreements with Cambrex which obligate them to provide us with any products for future clinical trials or future commercial sales.

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.

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 FDA-acceptable components from other suppliers 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.

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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 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 intend to locate our initial commercial 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.

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,

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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.

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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 Biotechnology GmbH, a wholly-owned subsidiary of Fresenius AG, 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., Dendreon Corporation, Favrilite, Inc., Genitope Corporation, IDM, S.A., Kirin Pharmaceutical and Valeocyte Therapies. Some 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.

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We plan significant growth, which we may not be able to effectively manage.

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 also intend to add personnel in our research and development and manufacturing departments as we expand our clinical trial and research capabilities. Our failure to manage our growth effectively 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. 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 relative to the US dollar may adversely affect us.

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. We do not engage in currency hedging. Accordingly, if the British pound strengthens against the US dollar, our payments to Lonza will increase in US dollar terms. We have paid a total of \$4.9 million to Lonza under our agreements with them as of December 31, 2003, consisting of approximately \$252,000, \$1.7 million, \$1.6 million and \$1.3 million during the years ended December 31, 2000, 2001, 2002 and 2003, respectively. At December 31, 2003, we had no significant outstanding obligations or future contractual commitments to Lonza. However, if our future purchases from Lonza require payments in British pounds, we will continue to be exposed to currency exchange risks.

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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.

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Risks Related To Our Intellectual Property

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 competitors may infringe upon our patents or successfully avoid them through design innovation. We may initiate litigation to police unauthorized use of our proprietary rights. 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.

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

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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 US 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

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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

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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 four United States patents presently issued related to this technology, two patents expire in 2016 and two others expire in 2019.

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 prevent 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.

Risks Relating To This Offering

You will suffer immediate and substantial dilution.

We expect the initial public offering price of our shares to be substantially higher than the book value per share of our outstanding common stock. Accordingly, investors purchasing shares of common stock in this offering will pay a price per share that substantially exceeds the value of our assets after subtracting liabilities.

To the extent outstanding stock options or warrants are exercised, there will be further dilution to new investors. See Dilution.

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, will beneficially own in the aggregate approximately 62.6% of our common stock following this offering. 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, will 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.

The future sale of our common stock could negatively affect our stock price.

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After this offering, based on shares outstanding as of January 31, 2004 we will have approximately 14,572,206 shares of common stock outstanding, or 15,172,206 shares if the underwriters exercise their over-allotment option in full. The 4,000,000 shares sold in this offering, or 4,600,000 shares if the underwriters exercise their over-allotment option in full, will be freely tradable without restriction under the federal securities laws unless purchased by our affiliates. The remaining shares of common stock outstanding after this offering will be available for public sale subject in some cases to volume, lock-up and other limitations. See Shares eligible for future sale.

If our common stockholders sell substantial amounts of common stock in the public market, or the market perceives that such sales may occur, the market price of our common stock could fall. After this offering,

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according to the terms of the investors rights agreement, assuming the exercise of all warrants that terminate upon the closing and including the issuance of approximately 1,346,771 shares of our common stock (as of January 31, 2004) pursuant to convertible promissory notes, the holders of approximately 9,150,141 shares of our common stock or warrants to purchase shares of our common stock will have 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 registrations rights, the sale of those shares 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.

An active, liquid trading market for our common stock may never develop.

Prior to this offering, there was no public market for our common stock. An active trading market for our common stock may not develop following this offering. You may not be able to sell your shares quickly or at the market price if trading in our stock is not active. The initial public offering price may not be indicative of prices that will prevail in the trading market. See Underwriting for more information regarding the factors considered in determining the initial public offering price.

Our common 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 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;

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- 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, particularly following an initial public offering, 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.

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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 will 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 common 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 allocate the net proceeds from this offering in ways with which you may not agree.

We expect to use the net proceeds from this offering to fund clinical trial activities, manufacturing and preclinical research and development activities and for other general corporate purposes, including capital expenditures, complementary technology acquisition and working capital. See “Use of proceeds.” Our management, however, has broad discretion in the use of the net proceeds from this offering and could spend the net proceeds in ways that do not necessarily improve our operating results or the value of our common stock.

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.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, including the sections titled Prospectus summary, Risk factors, Management's discussion and analysis of financial condition and results of operations and Business, contains forward-looking statements. Forward-looking statements convey our current expectations or forecasts of future events. All statements contained in this prospectus other than statements of historical fact are forward-looking statements. Forward-looking statements include statements regarding our future financial position, business strategy, budgets, projected costs, plans and objectives of management for future operations. The words may, continue, estimate, intend, plan, will, believe, project, expect, similar expressions may identify forward-looking statements, but the absence of these words does not necessarily mean that a statement is not forward-looking.

Any or all of our forward-looking statements in this prospectus may turn out to be inaccurate. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. They may be affected by inaccurate assumptions we might make or by known or unknown risks and uncertainties, including the risks, uncertainties and assumptions described in Risk factors. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this prospectus may not occur as contemplated, and actual results could differ materially from those anticipated or implied by the forward-looking statements.

You should not unduly rely on these forward-looking statements, which speak only as of the date of this prospectus. Unless required by law, we undertake no obligation to publicly update or revise any forward-looking statements to reflect new information or future events or otherwise. You should, however, review the factors and risks we describe in the reports we will file from time to time with the SEC after the date of this prospectus. See Where you can find additional information.

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USE OF PROCEEDS

We estimate that the net proceeds to us from the sale of the 4,000,000 shares of common stock we are offering will be approximately \$28.4 million, assuming an initial public offering price of \$8 per share, after deducting underwriting discounts and commissions and the estimated offering expenses. If the underwriters exercise their over-allotment option in full, we estimate the net proceeds to us from this offering will be approximately \$32.9 million.

We expect to use the net proceeds of this offering for working capital and general corporate purposes, including:

- clinical trial activities, including our ongoing Phase I/II and Phase II clinical trials in chronic lymphocytic leukemia, or CLL, and multiple myeloma, and our plans to initiate a new Phase II clinical trial in non Hodgkin's lymphoma and in CLL in patients treated with Campath;
- manufacturing activities, including manufacture of Xcellerated T Cells for our ongoing and planned clinical trials;
- preclinical research and development activities;
- capital expenditures, including expansion and build-out of the Company's new manufacturing facilities; and
- complementary technology acquisition.

Although we have identified some types of uses above, we have and reserve broad discretion to use the proceeds from this offering differently. When and if the opportunity arises, we may use a portion of the proceeds to acquire or invest in complementary businesses, products or technologies. We currently have no commitments or agreements, and are not involved in any negotiations, to acquire any businesses, products or technologies. Pending any ultimate use of any portion of the proceeds from this offering, we intend to invest the proceeds in short-term, investment-grade and interest-bearing instruments.

Based on the current status of our product development and collaboration plans, we believe that the net proceeds of this offering, together with our cash, cash equivalents and investments, will be adequate to satisfy our capital needs through at least the end of the second quarter of 2005. See Management's Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources.

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. 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.

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CAPITALIZATION

The following table sets forth our cash, cash equivalents and short term investments and capitalization as of December 31, 2003:

- on an actual basis;

- on a pro forma as adjusted basis to further reflect:
 - the sale of 4,000,000 shares of our common stock we are offering at an assumed initial public offering price of \$8 per share, after deducting underwriting discounts and commissions and estimated offering expenses to be paid by us;
 - the filing of an amended and restated certificate of incorporation to provide for an authorized capital stock of 5,000,000 shares of preferred stock and 100,000,000 shares of common stock;
 - the conversion of all 6,781,814 shares of our preferred stock outstanding as of December 31, 2003 into 6,781,814 shares of our common stock, which will become effective at the closing of this offering;
 - the net exercise of warrants outstanding as of December 31, 2003, which will expire at the closing of this offering, to purchase 907,316 shares of our common stock at a weighted average exercise price of \$0.30 per share, resulting in the issuance of 873,764 shares of common stock, assuming an initial public offering price of \$8 per share;
 - the conversion of shares of our preferred stock issuable upon the net exercise of warrants outstanding as of December 31, 2003, which will expire at the closing of this offering, to purchase 66,983 shares of our preferred stock at a weighted average exercise price of \$5.23 per share, resulting in the issuance of 23,233 shares of common stock, assuming an initial public offering price of \$8 per share;
 - reclassification of warrants outstanding at December 31, 2003 to purchase 19,744 shares of our preferred stock at a weighted average exercise price of \$14.60 per share, which will expire at the closing of this offering;
 - the conversion of warrants outstanding as of December 31, 2003 to purchase 46,607 shares of our preferred stock into warrants to purchase 46,607 shares of our common stock, which will become effective at the closing of this offering; and
 - the conversion of the convertible promissory notes we issued in October 2003 for net proceeds of approximately \$12.7 million into approximately 1,339,943 shares of our common stock, which includes the conversion of approximately \$177,000 in accrued interest as of December 31, 2003, and the recognition of approximately \$12.4 million in interest expense associated with the discount on the notes, which will become effective upon the closing of this offering.

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	As of December 31, 2003	
	Actual	Pro forma as adjusted
	(unaudited, in thousands, except share and per share data)	
Cash, cash equivalents and short-term investments	\$ 13,540	\$ 41,950
Long-term obligations, less current portion	\$ 1,555	\$ 1,555
Redeemable convertible preferred stock; 6,781,814 shares issued and outstanding, actual; no shares issued and outstanding, pro forma as adjusted	64,604	
Redeemable convertible preferred stock warrants	2,467	
Stockholders' equity (deficit):		
Preferred stock, \$0.001 par value per share; 42,000,000 shares authorized, actual; 5,000,000 shares authorized, pro forma as adjusted; no shares issued pro forma as adjusted		
Common stock, par value \$0.001 per share; 70,000,000 shares authorized, actual; 100,000,000 shares authorized, pro forma as adjusted; 1,546,624 shares issued and outstanding, actual; 10,565,378 shares issued and outstanding, pro forma as adjusted	2	15
Additional paid-in capital	24,532	144,235
Deferred stock compensation	(2,774)	(2,774)
Accumulated other comprehensive income	(5)	(5)
Deficit accumulated during the development stage	(86,595)	(99,001)
Total stockholders' equity (deficit)	(64,840)	42,470
Total capitalization	\$ 3,786	\$ 44,025

The table above should be read in conjunction with our financial statements and related notes included in this prospectus. This table is based on 10,565,378 shares of our common stock outstanding as of December 31, 2003 and excludes:

- 46,607 shares of our common stock issuable upon the exercise of warrants outstanding as of December 31, 2003 at a weighted average exercise price of \$7.94 per share;
- 19,744 shares of our preferred stock issuable upon the exercise of warrants outstanding as of December 31, 2003, at a weighted average price of \$14.60 per share, which will expire at the closing of this offering;
- 717,615 shares of our common stock issuable upon the exercise of stock options outstanding as of December 31, 2003 under our 1996 Stock Option Plan at a weighted average exercise price of \$4.48 per share;

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- 278,691 shares of our common stock reserved for future issuance under our 1996 Stock Option Plan; and
- 636,363 shares of our common stock reserved for future issuance under our 2003 Stock Plan, 109,090 shares of our common stock reserved for future issuance under our 2003 Employee Stock Purchase Plan and 90,909 shares of our common stock reserved for future issuance under our 2003 Directors' Stock Option Plan, as of December 31, 2003.

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DILUTION

If you invest in our common stock, your interest will be diluted to the extent of the difference between the public offering price per share you pay in this offering and the net tangible book value per share of our common stock immediately after this offering. Our net tangible book value as of December 31, 2003 was approximately \$(64.8) million, or \$(41.92) per share of common stock. Net tangible book value per share is equal to our total tangible assets minus total liabilities, redeemable convertible preferred stock and redeemable convertible preferred stock warrants, all divided by the number of shares of common stock outstanding as of December 31, 2003. Our pro forma as adjusted net tangible book value as of December 31, 2003, before we receive the net proceeds from and issue shares in this offering, was approximately \$14.1 million, or \$1.33 per share of common stock. Pro forma as adjusted net tangible book value per share, before we receive the net proceeds from and issue shares in this offering, gives effect to:

- the conversion of all 6,781,814 shares of our preferred stock outstanding as of December 31, 2003, into 6,781,814 shares of our common stock, which will become effective at the closing of this offering;
- the conversion of warrants outstanding as of December 31, 2003 to purchase 46,607 shares of our preferred stock into warrants to purchase 46,607 shares of our common stock, which will become effective at the closing of this offering;
- the net exercise of warrants outstanding as of December 31, 2003, which will expire at the closing of this offering, to purchase 907,316 shares of our common stock at a weighted average exercise price of \$0.30 per share, resulting in the issuance of 873,764 shares of common stock, assuming an initial public offering price of \$8 per share;
- the conversion of shares of our preferred stock issuable upon the net exercise of warrants outstanding as of December 31, 2003, which will expire at the closing of this offering, to purchase 66,983 shares of our preferred stock at a weighted average exercise price of \$5.23 per share, resulting in the issuance of 23,233 shares of common stock, assuming an initial public offering price of \$8 per share;
- reclassification of warrants outstanding at December 31, 2003 to purchase 19,744 shares of our preferred stock at a weighted average exercise price of \$14.60 per share, which will expire at the closing of this offering; and
- the conversion of the convertible promissory notes we issued in October 2003 for net proceeds of approximately \$12.7 million into approximately 1,339,943 shares of our common stock, which includes the conversion of approximately \$177,000 in accrued interest as of December 31, 2003, and the recognition of approximately \$12.4 million in interest expense associated with the discount on the notes, which will become effective upon the closing of this offering.

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After giving effect to the sale of the 4,000,000 shares of common stock we are offering at an assumed initial public offering price of \$8 per share, and after deducting underwriting discounts and commissions and our estimated offering expenses, our pro forma as adjusted net tangible book value as of December 31, 2003 would have been approximately \$42.5 million, or \$2.92 per share of common stock. This represents an immediate increase in pro forma net tangible book value of \$44.84 per share to existing stockholders and an immediate dilution of \$5.08 per share to new investors. The following table illustrates this calculation on a per share basis:

Assumed initial public offering price per share	\$ 8.00
Net tangible book value per share as of December 31, 2003, actual	\$ (41.92)
Increase attributable to the conversion of convertible promissory notes into shares of our common stock, the recognition of interest expense associated with the discount on the notes, the conversion of our convertible preferred stock and the net exercise and conversion of warrants	43.25
Pro forma as adjusted net tangible book value per share as of December 31, 2003, before we receive the net proceeds from and issue shares in this offering	1.33
Pro forma increase per share attributable to the offering	1.59
Pro forma as adjusted net tangible book value per share after this offering	2.92
Pro forma dilution per share to new investors	\$ 5.08

If the underwriters exercise their over-allotment option in full, pro forma as adjusted net tangible book value as of December 31, 2003 will increase to \$3.09 per share, representing an increase to existing stockholders of \$45.01 per share, and there will be an immediate dilution of \$4.91 per share to new investors.

The following table summarizes, on a pro forma as adjusted basis as of December 31, 2003, after giving effect to this offering, at an assumed initial public offering price of \$8 per share, and the pro forma adjustments referred to above, the total number of shares of our common stock purchased from us and the total consideration and average price per share paid by existing stockholders and by new investors:

	Total shares		Total consideration		Average price per share
	Number	%	Amount	%	
Existing stockholders	10,565,378	72.5%	\$ 89,038,000	73.6%	\$ 8.43
New investors	4,000,000	27.5	32,000,000	26.4	\$ 8.00
Total	14,565,378	100.0%	\$ 121,038,000	100.0%	

If the underwriters exercise their over-allotment option in full, the following will occur:

- the pro forma as adjusted percentage of shares of our common stock held by existing stockholders will decrease to approximately 69.7% of the total number of pro forma as adjusted shares of our common stock outstanding after this offering; and

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- the pro forma as adjusted number of shares of our common stock held by new public investors will increase to 4,600,000, or approximately 30.3% of the total pro forma as adjusted number of shares of our common stock outstanding after this offering.

The tables and calculations above are based on pro forma 10,565,378 shares of our common stock outstanding as of December 31, 2003 and exclude:

- 46,607 shares of our common stock issuable upon the exercise of warrants outstanding as of December 31, 2003, at a weighted average exercise price of \$7.94 per share;
- 19,744 shares of our preferred stock issuable upon the exercise of warrants outstanding as of December 31, 2003, at a weighted average price of \$14.60 per share, which will expire at the closing of this offering;

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- 717,615 shares of our common stock issuable upon the exercise of stock options outstanding as of December 31, 2003 under our 1996 Stock Option Plan at a weighted average exercise price of \$4.48 per share;
- 278,691 shares of our common stock reserved for future issuance under our 1996 Stock Option Plan; and
- 636,363 shares of our common stock reserved for future issuance under our 2003 Stock Plan, 109,090 shares of our common stock reserved for future issuance under our 2003 Employee Stock Purchase Plan and 90,909 shares of our common stock reserved for future issuance under our 2003 Directors Stock Option Plan, as of December 31, 2003.

The exercise of outstanding options and warrants having an exercise price less than the initial public offering price will increase dilution to new investors.

Table of Contents**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 prospectus, 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, 2001, 2002 and 2003 and the balance sheet data as of December 31, 2002 and 2003 have been derived from our audited financial statements included elsewhere in this prospectus. The statement of operations data for the years ended December 31, 1999 and 2000 and the balance sheet data as of December 31, 1999, 2000 and 2001 have been derived from our audited financial statements that are not included in this prospectus.

	Years ended December 31,				
	1999	2000	2001	2002	2003
	(in thousands, except per share data)				
Statement of Operations Data					
Revenue:					
Collaborative agreement	\$	\$	\$	\$	\$ 170
Government grant	16	98	30		
Total revenue	16	98	30		170
Operating expenses:					
Research and development	5,471	11,257	14,701	14,663	13,685
General and administrative	1,654	2,403	5,204	4,979	4,322
Total operating expenses	7,125	13,660	19,905	19,642	18,007
Loss from operations	(7,109)	(13,562)	(19,875)	(19,642)	(17,837)
Other income (expense), net	162	621	363	189	(620)
Net loss	(6,947)	(12,941)	(19,512)	(19,453)	(18,457)
Accretion of preferred stock			(8,411)	(8,001)	
Net loss applicable to common stockholders	\$ (6,947)	\$ (12,941)	\$ (27,923)	\$ (27,454)	\$ (18,457)
Basic and diluted net loss per common share	\$ (6.32)	\$ (11.86)	\$ (22.14)	\$ (19.34)	\$ (12.40)
Shares used in basic and diluted net loss per common share calculation	1,100	1,091	1,261	1,420	1,488
Pro forma basic and diluted net loss per common share (unaudited) ⁽¹⁾					\$ (2.10)
Shares used in pro forma basic and diluted net loss per common share calculation (unaudited) ⁽¹⁾					8,570

⁽¹⁾The pro forma basic and diluted net loss per share reflects the weighted effect of the assumed conversion of redeemable convertible preferred stock and convertible promissory notes into common stock. See note 12 to our financial statements for information regarding computation of basic and diluted net loss per share and pro forma basic and diluted net loss per share.

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	As of December 31,				
	1999	2000	2001	2002	2003
	(in thousands)				
Balance Sheet Data					
Cash, cash equivalents and short-term investments	\$ 7,363	\$ 23,926	\$ 21,098	\$ 17,344	\$ 13,540
Working capital	6,100	21,785	19,135	15,570	(653)
Total assets	10,055	28,479	24,727	21,535	18,498
Long-term obligations, less current portion	854	952	1,046	1,514	1,555
Redeemable convertible preferred stock and warrants	23,405	49,053	57,629	65,673	67,071
Deficit accumulated during the development stage	(16,232)	(29,173)	(48,685)	(68,138)	(86,595)
Total stockholders' deficit	(15,804)	(25,384)	(36,260)	(48,125)	(64,840)

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**MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION
AND RESULTS OF OPERATIONS**

The following discussion of our financial condition and results of operations should be read in conjunction with our financial statements and the notes to those financial statements included elsewhere in this prospectus. This discussion contains forward-looking statements that involve risks and uncertainties. As a result of many factors, such as those set forth under "Risk factors" and elsewhere in this prospectus, our actual results may differ materially from those anticipated in these forward-looking statements.

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, 2003, our deficit accumulated during the development stage was \$86.6 million. Our operating expenses consist of research and development expenses and general and administrative expenses.

We have recognized revenues from inception through December 31, 2003 of approximately \$414,000 from sublicense fees, payments under a collaborative agreement and income from a National Institutes of Health Phase I Small Business Innovation Research, or SBIR, grant in CLL. We intend to continue to apply for other grants in the future. 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 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;

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- 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.

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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, 2003, we incurred research and development expenses of approximately \$66.8 million, substantially all of which relate to the research and development of this technology. Currently, we are focusing our efforts on advancing our product through clinical trials. 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.

We determine 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 are made or revalued, viewed in light of this offering and the expected initial public offering price per share.

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 an 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 research and development

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period. 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' 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.

Results of Operations

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 in our inventory 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 13.2%, 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

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\$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.

Years Ended December 31, 2002 and 2001

Revenue

Revenue was approximately \$30,000 in the year ended December 31, 2001, consisting of income from a National Institutes of Health SBIR grant. We recognized no revenue in the year ended December 31, 2002.

Research and Development

Research and development expenses represented approximately 75% and 74% of our operating expenses for the years ended December 31, 2002 and 2001, respectively. Research and development expenses totaled \$14.7 million in each of the years ended December 31, 2002 and 2001. While total expenses were the same for 2002 and 2001, several individual components of research and development expense fluctuated significantly between the years. Technology license costs, contractual payments relating to developing our bead technology and salary and other personnel-related expenses increased from 2001 to 2002. Technology license costs comprised the largest increase and 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, 2001. These increases were offset by a reduction of \$1.1 million in contractual payments relating to developing our antibody technology, in addition to reduced non-cash compensation expense. The higher level of payments in 2001 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 in our inventory 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. The reduction in non-cash compensation expense resulted primarily from a decrease in management's estimate of the fair market value per share of common stock.

General and Administrative

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General and administrative expenses represented approximately 25% and 26% of our operating expenses for the years ended December 31, 2002 and 2001, respectively. General and administrative expenses decreased 4.3%, from \$5.2 million in the year ended December 31, 2001 to \$5.0 million in the year ended December 31, 2002. The decrease was due primarily to an \$880,000 reduction in professional fees related to an initial public offering that we withdrew in 2001, partially offset by a \$351,000 increase in non-cash stock compensation and increases in salary and other personnel-related expenses. The increase in non-cash stock compensation resulted from an increase in the number of options granted.

Other Income (Expense)

Other income, comprised primarily of interest income and interest expense, decreased 48%, from \$363,000 in the year ended December 31, 2001 to \$189,000 in the year ended December 31, 2002. Interest income decreased 33%, from \$698,000 in the year ended December 31, 2001 to \$467,000 in the year ended December 31, 2002.

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due to decreased cash and investment balances upon which interest is earned and declining interest rates. Interest expense increased 2.7%, from \$260,000 in the year ended December 31, 2001 to \$267,000 in the year ended December 31, 2002, due primarily to higher debt balances related to equipment financings.

Stock-Based Compensation

During the year ended December 31, 2003, we recorded deferred stock-based compensation totaling \$2.4 million. During the years ended December 31, 2001 and 2002, we recorded deferred stock-based compensation totaling \$1.7 million and \$3.2 million, respectively. We amortize the deferred stock-based compensation to expense using the graded vesting method. As of December 31, 2003, there was \$2.8 million of deferred stock-based compensation to be amortized in future periods as follows: \$1.7 million in 2004, \$711,000 in 2005, \$291,000 in 2006 and \$51,000 in 2007. In 2001 and 2002, we granted non-employee stock options to purchase 71,814 and 6,363 shares of our common stock, respectively. During the year ended December 31, 2003, we issued options and warrants to non-employees to purchase 24,543 shares of our common stock. 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 \$1.1 million, \$65,000 and \$360,000 for the years ended December 31, 2001, 2002 and 2003 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, 2003, we had net operating loss carryforwards of approximately \$74 million and research and development tax credit carryforwards of approximately \$3.2 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. We are currently not subject to these limitations. However, any future annual limitations may result in the expiration of our net operating loss and tax credit carryforwards before utilization.

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.

Liquidity and Capital Resources

As of December 31, 2003, we had cash, cash equivalents and short-term investments of \$13.5 million, with cash equivalents being held in highly liquid money market accounts with financial institutions. Cash, cash equivalents and short-term investments were \$21.1 million as of December 31, 2001, and \$17.3 million as of December 31, 2002.

In October 2003, we raised net proceeds of \$12.7 million from the sale of 6% convertible promissory notes. These convertible promissory notes will convert into approximately 1,339,943 shares of common stock (as of December 31, 2003) at the closing of this offering. If this offering does not close, the convertible promissory notes will be payable upon demand in October 2004, unless the holders of a majority of the aggregate

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principal amount of the notes elect after April 2004 to accelerate the maturity date, in which case we will have to repay the \$12.7 million aggregate principal amount of the notes plus accrued and unpaid interest. Additionally, holders of our preferred stock may elect to require us to redeem their shares at any time at the original price paid per share. As of December 31, 2003, 6,781,814 shares of our preferred stock were outstanding. If the holders of these shares elect to require us to redeem their shares, we would have to pay an aggregate redemption price of approximately \$76.5 million. However, the holders of our preferred stock will not have the right to force us to

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redeem their shares after their shares convert into shares of our common stock, which will occur immediately before completion of our initial public offering.

We have financed our operations since inception through private placements of equity securities, grant revenue, fees from a sublicense agreement, payments under a collaborative agreement, equipment financings and interest income earned on cash, cash equivalents and investments. From inception through December 31, 2003, we have raised net proceeds of \$75.6 million from private equity financings and \$12.7 million from the sale of convertible promissory notes. Since our inception to December 31, 2003, we have received \$414,000 in revenue, \$6.1 million in equipment financings and \$3.5 million in interest income. To date, inflation has not had a material effect on our business.

In August 2003, the National Institutes of Health awarded us a \$1.2 million SBIR grant to help fund our clinical trial to evaluate the use of Xcellerated T Cells to treat patients with CLL. The National Institutes of Health recently announced clarifications to the eligibility requirements for their SBIR grants. As a result, it is uncertain whether we may be eligible to receive any funds under this grant. Accordingly, we do not intend to accept any funds from this grant until this uncertainty is resolved.

Since our inception, investing activities, other than purchases and maturities of investments, have consisted primarily of purchases of property and equipment. As of December 31, 2003, our investment in property and equipment was \$5.9 million. We anticipate our capital expenditures will increase in the future as we construct and renovate our planned manufacturing plant and expand our current facilities.

Net cash used in operating activities was \$15.2 million for the year ended December 31, 2002 and \$15.5 million for the year ended December 31, 2003. Net cash used in operating activities was \$15.1 million in the year ended December 31, 2001. Expenditures in these periods were generally a result of research and development expenses and general and administrative expenses in support of our operations.

We have entered into agreements to develop bead and antibody technology that require significant cash expenditures, including an agreement with Dynal under which we have 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 \$4.9 million. As of December 31, 2003, we have paid \$2.5 million to Dynal and the entire \$4.9 million to Lonza. 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, 2003 (in thousands):

	Total	Payments due by period			
		Less than 1 year	1 to 3 years	4 to 5 years	After 5 years
Contractual obligations					
Operating leases	\$ 9,046	\$ 1,571	\$ 3,010	\$ 2,205	\$ 2,260
Equipment financing	1,923	845	1,052	26	
Total⁽¹⁾	\$ 10,969	\$ 2,416	\$ 4,062	\$ 2,231	\$ 2,260



⁽¹⁾Does not include commitments for product development spending under the Genetics Institute license agreement, as described above and does not include commitments for payment of the convertible promissory notes issued in October 2003.

We have financed the acquisition of laboratory and scientific equipment, furniture and fixtures, computer equipment and leasehold improvements through financing arrangements with General Electric Capital Corporation, Oxford Finance Corporation and Phoenix Leasing Incorporated. In connection with the financings,

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we have issued preferred stock warrants to these lenders. At December 31, 2003, we had two financing arrangements. Under the first arrangement, with General Electric Capital Corporation, we could borrow up to \$1.7 million; however, borrowings under this arrangement were limited to \$500,000 until we received additional funding acceptable to the lender. At December 31, 2003, we had \$170,000 available under this outstanding arrangement, which expired in January 2004. Under the second arrangement, with Oxford Finance Corporation, we can borrow up to \$2.5 million. At December 31, 2003, we had \$1.9 million available under the outstanding arrangement, which expires in April 2004 unless renewed. Outstanding borrowings under the current and previous financing arrangements were \$1.9 million at each of the years ended December 31, 2002 and 2003. Outstanding borrowings require monthly principal and interest payments and mature at various dates through 2007. Interest rates applicable to the outstanding borrowings at December 31, 2003 range from 9.18% to 14.11%. Borrowings are secured by the acquired assets that have a net book value of \$2.3 million at December 31, 2003. Under all agreements, we are required to comply with certain nonfinancial covenants.

We expect to use the net proceeds from this offering to fund clinical trial activities, manufacturing and preclinical research and development activities and for other general corporate purposes, including capital expenditures, technology acquisition and working capital to fund anticipated operating losses. See Use of proceeds.

Based on the current status of our product development and collaboration plans, we believe that the net proceeds of this offering, together with our cash, cash equivalents and investments, will be adequate to satisfy our capital needs through at least the end of the second quarter of 2005. However, we may need additional financing prior to that time to, among other things, support our product development for Phase II or Phase III clinical trials. 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 technologies to others that we would prefer to develop internally.

Certain Relationships and Related Party Transactions

For a description of our related party transactions, see Certain relationships and related party transactions.

Recent Accounting Pronouncements

In June 2002, the FASB issued SFAS 146, *Accounting for Costs Associated with Exit or Disposal Activities*, which addresses accounting for restructuring, discontinued operation, plant closing or other exit or disposal activity. SFAS 146 requires companies to recognize costs associated with exit or disposal activities when they are incurred rather than at the date of a commitment to an exit or disposal plan. SFAS 146 is to be applied prospectively to exit or disposal activities initiated after December 31, 2002. We do not expect the adoption of SFAS 146 to have a material impact on our financial position or results of operations.

In November 2002, the FASB issued FIN 45, *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others, and Interpretation of FASB Statements No. 5, 57 and 107 and Rescission of FASB Interpretation No. 34*. FIN 45 clarifies the requirements of SFAS 5, *Accounting for Contingencies*, relating to a guarantor's accounting for, and disclosure of, the issuance of certain types of guarantees. The disclosure provisions of FIN 45 apply to financial statements for the periods ending after December 15, 2002. However, the provisions for initial recognition and measurement apply on a prospective basis to guarantees that are issued or modified after December 31, 2002. We do not expect the adoption of FIN 45 to have a material impact on our financial position or results of operations.

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In January 2003, the FASB issued FIN 46, *Consolidation of Variable Interest Entities*. FIN 46 clarifies the application of Accounting Research Bulletin No. 51, *Consolidated Financial Statements*, to entities in which the equity investors do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties.

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FIN 46 applies immediately to variable interest entities created after January 31, 2003 and to variable interest entities in which an enterprise obtains an interest after that date. It applies in the first fiscal year or interim period beginning after June 15, 2003 to variable interest entities in which an enterprise holds a variable interest that it acquired before February 1, 2003. FIN 46 applies to public enterprises as of the beginning of the applicable interim or annual period. We do not believe there will be a material effect on our financial condition or results of operations from the adoption of the provisions of FIN 46.

In November 2002, the Emerging Issues Task Force reached a consensus on Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables* (EITF Issue No. 00-21). This Issue provides guidance on how to account for arrangements that involve the delivery or performance of multiple products, services and/or rights to use assets. The provisions of EITF Issue No. 00-21 will apply to revenue arrangements entered into in fiscal periods beginning after June 15, 2003. We are currently evaluating the effect that the adoption of EITF Issue No. 00-21 will have on our financial statements.

In May 2003, the FASB issued SFAS 150, *Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity*. SFAS 150 establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. SFAS 150 requires that an issuer classify a financial instrument that is within SFAS 150's scope as a liability by reporting the cumulative effect of a change in accounting principle. The requirements of SFAS 150 apply to the first fiscal period beginning after December 15, 2004. We are currently evaluating the impact of adopting SFAS 150.

Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

Our short-term investments as of December 31, 2003 consisted of \$9.7 million in corporate bonds, \$854,000 in municipal bonds, and \$770,000 in federal agency obligations 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 highly liquid money market accounts. A hypothetical 10% change in short-term interest rates from those in effect at December 31, 2003 would not have a significant impact on our financial position or on 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

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. We do not engage in currency hedging, and, if the British pound strengthens against the US dollar, our payments to Lonza will increase in US dollar terms. We have paid a total of \$4.9 million to Lonza under our agreements with them as of December 31, 2003, consisting of approximately \$1.7 million, \$1.6 million and \$1.3 million during the years ended December 31, 2001, 2002 and 2003, respectively. At December 31, 2003, we had no outstanding significant obligations or future contractual commitments to Lonza. However, we may elect to purchase additional antibodies from Lonza, in which case we would have to make payments in British pounds,

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exposing us to currency exchange risks in the future. A hypothetical 10% change in the British pound from the rate in effect at December 31, 2003 would not have a significant impact on our financial position or our expected results of operations.

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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 plan to submit these findings to the FDA for review in our 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 10 of 11 patients evaluated to date. In addition, there was a 50% or greater reduction in spleen size as measured below the rib cage by physical examination in all 10 of the patients with enlarged spleens. We plan to submit these findings to the FDA for review in our annual report.
- ***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 32 patients evaluated to date 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 on the first 25 patients evaluated for tumor responses in our clinical trial have, in the majority of patients, documented a greater than 90% decrease in the tumor marker, which is used to measure disease. We have not yet submitted these findings to the FDA, and 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 have also recently initiated 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 recently 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

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submitted to the FDA. We plan to initiate a Phase II clinical trial in the first half of 2004 in patients with non-Hodgkin's lymphoma who have failed prior therapies.

- ***Kidney cancer.*** In our completed Phase I clinical trial in 25 patients with metastatic kidney cancer, treatment with Xcellerated T Cells and low doses of the T cell activating agent, interleukin-2, or IL-2, led to a median survival of 21 months. Previous independent clinical studies have demonstrated median survival of patients with metastatic kidney cancer of approximately 12 months. The results of this study were recently published in a peer-reviewed journal, *Clinical Cancer Research*, in September 2003, and have been submitted to the FDA for review.
- ***Prostate cancer.*** In our recently completed Phase I/II clinical trial in prostate cancer, treatment with Xcellerated T Cells led to greater than 50% decreases in the serum tumor marker, prostate specific antigen, or PSA, in two out of 19 patients. We have not yet submitted these findings to the FDA. In some independent clinical studies, decreases in PSA levels have been shown to correlate with increased patient survival.
- ***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. The results of this study were recently published in a peer-reviewed journal, *Blood*, in September 2003. These data were derived from an independent clinical trial, which we did not control, and 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. In several independent clinical studies, increased levels of T cells have been shown to correlate with increased patient survival and improved clinical outcome. In addition, Fresenius Biotechnology GmbH initiated a Phase I clinical trial under our collaboration to treat HIV patients with genetically-modified T cells produced using our Xcellerate Technology.

In clinical trials, we have observed few side effects in most patients. To date, in over 115 infusions of Xcellerated T Cells, we have had only two 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. 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 not been randomized nor double-blinded to ensure that the results are due to the effects of the Xcellerate Technology. Success in early clinical trials does not ensure that large-scale trials will be successful nor does it predict 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, represent major potential markets for Xcellerated T Cells. In addition, these types of cancer 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. We plan to initiate one or more pivotal clinical trials in these hematological malignancies in 2005.

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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.

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.

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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 congenital 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-

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Hodgkin's lymphoma. Patients with HIV have an increased risk of developing non-Hodgkin's lymphoma and multiple myeloma. Patients with certain types of congenital 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.

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- ***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

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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.

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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 approximately 10-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.

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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 were published in the peer-reviewed *BioProcessing Journal* in November 2003 and we have submitted these data to the FDA 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 I/II clinical trial in multiple myeloma, we already 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. We have also observed that the Xcellerated T Cells can directly kill the patients' tumor cells. 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 10 of 11 patients evaluated and a 50% or greater reduction in spleen size as measured below the ribcage by physical examination in all 10 of the patients with enlarged spleens. We plan to submit these findings to the FDA for review in our annual report.
- ***Broadened T cell diversity.*** We have observed the generation of T cells with broad variety of T cell receptors using our Xcellerate Technology. We have shown in the laboratory that our Xcellerate Technology can be used to significantly broaden the diversity of the narrow T cell repertoire found in many cancer patients. In laboratory studies, one of our scientific founders has independently demonstrated similar results in a clinical trial in HIV patients. In our Phase I/II ongoing clinical trial in multiple myeloma, we have preliminary evidence that Xcellerated T Cells can be used to restore a broad T cell repertoire after administration into patients.

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- ***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 170 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 two serious adverse events reportable to the FDA that were judged as possibly or probably related to the therapy, both 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 protocol to identify patients with anemia prior to administering Xcellerated T Cells.
- ***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 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 recently entered into a collaboration under which Fresenius Biotechnology GmbH will treat HIV patients with genetically-modified T cells produced using our Xcellerate Technology. One patient has been enrolled to date in a recently initiated Phase I clinical trial under this collaboration. 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.
- ***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

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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 plan to initiate one or more pivotal clinical trials in CLL, multiple myeloma or non-Hodgkin's lymphoma in 2005. We believe these clinical indications 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. In addition, we intend to apply for FDA orphan drug status for Xcellerated T Cells for those cancers that qualify, including CLL, multiple myeloma and kidney cancer.
- **Expand the application 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, such as those with congenital immunodeficiencies. We may also expand the application of Xcellerated T Cells to other types of cancer. We are also exploring the use of Xcellerated T Cells in patients with autoimmune diseases who have been treated with immunosuppressive drugs. 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 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

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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:

<u>Disease and indication</u>	<u>Clinical trial status</u>	<u>Sponsor</u>	<u># of patients treated/planned</u>
Cancer Hematological malignancies			
CLL			
• Progressive disease	Ongoing Phase I/II	Xcyte	14/18
• Post-Campath	Planned Phase II	Xcyte	
Multiple myeloma			
• Post-autologous stem cell transplant	Ongoing Phase I/II	Xcyte	36/36
	Ongoing Phase I/II	Physician	40/40
• Relapsed	Ongoing Phase II	Xcyte	1/30
Non-Hodgkin's lymphoma	Completed Phase I	Physician	16/16
	Planned Phase II ⁽¹⁾	Xcyte	
Cancer Solid tumors			
Kidney cancer	Completed Phase I/II	Xcyte	25/25
Prostate cancer	Completed Phase I/II	Xcyte	19/20
HIV			
	Completed Phase I	Physician	8/8
	Ongoing Phase I ⁽²⁾	Fresenius	
	Ongoing Phase II	Physician	12/24

⁽¹⁾ We plan to initiate this Phase II clinical trial with 40 patients in the first half of 2004.

⁽²⁾ One of the 10 planned patients has been enrolled in this Phase I clinical trial.

Cancer

The American Cancer Society estimated that there would be 1.3 million new cases of cancer in the United States in 2003. Many cancer patients are treated with chemotherapy drugs, which often have limited efficacy and are associated with severe and sometimes life-threatening side effects. Physicians have recently begun to recognize the important role that the immune system may play in controlling cancer. As a result, immune-based therapeutic products, such as monoclonal antibodies, have become important drugs used to treat patients with cancer. These

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therapeutic products have become more widely used not only because of their efficacy, but also because they are generally better tolerated than chemotherapy.

Hematological Malignancies

Hematological malignancies are cancers of the blood or bone marrow. The American Cancer Society estimated that there would be approximately 106,200 new cases of hematological malignancies in the United States in

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2003. 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.

CLL

- **Background.** According to third party sources, approximately 73,000 patients have CLL in the United States, and there would be 7,300 new cases of CLL and 4,400 deaths due to this disease in the United States in 2003. 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, including those that are normal as well as malignant. Consequently, patients treated with these drugs suffer from severe T cell deficiencies, which increase the risk of infection.
- **Clinical data.** 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. The National Institutes of Health awarded us an SBIR grant of approximately \$1.2 million to help fund this trial. We are treating a minimum of three patients at each of three different dose levels of 10, 30 and 60-100 billion Xcellerated T Cells and a total of approximately 18 patients in this clinical trial. 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 14 patients have been treated to date. We have observed few side effects in most patients. To date, 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. The event was reported by the attending physician in his judgment as unlikely related to the therapy. In addition, we have documented a 50% to 100% reduction in the size of enlarged lymph nodes in 10 of 11 patients evaluated and a 50% or greater reductions in spleen size as measured below the ribcage by physical examination in all 10 of the patients with enlarged spleens. To date, we have not observed any significant decrease in leukemia counts in the blood of these patients. We plan to submit these findings to the FDA for review in our annual report. 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 not been randomized nor double-blinded to ensure that the results are due to the affects of the Xcellerate Technology. Success in early clinical trials does not ensure that large-scale trials will be successful nor does it predict final results.

We plan to initiate a randomized, Phase II clinical trial in which patients will be treated with Campath with or without subsequent treatment 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.

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Multiple Myeloma

- **Background.** 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 45,000 patients have multiple myeloma in the United States, approximately 14,600 new patients will be diagnosed with multiple myeloma and 10,900 patients will die of the disease in the United States in 2003. 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.
- **Clinical data.** We recently completed treatment of all 36 of the planned patients in an 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 32 patients evaluated to date 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. Additionally, we and others have demonstrated that the diversity of the T cell receptor repertoire is often extremely limited in patients with multiple myeloma. In our clinical trial, the T cell receptor repertoire demonstrated a normal pattern in four of the first five evaluable patients by four weeks after stem cell transplantation. In contrast, in multiple myeloma patients who do not receive Xcellerated T Cells, it typically takes more than a year for the limited T cell receptor repertoire to return to normal after transplant. We believe the improvements in the time to lymphocyte recovery and diversity of the T cell repertoire 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 clinical results on the first 25 patients evaluated for tumor responses in our clinical trial have, in the majority of patients, documented a greater than 90% decrease in the tumor marker, which is used to measure disease. We have not submitted these findings to the FDA and 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 recently initiated a Phase II clinical trial in multiple myeloma in which we plan to enroll approximately 30 patients who have failed prior therapies. Patients in this trial are randomized to treatment with either a single

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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. To date, we have treated one patient in this trial. 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 not been randomized nor double-blinded to ensure that the results are due to the effects of the Xcellerate Technology. Success in early clinical trials does not ensure that large-scale trials will be successful nor does it predict final results.

Non-Hodgkin s Lymphoma

- Background.** Non-Hodgkin s lymphoma is a cancer that originates in the lymph nodes of the body. According to third-party sources, approximately 300,000 patients have non-Hodgkin s lymphoma, and approximately 53,000 new patients were diagnosed with this disease in the United States in 2003. 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.
- Clinical data.** An independent clinical trial was conducted by one of our scientific founders under a physician-sponsored IND application 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. Based on the effects that we have documented in the lymph nodes in patients with CLL, we plan to initiate a Phase II clinical trial in the first half of 2004 to test whether Xcellerated T Cells can be used to treat patients with low-grade lymphoma. 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 not been randomized nor double-blinded to ensure that the results are due to the effects of the Xcellerate Technology. Success in early clinical trials does not ensure that large-scale trials will be successful nor does it predict final results.

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Solid Tumors

Solid tumors are cancers that originate in organs of the body. The American Cancer Society estimated that there would be over one million new patients with solid tumors, such as breast, prostate, kidney, lung, liver and colon cancers and approximately 500,000 people would die from these types of cancers in the United States in 2003. 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

- **Background.** The American Cancer Society estimated that approximately 31,900 patients would be diagnosed with kidney cancer in the United States in 2003. 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 12,000 deaths were expected to occur in the United States in 2003. 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.
- **Clinical data.** 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.

We are evaluating the feasibility of a pivotal clinical trial in kidney cancer. We are also evaluating partnership opportunities to support further development of this clinical indication. 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 not been randomized nor double-blinded to ensure that the results are due to the effects of the Xcellerate Technology. Success in early clinical trials does not ensure that large-scale trials will be successful nor does it predict final results.

Prostate Cancer

- **Background.** Prostate cancer is the most common form of cancer in men in the United States. The American Cancer Society estimated that there would be 220,900 new cases and approximately 28,900 patients would die of prostate cancer in the United States in 2003. 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 the current standard treatment,

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which is hormonal therapy. For patients with advanced prostate cancer who have failed standard hormonal therapy, there are currently no treatments that have been demonstrated to improve survival.

- Clinical data.** 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 not yet 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 not been randomized nor double-blinded to ensure that the results are due to the effects of the Xcellerate Technology. Success in early clinical trials does not ensure that large-scale trials will be successful nor does it predict final results.

HIV

- Background.** According to third party sources, there are estimated to be approximately 900,000 individuals infected with HIV in the United States. 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 being effective in a significant number of patients. HAART is also associated with serious side effects.
- Clinical data.** 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. Based on this observation, he and his collaborators conducted a preclinical study in an HIV model in monkeys and a clinical trial in HIV patients who had decreased T cell counts. The preclinical monkey model study showed that T cells activated using our 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. In an independent clinical trial conducted by one of our scientific founders under a physician sponsored IND application 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.

Based on these preclinical and clinical studies, we have initiated preclinical studies in HIV. We recently entered into a collaboration under which Fresenius Biotechnology GmbH plans to treat HIV patients with genetically-modified

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T cells produced using our Xcellerate Technology. One patient has been enrolled to date in a recently initiated 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 been required to be designed to produce statistically significant results as to efficacy. These trials have not been randomized nor double-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 does not ensure that large-scale trials will be successful nor does it predict final results.

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. We plan to initiate a clinical trial using this approach, in which patients will be treated with drugs that eliminate T cells from their body, followed by administration of Xcellerated T Cells, in patients with serious forms of autoimmune diseases if future preclinical studies achieve successful results.

Research and Development

As of January 31, 2004, we had a total of 28 employees dedicated to research and development, including 8 with advanced degrees. We spent approximately \$54.3 million from January 1, 2000 through December 31, 2003 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 reduced our overall average process time for manufacturing Xcellerated T Cells from approximately 14 days to approximately 10 days. 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.
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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 are working with several groups to evaluate

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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.

- ***Developing additional clinical indications for Xcellerated T Cells.*** There are many medical conditions that are associated with deficiencies in T cells. We are currently studying the potential to use Xcellerated T Cells to treat these illnesses. 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 are planning to study the use of Xcellerated T Cells in patients with congenital immunodeficiencies. 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 manufacturing facility in Seattle, Washington in accordance with cGMP. We use this facility to manufacture Xcellerated T Cells for clinical trials. We have also leased an additional facility that we have designed and intend to build to manufacture Xcellerated T Cells for our planned clinical trials and, if we obtain FDA approval, initial commercialization. We expect to begin manufacturing Xcellerated T Cells at this facility in the second half of 2004. 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. For completed milestones, we have paid Dynal \$2.5 million as of December 31, 2003 and, assuming the remaining milestones are completed, we will be obligated to pay an additional \$0.5 million. 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 \$4.9 million as of December 31, 2003. 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. We currently do not have agreements with third parties to supply us with tissue culture media or 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

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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

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a method of treating cancer and infectious diseases. These competitors include Antigenics, Inc., CancerVax Corporation, Cell Genesys, Inc., CellExSys, Inc., Dendreon Corporation, Favril, Inc., Genitope Corporation, IDM, S.A., Kirin Pharmaceutical and Valeocyte Therapies. Even if our Xcellerate Technology proves successful, we might not be able to remain competitive in this rapidly advancing area of technology. Some 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 US 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 January 31, 2004, we owned or held exclusive rights to six issued patents, three allowed patent applications and numerous pending patent applications in the United States in the field of or directed to *ex vivo* T cell stimulation. Two of the issued patents relate to methods of stimulating T cells utilized by our Xcellerate Technology and expire in 2019, 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. The final two 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 two 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 all likely derivatives of this compound. We also have licensed numerous currently pending foreign patent applications and 2 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

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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 Biotechnology 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 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.

We believe that partnering with Fresenius will optimize time to market of our Xcellerate Technology in the HIV field by utilizing their existing development, marketing and sales force. Fresenius initiated a Phase I trial to treat HIV patients with genetically-modified T cells produced using our Xcellerate Technology.

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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 December 31, 2003. 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 US\$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. 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

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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. To date, two licensed patents whose terms expire in 2016 and two other patents whose terms expire in 2019 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 preferred stock to Genetics Institute and issued a warrant under which Genetics Institute has the right to purchase 35,362 additional shares of our preferred stock, which will convert into a warrant to purchase our common stock after the closing of this offering. 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. 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 pharmaceutical 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 and efficacy as well as detailed information on the manufacture, quality, composition and labeling of the product in a new drug application or a biologics license application. 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 an FDA advisory panel of outside experts are expensive and typically take many years to complete. Additionally, 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 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 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 compound. An investigational new drug application generally must be submitted by a commercial sponsor who intends to collect data on the safety and efficacy of a new drug or biological product prior to conducting human trials and submitting an application for marketing approval. In certain circumstances,

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an investigational new drug application may also be submitted which allows physicians to gain an initial understanding of the compound through an expanded access program. Data from expanded access trials can generally be used to support the safety, but not the efficacy, of a product.

After an investigational new drug application becomes effective, a sponsor may commence human clinical trials. 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 clinical trials typically involve additional testing for safety and clinical efficacy in an expanded population at geographically dispersed test sites and are intended to generate the pivotal data on which a marketing 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 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 for a site participating in the trials. The sponsor must also ensure that investigators obtain informed consent 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 a new drug application or, in the case of a biologic, a biologics license application. 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. 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 biologics license applications to the FDA to obtain approval of our products. A biologics license application 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 compound is both safe and effective and that other applicable requirements have been met, approves the drug or 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 compound 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 approval of fast track products, including qualifying biologics. We may, from time to time, decide to request fast track approval for Xcellerated T Cells. A fast track product is defined as a new drug or biologic intended for the treatment of a serious or life-

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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.

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 product on an expedited basis 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 have requested, and may from time to time continue to 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.

The labeling, advertising, promotion, marketing and distribution of a drug or biologic product must be in compliance with FDA regulatory requirements. Our distribution of pharmaceutical samples to physicians must comply with the Prescription Drug Marketing Act. 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

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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. 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 filed 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. We anticipate having clinical data regarding safety and tumor responses in 2004. In November 2002, we amended the IND to add a Phase I/II study to treat CLL. We anticipate completion of the trial in 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 anticipate completion of the trial in 2005. In December of 2003, we amended the IND to add a Phase II study to treat non-Hodgkin's lymphoma patients. We anticipate completion of the trial in 2005.

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Legal Proceedings

From time to time, we may be involved in various legal proceedings in the ordinary course of business. Although it is not feasible to predict the outcome of these proceedings or any claims made against us, we do not anticipate that our ultimate liability arising from these proceedings or claims will have a materially adverse effect on our financial position or results of operations.

On July 26, 2000, Karen Lenahan filed suit against the University of Chicago, the University of Chicago Hospitals, Central DuPage Hospital and various doctors, seeking to recover damages in an unspecified amount in excess of \$100,000 arising out of the death of Mrs. Lenahan's husband, Shawn Lenahan. The complaint, filed in the Circuit Court of Cook County, Illinois, alleged that the physicians committed medical malpractice. Mr. Lenahan was treated in an independent clinical trial conducted by one of our scientific founders using an earlier version of our proprietary technology. This trial was initiated prior to our licensing of this technology. The complaint was amended to add additional defendants, and, on February 26, 2001, a second amended complaint was filed that named us as a defendant. The second amended complaint attempted to allege that we participated in an unlawful conspiracy to induce Mr. Lenahan to participate in a drug protocol for an experimental treatment for his non-Hodgkin's lymphoma.

On May 7, 2001, we filed a motion seeking to dismiss the conspiracy claims, the only counts in the second amended complaint in which we were named as a defendant. On June 29, 2001, the court granted the motion to dismiss. On July 27, 2001, the plaintiff filed a fourth amended complaint, which again named us as a defendant and attempted to allege that we and our co-defendants unlawfully conspired against Mr. Lenahan. On August 31, 2001, we filed a motion to dismiss the conspiracy claims against us. On February 25, 2002, the court granted the motion to dismiss. However, the court granted the plaintiff one final chance to file an amended complaint. On March 26, 2002, the plaintiff filed a fifth amended complaint, which alleged similar claims as the fourth amended complaint. We filed a motion to dismiss the conspiracy claims, and, on July 22, 2002, the court granted our motion to dismiss the plaintiff's fifth amended complaint with prejudice. On August 20, 2002, the plaintiff filed a notice of appeal in the Appellate Court of Illinois, First Judicial District, from the circuit court's order granting our motion to dismiss. On April 7, 2003, we filed our response brief, and, on April 21, 2003, the plaintiff filed a reply brief. Oral arguments for the appeal are currently scheduled to be heard by the court on March 16, 2004. We cannot predict when we will obtain a decision on the appeal. We deny having committed any conspiracy against Mr. Lenahan, however, because of the nature of the complaint against us, we cannot predict the probability of a favorable or unfavorable outcome or estimate the amount or range of potential loss.

Employees

As of January 31, 2004, we had 71 employees, 28 of whom are directly involved in research and development and 28 of whom are involved in manufacturing operations. We consider our relations with our employees to be good.

Facilities

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 \$48,000. 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 \$77,000. We plan initially to renovate 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.

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SCIENTIFIC ADVISORY BOARD

Our Scientific Advisory Board is our network of medical, scientific and clinical advisors and collaborators who consult with our scientists. In addition, our Scientific Advisory Board members, none of whom are our employees, advise us regarding our research and development programs, the design of our clinical trials as well as other medical and scientific matters relating to our business. The following persons serve on our Scientific Advisory Board:

Joseph Bertino, M.D., is the Associate Director of the Cancer Institute of New Jersey and University Professor of Medicine and Pharmacology at the University of Medicine and Dentistry of New Jersey.

Jeffrey Bluestone, Ph.D., is one of our scientific founders and is a Professor at the University of California, San Francisco and the Director of the UCSF Diabetes Center.

Edward Clark, Ph.D., is a Professor of Immunology and a Professor of Microbiology at the University of Washington.

John Hansen, M.D., is a Member of Clinical Research at the Fred Hutchinson Cancer Research Center and Professor of Medicine at the University of Washington.

Carl June, M.D., is one of our scientific founders and is the Vice Chairman of the Department of Molecular and Cellular Engineering at the University of Pennsylvania.

Hyam Levitsky, M.D., is a Professor of Oncology, Medicine and Urology at Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins University.

Ronald Levy, M.D., is the Chief of the Division of Medical Oncology at the Stanford Medical Center.

Gerald Nepom, M.D., Ph.D., is the Director, Benaroya Research Institute at Virginia Mason.

E. Donnell Thomas, M.D., is a Member and former Director of Clinical Research at the Fred Hutchinson Cancer Research Center. Dr. Thomas was awarded the 1990 Nobel Prize in Medicine.

Craig Thompson, M.D., is one of our scientific founders and is the Scientific Director of the Abramson Family Cancer Research Institute at the University of Pennsylvania.

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Robert M. Williams, Ph.D., is a University Distinguished Professor, Department of Chemistry, at Colorado State University. Dr. Williams is also a member of our board of directors.

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Set forth below is the name, age, position and a brief account of the business experience of each of our executive officers and directors:

<u>Name</u>	<u>Age</u>	<u>Position(s)</u>
Ronald J. Berenson, M.D.	51	President, Chief Executive Officer and Director
Robert L. Kirkman, M.D.	55	Chief Business Officer and Vice President
Stewart Craig, Ph.D.	42	Chief Operating Officer and Vice President
Mark Frohlich, M.D.	42	Medical Director and Vice President
Mark L. Bonyhadi, Ph.D.	50	Vice President of Research
Kathi L. Cordova, C.P.A.	43	Senior Vice President of Finance and Treasurer
Joanna S. Black, J.D.	30	General Counsel, Vice President and Secretary
Robert E. Curry, Ph.D.	57	Director
Jean Deleage, Ph.D.	63	Director
Dennis Henner, Ph.D.	52	Director
Peter Langecker, M.D., Ph.D.	53	Director
Robert T. Nelsen, M.B.A.	40	Director
Stephen N. Wertheimer, M.M.	53	Director
Robert M. Williams, Ph.D.	51	Director

Ronald J. Berenson, M.D., is our founder and has served as our President, Chief Executive Officer and as a member of our board of directors since our inception. From April 1989 until February 1995, Dr. Berenson held several positions at CellPro, Inc., a stem cell therapy company that he founded, with his last positions being Executive Vice President, Chief Medical and Scientific Officer and Director. Dr. Berenson also serves on the board of directors of the Fred Hutchinson Cancer Research Center Foundation. Dr. Berenson was a faculty member at the Fred Hutchinson Cancer Research Center, where he last held the position of Assistant Member. Dr. Berenson is a board-certified internist and medical oncologist who completed his medical oncology fellowship training at Stanford University Medical Center. Dr. Berenson received a B.S. in biology from Stanford University and an M.D. from Yale University School of Medicine.

Stewart Craig, Ph.D., has served as our Chief Operating Officer and Vice President since October 1999. From July 1996 to September 1999, Dr. Craig served as Vice President of Development and Operations at Osiris Therapeutics, Inc., a stem cell therapy company. From January 1994 to June 1996, Dr. Craig served as Vice President of Product and Process Development at SyStemix Inc., a stem cell and gene therapy company. From June 1987 to December 1993, Dr. Craig held the positions of Group Leader and Senior Scientist at British Biotech, a biotechnology company. Dr. Craig received a B.Sc. in biochemistry and a Ph.D. in physical biochemistry from the University of Newcastle upon Tyne, UK.

Mark Frohlich, M.D., has served as our Medical Director since October 2001 and has served as our Vice President since January 2002. Dr. Frohlich is a board-certified medical oncologist with an appointment as Clinical Assistant Professor of Medicine at the University of Washington. From July 1998 to October 2001, Dr. Frohlich held the position of Assistant Adjunct Professor of Medicine at the University of California at San Francisco. From July 1994 to June 1998, Dr. Frohlich completed his fellowship in medical oncology at the University of California at San Francisco. Dr. Frohlich received a B.S. in electrical engineering and economics from Yale University and an M.D. from Harvard Medical School.

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Mark L. Bonyhadi, Ph.D., has served as our Vice President of Research since January 2003. Dr. Bonyhadi previously served as our Director of Research from January 2002 to January 2003, Director of Strategic

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Scientific Development from April 2001 to December 2001 and Director of Biological Research from May 1997 to March 2001. From September 1990 to April 1997, Dr. Bonyhadi served as Senior Scientist with SyStemix, Inc., a stem cell and gene therapy company. Dr. Bonyhadi received a B.A. in biology from Reed College and a Ph.D. in immunology from the University of California at Berkeley.

Kathi L. Cordova, C.P.A., has served as our Senior Vice President of Finance and Treasurer since September 2003. Ms. Cordova previously served as our Vice President of Finance from March 1997 to September 2003. From February 1994 to February 1997, Ms. Cordova held the position of Assistant Controller in a joint venture between American Life Insurance Company, a subsidiary of American International Group, an insurance company, and Italy's Confederazione Italiana Sindacati dei Lavoratori, a labor union. From August 1991 to January 1994, Ms. Cordova served as Management Associate with the Life Division of American International Group, an insurance company. Ms. Cordova received a B.A. in international relations from Stanford University and an M.A. in international relations from The Johns Hopkins University.

Robert Kirkman, M.D., Vice President and Chief Business Officer, joined us in January, 2004. Prior to joining us, Dr. Kirkman held the position of Vice President of Business Development and Corporate Communications at Protein Design Labs, Inc. from 1998 to 2003. Prior to that, Dr. Kirkman served as Chief of the Division of Transplantation at Brigham and Women's Hospital, and as an Associate Professor of Surgery at Harvard Medical School. Dr. Kirkman received a B.A. in Economics from Yale University and an M.D. from Harvard Medical School. He is a Fellow of the American College of Surgeons.

Joanna S. Black, J.D., has served as our General Counsel and Secretary since January 2002 and has served as our Vice President since September 2003. From September 1998 to January 2002, Ms. Black worked as an attorney at Venture Law Group, A Professional Corporation, a law firm. From August 1997 to August 1998, Ms. Black worked as an attorney at Wilson Sonsini Goodrich & Rosati, P.C., a law firm. Ms. Black received a B.A. in economics and public policy from Stanford University and a J.D. from Columbia University School of Law.

Robert E. Curry, Ph.D., has served as one of our directors since July 2002 and from May 2000 to January 2002. Dr. Curry has been a Venture Partner at Alliance Technology Ventures, a venture capital firm, since July 2002. Dr. Curry previously served as a General Partner and a Venture Partner of the Sprout Group from May 1991 to June 2002. He currently is a director of Emerald Bio-Agricultural Corporation, a medical products company, and Tripath Imaging, Inc., a cancer therapy company. Dr. Curry received a B.S. in physics from the University of Illinois and an M.S. and Ph.D. in chemistry from Purdue University.

Jean Deleage, Ph.D., has served as one of our directors since August 1996. Dr. Deleage is a founder and managing director of Alta Partners, a venture capital firm, and was previously a founder of Burr, Egan, Deleage & Company and Sofinnova Ventures, Inc., a venture capital fund. Dr. Deleage is director of Crucell N.V., Kosan Biosciences Incorporated and Rigel Pharmaceuticals, Inc. and several private companies, all biopharmaceutical companies. Dr. Deleage received an M.S. in electrical engineering from the Ecole Supérieure d'Electricité and a Ph.D. in economics from the Sorbonne.

Dennis Henner, Ph.D., has served as one of our directors since July 2002. Dr. Henner has been a General Partner at MPM Capital, a venture capital firm, since January 2002 and was a Venture Partner at MPM Capital from May 2001 through December 2001. From April 1996 to February 2001, Dr. Henner held the positions of Senior Vice President of Research and Vice President of Research at Genentech, Inc., a biotechnology company. Dr. Henner is currently director of biotechnology companies Tercica Medica, Inc., Rigel, Inc., Synergia Pharma, Inc. and Rinat Neuroscience Corporation. Dr. Henner received his B.A. in Life Sciences and his Ph.D. from the Department of Microbiology at the University of Virginia.

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Peter Langecker, M.D., Ph.D., has served as one of our directors since January 2000. Since October 1999, Dr. Langecker has served as Chief Medical Officer and Vice President of Clinical Affairs of BioMedicines, Inc., a biotechnology company. From July 1997 to September 1999, Dr. Langecker served as Vice President of Clinical

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Affairs and Regulatory Affairs of Sugen, Inc., a biotechnology company. From March 1995 to July 1997, Dr. Langecker served as Vice President of Clinical Affairs of Coulter Pharmaceuticals, Inc., a biotechnology company. Before that, Dr. Langecker held various medical positions at Ciba Geigy and Schering-Plough. Dr. Langecker received an M.D. and a Ph.D. in medical sciences from Ludwig Maximilians University in Munich.

Robert T. Nelsen, M.B.A., has served as one of our directors since August 1996. Since 1992, Mr. Nelsen has served as a managing director of ARCH Venture Partners, a venture capital firm. Mr. Nelsen also serves as a director of Adolor Corporation (ADLR), an analgesics development company and Illumina Corporation (ILMN), a biotechnology company. Mr. Nelsen received a B.S. in biology and economics from the University of Puget Sound and an M.B.A. from the University of Chicago.

Stephen N. Wertheimer, M.M., has served as one of our directors since November 2003. Mr. Wertheimer has served as a managing director of W Capital Partners, a private equity firm, since 2001. From 1996 to 2001, Mr. Wertheimer held the position of managing director of CRT Capital Group. Mr. Wertheimer is currently director of El Paso Electric Company, an electric utility, and Trikon Technologies, Inc., a semiconductor equipment company. Mr. Wertheimer received an M.M. from the Kellogg School, Northwestern University, and earned a B.S. in finance and economics at Indiana University.

Robert M. Williams, Ph.D., has served as one of our directors since November 1996 and a member of our Scientific Advisory Board since 1995. Since September 1980, Professor Williams has served as a Professor of Chemistry at Colorado State University, and, in 2001, he was appointed University Distinguished Professor. During his career, Professor Williams has provided consulting services to several biotechnology and pharmaceutical companies, including Cubist Pharmaceutical Company, Microcide Pharmaceuticals, Hoffman-La Roche, G.D. Searle, and EPIX Medical, Inc. Professor Williams received a B.A. in chemistry from Syracuse University and a Ph.D. in organic chemistry from the Massachusetts Institute of Technology. Following graduate school, Professor Williams served as a postdoctoral fellow at Harvard University.

Board Composition

Our board of directors is currently comprised of eight directors. Following the closing of this offering, the board will be divided into three classes, with each director serving a three-year term and one class being elected at each year's annual meeting of stockholders. Dr. Langecker and Dr. Williams will be in the class of directors whose initial term expires at the 2004 annual meeting of stockholders. Dr. Deleage, Dr. Henner and Mr. Wertheimer will be in the class of directors whose initial term expires at the 2005 annual meeting of stockholders. Dr. Berenson, Dr. Curry and Mr. Nelsen will be in the class of directors whose initial term expires at the 2006 annual meeting of stockholders.

Board Committees

Our board of directors has established an audit committee, a compensation committee and a pricing committee.

The audit committee currently consists of Dr. Curry, Dr. Deleage and Mr. Wertheimer. In connection with Dr. Curry's consultancy to affiliates of the Sprout Group, he is required to resign from the audit committee upon the closing of this offering. We intend to add a third member to the audit committee to replace Dr. Curry within 90 days following the closing, in accordance with Nasdaq Marketplace Rule 4350(d)(4). The audit committee is responsible for assuring the integrity of our financial control, audit and reporting functions and reviews with our management and our independent auditors the effectiveness of our financial controls and accounting and reporting practices and procedures. In addition, the audit

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committee reviews the qualifications of our independent auditors, is responsible for their appointment, compensation, retention and oversight and reviews the scope, fees and results of activities related to audit and non-audit services. Prior to the formation of the audit committee, the full board of directors conducted the responsibilities of the audit committee, which met annually with representatives of our independent auditors, including in executive sessions where members of management were excused.

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The pricing committee consists of Dr. Berenson, Dr. Deleage, Dr. Curry and Mr. Nelsen. The pricing committee is responsible for determining the terms of this initial public offering, including, but not limited to, determining the number of shares to be sold by us and the initial public offering price per share.

Effective upon this offering, the compensation committee will consist of Dr. Curry, Mr. Nelsen and Dr. Langecker. The compensation committee's principal responsibility is to administer our stock plans and to set the salary and incentive compensation, including stock option grants, for our Chief Executive Officer and other executive officers.

Director Compensation

Our seven outside directors are compensated with options to purchase our common stock. The only cash compensation they receive is reimbursement for out-of-pocket expenses incurred in connection with attending board and committee meetings. In November 1996, Dr. Deleage and Dr. Williams were each awarded non-statutory options for 5,454 shares of our common stock. In November 1999, Dr. Langecker was awarded a non-statutory option for 5,454 shares of our common stock. These shares vest over a four-year period at a rate of 25% of the total number of shares one year after the date of grant, with the remaining shares vesting monthly in equal installments over the next 36 months. In November 2003, Dr. Williams was awarded non-statutory options for 2,727 fully vested shares of our common stock in connection with his service on our Scientific Advisory Board. Directors who are our employees are eligible to participate in our 1996 Stock Option Plan and, effective at the closing of this offering, will also be eligible to participate in our 2003 Stock Plan and 2003 Employee Stock Purchase Plan. Until the closing of this offering, directors who are not our employees have been eligible to participate in our 1996 Stock Option Plan. Effective at the closing of this offering, directors who are not our employees will be eligible to participate in our 2003 Directors' Stock Option Plan as well but will no longer be eligible to participate in our 1996 Stock Option Plan.

Compensation Committee Interlocks and Insider Participation

Dr. Deleage, Mr. Nelsen, Dr. Curry and Dr. Berenson served on our compensation committee in 2002. During 2002, none of our executive officers served as a director or member of the compensation committee of any other entity that had any executive officer who served on our board of directors or on our compensation committee.

Limitations on Liability and Indemnification of Officers and Directors

Upon the closing of this offering, our amended and restated certificate of incorporation will limit the liability of our directors to the maximum extent permitted by Delaware law. Delaware law provides that a corporation may eliminate the personal liability of its directors for monetary damages for breach of their fiduciary duties as directors, except liability for any of the following acts:

- breach of their duty of loyalty to us or our stockholders;
- acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;

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- unlawful payments of dividends or unlawful stock repurchases or redemptions; and
- any transaction from which the director derived an improper personal benefit.

Our amended and restated bylaws, which will be effective upon the closing of this offering, provide that we will indemnify our directors, officers, employees and other agents to the fullest extent permitted by the Delaware General Corporation Law. Our amended and restated bylaws also permit us to secure insurance on behalf of any officer, director, employee or other agent of ours for any liability arising out of his or her actions in such capacity, regardless of whether the Delaware General Corporation Law would permit a corporation to indemnify for such liability.

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We have obtained directors' and officers' insurance providing indemnification for all of our directors, officers and employees for certain liabilities. In addition to the indemnification provided for in our amended and restated bylaws, we have entered into agreements to indemnify our directors and executive officers. These agreements, among other things, indemnify our directors and executive officers for expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by any of them in any action or proceeding arising out of his or her services as a director, officer, employee, agent or fiduciary of ours, any subsidiary of ours or any other company or enterprise to which he or she provides services at our request. We believe that these provisions and agreements are necessary to attract and retain qualified persons as directors and executive officers. At present, there is no litigation or proceeding involving any of our directors or officers in which indemnification is required or permitted, and we are not aware of any threatened litigation or proceeding that may result in a claim for indemnification.

Executive Compensation

The following table summarizes the compensation paid to, awarded to or earned during the years ended December 31, 2002 and 2003 by our Chief Executive Officer and each of our four other most highly compensated executive officers whose total salary and bonus exceeded \$100,000 for services rendered to us in all capacities during the years ended December 31, 2002 and 2003. The executive officers listed in the table below are referred to in this prospectus as our named executive officers.

Summary Compensation Table

Name and principal position(s)	Year	Annual compensation		Long-term compensation Securities underlying options	All other compensation
		Salary	Bonus		
Ronald J. Berenson, M.D. President and Chief Executive Officer	2003	\$ 249,714	\$ 35,000	\$	\$ 286 ⁽¹⁾
	2002	239,276	25,051		595 ⁽²⁾
Stewart Craig, Ph.D. Chief Operating Officer and Vice President	2003	215,176			284 ⁽³⁾
	2002	205,714	51		527 ⁽⁴⁾
Kathi L. Cordova, C.P.A. Senior Vice President of Finance and Treasurer	2003	150,547			286 ⁽⁵⁾
	2002	139,588			391 ⁽⁶⁾
Mark Frohlich, M.D. Medical Director and Vice President	2003	181,759	17,447		513 ⁽⁷⁾
	2002	172,183	16,043		534 ⁽⁸⁾
Lewis Chapman Chief Business Officer	2003	201,488	35,000		380 ⁽⁹⁾
	2002	100,403	40,051		312 ⁽¹⁰⁾
Joanna S. Black, J.D. General Counsel and Vice President	2003	154,882			264 ⁽¹¹⁾
	2002	(12)			

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- (1) Dr. Berenson received other compensation consisting of the payment of insurance premiums for group term life benefits in the amount of \$286.
- (2) Dr. Berenson received other compensation consisting of the payment of insurance premiums for group term life benefits in the amount of \$595.
- (3) Dr. Craig received other compensation consisting of the payment of insurance premiums for group term life benefits in the amount of \$284.
- (4) Dr. Craig received other compensation consisting of the payment of insurance premiums for group term life benefits in the amount of \$527.
- (5) Ms. Cordova received other compensation consisting of the payment of insurance premiums for group term life benefits in the amount of \$286.
- (6) Ms. Cordova received other compensation consisting of the payment of insurance premiums for group term life benefits in the amount of \$391.
- (7) Dr. Frohlich received other compensation consisting of the payment of insurance premiums for group term life benefits in the amount of \$513.
- (8) Dr. Frohlich received other compensation consisting of the payment of insurance premiums for group term life benefits in the amount of \$534.
- (9) Mr. Chapman received other compensation consisting of the payment of insurance premiums for group term life insurance in the amount of \$380. Mr. Chapman's employment with us ended in August 2003.
- (10) Mr. Chapman received other compensation consisting of the payment of insurance premiums for group term life insurance in the amount of \$312. Mr. Chapman's employment with us ended in August 2003.
- (11) Ms. Black received other compensation consisting of the payment of insurance premiums for group term life benefits in the amount of \$264.
- (12) Ms. Black joined our Company in January 2002.

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The following table provides summary information concerning the individual grants of stock options to each of our named executive officers for the fiscal year ended December 31, 2003. The exercise price per share was valued by our board of directors on the date of grant, and each option was issued at the estimated fair market value on the date of grant based upon the purchase price paid by investors for shares of our preferred stock, taking into account the liquidation preferences and other rights, privileges and preferences associated with such preferred stock.

Each option represents the right to purchase one share of our common stock. The options generally vest over four years. See Management Equity compensation plan information for more details regarding these options. In 2003, we granted options to purchase an aggregate of 225,470 shares of our common stock to various officers, employees, directors and others.

The potential realizable value at assumed annual rates of stock price appreciation for the option term represents hypothetical gains that could be achieved for the respective options if exercised at the end of the option term. SEC rules specify the 0%, 5% and 10% assumed annual rates of compounded stock price appreciation, which do not represent our estimate or projection of our future common stock prices. These amounts represent assumed rates of appreciation in the value of our common stock from the initial public offering price, assuming an initial public offering price of \$8 per share. Actual gains, if any, on stock option exercises depend on the future performance of our common stock and overall stock market conditions. The amounts reflected in the table may not necessarily be achieved.

Option Grants in Fiscal Year 2003⁽¹⁾

Named executive officer	Number of securities underlying options granted	Percentage of total options granted to employees	Exercise price per share	Expiration date	Potential realizable value at assumed annual rates of stock appreciation for option term		
					0%	5%	10%
Ronald J. Berenson, M.D.	45,453	21.18%	\$ 5.50	09/22/13	\$ 113,633	\$ 342,314	\$ 693,156
Stewart Craig, Ph.D.	18,181	8.47%	5.50	09/22/13	45,453	136,924	277,259
Mark Frohlich, M.D.	36,363	16.94%	5.50	09/22/13	90,908	273,855	554,534
Kathi L. Cordova, C.P.A.	18,181	8.47%	5.50	09/22/13	45,453	136,924	277,259
Joanna S. Black, J.D.	13,636	6.35%	5.50	09/22/13	34,090	102,695	207,948

⁽¹⁾These options were granted under our 1996 Stock Option Plan and vest over a four-year period.

The following table shows information as of December 31, 2003 concerning the number and value of exercised options and unexercised options held by each of our named executive officers. There was no public trading market for our common stock as of December 31, 2003. Accordingly, the value of the unexercised in-the-money options listed below has been calculated on the basis of the assumed initial public offering price of \$8 per share, less the applicable exercise price per share multiplied by the number of shares underlying the options.

Aggregated Option Exercises During 2003 and Year-End Option Values

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Named executive officer	Shares acquired upon exercise	Value realized	Number of securities underlying unexercised options at		Value of unexercised	
			December 31, 2003		in-the-money options at December 31, 2003	
			Exercisable	Unexercisable	Exercisable	Unexercisable
Ronald J. Berenson, M.D.		\$	40,150	78,029	\$ 225,322	\$ 195,073
Stewart Craig, Ph.D.			60,301	39,696	347,347	99,240
Mark Frohlich, M.D.			16,907	55,818	42,268	139,545
Kathi L. Cordova, C.P.A.			11,029	26,242	48,395	65,605
Joanna S. Black, J.D.			8,521	23,295	21,303	58,238

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Employment Agreements

Ms. Black's employment agreement, dated December 31, 2001, provides for at-will employment for an unspecified term. Under this agreement, Ms. Black is entitled to an annual base salary of \$150,000 per year and an initial stock option grant for 9,090 shares of our common stock. This employment agreement also provides that Ms. Black will receive severance payments equal to three months of her then current base salary, paid ratably over a three-month period, and three months of continued health coverage if her employment is terminated other than for cause and she signs a standard release of any claims against us.

Mr. Chapman's employment agreement, dated May 29, 2002, provides for at-will employment for an unspecified term. Under this agreement, Mr. Chapman is entitled to an annual base salary of \$200,000 per year, an initial stock option grant for 72,727 shares of our common stock, a one-time signing bonus of \$40,000 and a one-time home purchase bonus of \$35,000. This employment agreement also provides that Mr. Chapman will receive severance payments equal to six months of his then current base salary, paid ratably over a six-month period, and six months of continued health coverage if his employment is terminated other than for cause and he signs a standard release of any claims against us. Mr. Chapman's employment with us ended in August 2003, and we are currently making these severance payments to him.

Dr. Frohlich's employment agreement, dated August 27, 2001, provides for at-will employment for an unspecified term. Under this agreement, Dr. Frohlich is entitled to an annual base salary of \$170,000, an initial stock option grant for 7,272 shares of our common stock, a one-time signing bonus of \$40,000 and a loan of \$50,000 for a down payment of a principal residence forgiven over four years. This employment agreement also provides that Dr. Frohlich will receive severance payments equal to three months of his then current base salary, paid ratably over a three-month period, and three months of continued health coverage if his employment is terminated other than for cause and he signs a standard release of any claims against us. In this event, Dr. Frohlich's employment agreement provides that we will forgive the outstanding principal of the amount loaned to him for a down payment on a principal residence.

Dr. Kirkman's employment agreement, dated January 15, 2004, provides for at-will employment for an unspecified term. Under this agreement, Dr. Kirkman will receive an annual base salary of \$240,000, a stock option grant for 72,727 shares of our common stock, a one-time signing bonus of \$85,000 and relocation assistance reimbursement up to an aggregate of \$15,000. This employment agreement also provides that Dr. Kirkman will receive severance payments equal to six months of his then current base salary, paid ratably over a six-month period, and six months of continued health coverage if his employment is terminated other than for cause, provided that he signs a standard release of any claims against us at such time.

Equity Compensation Plan Information

2003 Stock Plan

Our 2003 Stock Plan was adopted by our board of directors in September 2003 and will be submitted for approval by our stockholders prior to completion of this offering. This plan provides for the grant of incentive stock options to employees (including employee directors) and nonstatutory stock options and stock purchase rights to employees, directors (excluding non-employee directors) and consultants. The purposes of this plan are to attract and retain the best available personnel, to provide additional incentives to our employees and consultants and to promote the success of our business. A total of 636,363 shares of common stock are reserved for issuance under this plan. The number of shares reserved for issuance under this plan will automatically increase on the first day of each fiscal year beginning in 2005 and ending in 2010 by the lesser of:

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- 109,090 shares;
- 4% of the number of shares of our common stock outstanding on the last day of the immediately preceding fiscal year; or
- any lesser number of shares that our board of directors determines.

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All share numbers reflected in this plan summary, as well as the exercise price or purchase price applicable to outstanding options or purchase rights, will be automatically proportionately adjusted in the event we undertake certain changes in our capital structure, such as a stock split, stock dividend or other similar transaction.

The administrator of the plan is our board of directors or a committee of our board. In the case of options and stock purchase rights intended to qualify as performance-based compensation within the meaning of Section 162(m) of the Internal Revenue Code of 1986, as amended, the committee will consist of two or more outside directors within the meaning of Section 162(m). In addition, in administering the plan, we intend to comply with other applicable legal and regulatory requirements as may apply from time to time, including any NASDAQ listing requirements. The administrator determines the terms of options and stock purchase rights granted under this plan, including the number of shares subject to the award, the exercise or purchase price and the vesting and/or exercisability of the award and any other conditions to which the award is subject. No employee, however, may receive awards for more than 181,818 shares under this plan in any fiscal year. Incentive stock options granted under this plan must have an exercise price of at least 100% of the fair market value of the common stock on the date of grant. Incentive stock options granted to an employee who holds more than 10% of the total voting power of all classes of our stock or any parent or subsidiary's stock cannot be less than 110% of the fair market value of the common stock on the date of grant. The exercise price of nonstatutory stock options and the purchase price of stock purchase rights will be the price determined by the administrator, although nonstatutory stock options and stock purchase rights granted to our Chief Executive Officer and our four other most highly compensated officers will generally equal at least 100% of the grant date fair market value if we intend that the awards to those individuals will qualify as performance-based compensation within the meaning of Section 162(m) of the Internal Revenue Code. Payment of the exercise or purchase price may be made in cash or any other consideration determined by the administrator, subject to applicable legal requirements.

The administrator will determine the term of options granted under this plan, which may not exceed 10 years, or 5 years in the case of an incentive stock option granted to a holder of more than 10% of the total voting power of all classes of our stock or a parent or subsidiary's stock. Generally, an option granted under this plan is non-transferable, other than by will or the laws of descent or distribution, and may be exercised during the lifetime of the optionee only by the optionee. However, the administrator may, in its discretion, provide for the limited transferability of non-statutory stock options granted under this plan. We generally have the right to repurchase any stock issued pursuant to stock purchase rights granted under this plan upon the termination of the holder's employment or consulting relationship with us for any reason, including death or disability. The repurchase price is the original purchase price paid by the purchaser or the fair market value of the shares at the date of the repurchase, whichever is less. This repurchase right will lapse at a rate that the administrator may determine.

If we sell all or substantially all of our assets or if we are acquired by another corporation, each outstanding option and stock purchase right may be assumed or an equivalent award may be substituted by the successor corporation, with appropriate adjustments made to both the price and number of shares subject to the option or purchase right. If the successor does assume the outstanding options and purchase rights, the lesser of 25% of the shares subject to an option or initially subject to repurchase or the remaining unvested shares will vest immediately prior to the closing of the transaction, and, if the holder is involuntarily terminated within one year after the closing, the lesser of another 25% of the shares subject to the option or initially subject to repurchase or the remaining unvested shares will vest on termination. Involuntary termination includes termination by us without cause, or voluntary resignation within 30 days following: (A) a reduction in the optionholder's base salary of more than 20% (except where there is a similar reduction in the base salaries of similarly situated employees) or (B) relocation of the optionholder's principal work site by more than 50 miles. If the successor corporation does not assume options and purchase rights or substitute equivalent options or purchase rights, then vesting of all shares subject to options will accelerate fully, all repurchase rights will lapse immediately prior to the closing of the transaction and options and purchase rights will terminate as of the closing of the transaction.

The administrator has authority to amend or terminate this plan, but no action may be taken that impairs the rights of any holder of an outstanding option or stock purchase right without the holder's consent. In addition, we

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must obtain stockholder approval of amendments to the plan as required by applicable law. Unless terminated earlier by the board of directors, this plan will terminate in 2013.

1996 Stock Option Plan

Our 1996 Stock Option Plan was adopted by our board of directors in September 1996. As of December 31, 2003:

- 717,615 shares of common stock were issuable upon exercise of outstanding options granted under this option plan at a weighted average exercise price of \$4.48
- 167,327 shares of common stock were issued upon exercise of options at purchase prices ranging between \$0.55 and \$5.50; and
- 278,691 shares of common stock remained available for future grants under this plan.

The board of directors amended this plan in September 2003 to increase the number of shares reserved for issuance under the plan by an additional 363,636 to 1,163,636. The amended plan will be submitted to our stockholders for approval prior to completion of this offering. All share numbers reflected in this plan summary, as well as the exercise price applicable to outstanding options, will be automatically proportionately adjusted in the event we make certain changes in our capital structure, such as a stock split, stock dividend or other similar transaction.

The terms of the awards under this plan are generally the same as the terms of the awards that may be issued under the 2003 Stock Plan, except for the following features:

- only options can be granted under this plan;
- stock options granted under this plan are non-transferable except by will or the laws of descent and distribution; and
- options granted to residents of California prior to the closing of this offering must meet certain specific requirements with respect to a minimum 20% vesting per year, a minimum post-termination exercise period of 30 days in circumstances other than death or disability (and 6 months in the case of death or disability) and a minimum exercise price of 85% of fair market value for non-statutory options.

If we sell all or substantially all of our assets, or if we are acquired by another corporation, each outstanding option may be assumed or an equivalent award substituted by the successor corporation, with appropriate adjustments made to both the price and number of shares subject to the option. If the successor assumes the outstanding options or substitutes equivalent options, 25% of the shares subject to each option that are unvested immediately prior to the consummation of the transaction will vest immediately prior to the closing of the transaction. If the successor corporation does not assume options or substitute equivalent options or a comparable cash incentive program based on the value of the options at the closing, then vesting of all shares subject to options will accelerate fully immediately prior to the closing of the transaction unless otherwise

provided under an individual grant.

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2003 Employee Stock Purchase Plan

Our 2003 Employee Stock Purchase Plan was adopted by our board of directors in September 2003 and will be submitted for approval by our stockholders prior to completion of this offering. A total of 109,090 shares of common stock are reserved for issuance under this plan, none of which have been issued as of the date of this prospectus. The number of shares reserved for issuance under this plan will automatically increase on the first day of each of our fiscal years beginning in 2005 and ending in 2010 by the lesser of:

- 54,545 shares;
- 1% of the number of shares of common stock outstanding on the last day of the immediately preceding fiscal year; or
- any lesser number of shares that our board of directors determines.

All share numbers reflected in this plan summary, as well as the purchase price applicable to outstanding purchase rights, will be automatically proportionately adjusted in the event we make certain changes in our capital structure, such as a stock split, stock dividend or other similar transaction. If approved by our stockholders, this plan becomes effective upon the date of this offering. Unless terminated earlier by our board of directors, this plan terminates in 2023.

This plan, which is intended to qualify under Section 423 of the Internal Revenue Code, allows employees to purchase our common stock at a discount from the market price through payroll deductions. The plan will be implemented by a series of offering periods, each of which has a duration of approximately six months, commencing generally on May 1 and November 1 of each year. We expect the first offering period to commence on the effective date of the registration statement of which this prospectus is a part and end on October 31, 2004. Each eligible employee will automatically be granted an option to participate in the plan and will be automatically enrolled in the first offering period. Payroll deductions and continued participation in the initial offering period will not be determined until after the effective date of the Form S-8 registration statement, which we intend to file to register the shares reserved for issuance under this plan, as described below. An automatic purchase will be made for participants on the last trading day of each offering period.

Our board of directors, or a committee appointed by the board, will administer this plan. In addition, in administering the plan, we intend to comply with other applicable legal and regulatory requirements as may apply from time to time, including any NASDAQ listing requirements. Our employees, including officers and employee directors or employees of any majority-owned subsidiary designated by the board, are eligible to participate in this plan if they are customarily employed by us or any such subsidiary for at least 20 hours per week and more than five months per year. The plan prohibits granting purchase rights to an employee in the following circumstances:

- where, immediately after the grant, the employee would own stock and/or hold outstanding options to purchase stock equaling 5% or more of the total voting power or value of all classes of our stock or the stock of our subsidiaries; or
- where the option would permit the employee to purchase stock under this plan at a rate that exceeds \$25,000 per calendar year in which the option is outstanding.

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This plan permits eligible employees to purchase common stock through payroll deductions of up to 15% of an employee's eligible cash compensation, which includes salary, bonuses and other wage payments made by us to the participants. A participant may purchase a maximum of 454 shares of our common stock under this plan in any one offering period.

Amounts deducted and accumulated by plan participants are used to purchase shares of our common stock at the end of each six-month offering period. The purchase price is equal to 85% of the fair market value of the

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common stock at the first trading day of the offering period or at the last trading day of the offering period, whichever is less. Employees may end their participation in this plan at any time prior to the last trading day of an offering period, and participation ends automatically on termination of employment.

If we merge or consolidate with or into another corporation or sell all or substantially all of our assets, each right to purchase stock under this plan may be assumed, or an equivalent right substituted, by the successor corporation. However, if the successor corporation refuses to assume each purchase right or to substitute an equivalent right, the board of directors will shorten any ongoing offering period so that employees' rights to purchase stock under this plan are exercised prior to the transaction. Our board of directors may extend future offering periods to up to 27 months and may increase or decrease the maximum contribution rate of an employee's eligible cash compensation. Our board of directors has the power to amend or terminate this plan as long as the action does not adversely affect any outstanding rights to purchase stock under the plan. However, our board of directors may amend or terminate this plan or an offering period even if it would adversely affect outstanding purchase rights in order to avoid our incurring adverse accounting charges or if the board of directors determines that termination of the plan or offering period is in our best interests and the best interests of our stockholders. We must obtain stockholder approval for any amendment to the purchase plan to the extent required by law.

2003 Directors' Stock Option Plan

Our 2003 Directors' Stock Option Plan was adopted by our board of directors in September 2003 and will be submitted for approval by our stockholders prior to completion of this offering. If approved by our stockholders, this plan will become effective on the effective date of the registration statement of which this prospectus is a part. A total of 90,909 shares of common stock are reserved for issuance under the this plan, all of which remain available for future grants as of the date of this prospectus. All share numbers reflected in this plan summary, as well as the exercise price applicable to outstanding options, will be automatically proportionately adjusted in the event we make certain changes in our capital structure, such as a stock split, stock dividend or other similar transaction.

This plan is designed to work automatically, without administration. However, to the extent administration is necessary, it will be performed by our board of directors. It is expected that any conflicts of interest that may arise will be addressed by abstention of any interested director from both deliberations and voting regarding matters in which the director has a personal interest. Unless terminated earlier by the board of directors, this plan will terminate in 2013.

This plan provides that each person who becomes a non-employee director after the completion of this offering will be granted a non-statutory stock option to purchase 4,545 shares of our common stock on the date when the person first becomes a member of our board of directors. On the date of each annual meeting of our stockholders, each of our non-employee directors (including non-employee directors who did not receive the 4,545 share grant described above) will be granted an option to purchase 1,818 shares of common stock if, on that date, the director has served on our board of directors for at least six months. The exercise price of all stock options granted under this plan will be equal to the fair market value of the common stock on the date of grant of the option. This plan provides that one third of the total number of shares subject to each option granted to a new director will vest 12 months after the date of grant. Afterwards, the remaining shares will vest in equal monthly installments over the next two years so that the option will be fully vested after three years. Options granted to directors on the date of each annual meeting of our stockholders will vest in full on the day prior to the first anniversary of the date of the grant of the option.

All options granted under this plan will have a term of 10 years and an exercise price equal to the fair market value on the date of grant. If a non-employee director ceases to serve as a director for any reason other than death or disability, he or she may, within the 90 days after the date he or she ceases to be a director, exercise options that were vested as of the date of termination. If the former director does not exercise the option within this

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90-day period, the option will terminate. If a director's service terminates as a result of his or her disability or death, or if a director dies within three months following termination, the director or his or her estate may exercise options that were vested as of the date of termination or death at any time during the 12 months after the date of termination or death. Options granted under this plan are generally non-transferable by the option holder other than by will or the laws of descent or distribution, pursuant to a qualified domestic relations order or to family members or family trusts or foundations. Generally, only the option holder or a permitted transferee may exercise the option during the lifetime of the option holder.

If we are acquired by another corporation, each option outstanding under this plan will be assumed or equivalent options will be substituted by our acquirer, unless our acquirer does not agree to this assumption or substitution. If our acquirer does not agree to assume the options or substitute them, the options will terminate upon consummation of the transaction. In connection with an acquisition that qualifies as a change of control as defined in the option plan, the vesting of each outstanding option will accelerate in full, and each director holding options under this plan will have the right to exercise his or her options immediately before the consummation of the acquisition as to all shares underlying the options. Our board of directors may amend or terminate this plan as long as we obtain stockholder approval for any amendment to the extent required by applicable law and the procedure for option grants are not amended more than once every 6 months, other than to the extent required by applicable law.

401(k) Plan

Effective February 1, 1997, we established a tax-qualified employee savings and retirement plan, or 401(k) plan, which covers all of our employees. This plan is intended to qualify under Section 401 of the Internal Revenue Code so that contributions by us to the plan, if any, will be deductible by us when made. Under this plan, eligible employees may elect to reduce their current compensation and defer their pre-tax earnings, subject to the Internal Revenue Service's annual contribution limits. Deferral contributions are fully vested at all times. This plan permits, but does not require, discretionary matching contributions by a percentage amount that our board of directors may annually determine. The plan also permits additional discretionary contributions by us on behalf of all participants in the plan. These additional company contributions vest 25% per year of service and will be fully vested after four years of service. The trustee under the plan invests an employee's account balance under the plan in accordance with the employee's written direction. To the extent an employee directs the investment of his or her account balance under the plan, the Employment Retirement Income Security Act relieves the trustee from liability for any loss resulting from the employee's direction of the investment.

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CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

During the last three fiscal years, there has not been any transaction or series of similar transactions to which we were or are a party in which the amount involved exceeded or exceeds \$60,000 and in which any of our directors or executive officers, any holder of more than 5% of any class of our voting securities or any member of the immediate family of any of these persons had or will have a direct or indirect material interest, other than the compensation arrangements described in Management and the transactions described below.

We believe that we have executed all of the transactions described below on terms no less favorable to us than we could have obtained from unaffiliated third parties. It is our intention to ensure that all future transactions between us and our officers, directors and principal stockholders and their affiliates are approved by a majority of our board of directors, including a majority of the independent and disinterested members of our board of directors, and are on terms no less favorable to us than those that we could obtain from unaffiliated third parties.

From our inception through December 31, 2003, we issued the following securities to various investors in private placement transactions:

- 1,151,664 shares of Series A preferred stock to investors including, but not limited to, entities affiliated with Alta Partners, ARCH Venture Partners, CV Sofinnova Venture Partners and Sprout Group at a purchase price of \$5.23 per share in August 1996;
- 683,125 shares of Series B preferred stock to investors including, but not limited to, entities affiliated with Alta Partners, ARCH Venture Partners, CV Sofinnova Venture Partners and Sprout Group at a purchase price of \$6.05 per share in August 1997;
- 1,306,470 shares of Series C preferred stock to investors including, but not limited to, entities affiliated with Alta Partners, ARCH Venture Partners, CV Sofinnova Venture Partners, Falcon Technology Partners, Fluke Capital Management, TGI Fund (W Capital Partners acquired these shares from TGI Fund), Sprout Group and Vulcan Ventures at a purchase price of \$9.19 per share in July 1998;
- 1,838,139 shares of Series D preferred stock to investors including, but not limited to, entities affiliated with Alta Partners, ARCH Venture Partners, MPM Capital, Sprout Group, Vector Fund, Vulcan Ventures and TGI Fund (W Capital Partners acquired these shares from TGI Fund) at a purchase price of \$15.29 per share in May 2000 and August 2000;
- 863,648 shares of Series E preferred stock to investors including, but not limited to, entities affiliated with Alta Partners, ARCH Venture Partners, China Development Industrial Bank Inc., MPM Capital, Sprout Group, Vulcan Ventures and TGI Fund (W Capital Partners acquired these shares from TGI Fund) at a purchase price of \$15.29 per share in November 2001; and
- 808,040 shares of Series F preferred stock to investors including, but not limited to, entities affiliated with Alta Partners, ARCH Venture Partners, RiverVest Venture Fund, Sprout Group, Vector Fund and V-Sciences Investments Pte Ltd at a purchase price of \$15.29 per share in February and March 2002.

In addition, we issued:

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- 545,434 shares of common stock and 95,690 shares of Series A preferred stock in exchange for all of the outstanding capital stock of CellGenEx, Inc. in August 1997 and April 1998; and
- 26,522 shares of Series B preferred stock in July 1998 and 3,636 shares of common stock in June 1999 in connection with license agreements.

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In addition, as of December 31, 2003, warrants to purchase an aggregate of 133,334 shares of preferred stock issued since our inception remained outstanding, and warrants to purchase an aggregate of 907,316 shares of common stock issued in August 2000, November 2001, February 2002 and March 2002 remained outstanding.

Since our inception, we have engaged in transactions with our executive officers, directors and holders of more than 5% of our voting securities and their respective affiliates. The following table summarizes the number of shares of our stock purchased by our executive officers, directors and 5% stockholders and persons and entities associated with them in private placement transactions. Each share of each series of preferred stock converts automatically upon closing of this offering into one share of common stock.

Investor⁽¹⁾	Common	Series A	Series B	Series C	Series D	Series E	Series F
	stock	preferred	preferred	preferred	preferred	preferred	preferred
Directors and executive officers							
Ronald J. Berenson, M.D. ⁽²⁾	431,499	10,526					
Robert M. Williams, Ph.D. .	36,363						
Entities affiliated with directors							
Alta Partners ⁽³⁾		344,496	146,414	176,604	106,280	63,941	1,460
ARCH Venture Partners ⁽⁴⁾		143,539	371,900	203,502	240,352	170,045	163,473
Sprout Group ⁽⁵⁾		478,466	99,172	207,814	58,861	64,741	660
MPM Capital ⁽⁶⁾	87,899				784,825	130,802	
5% stockholders							
Ronald J. Berenson, M.D. ⁽²⁾	431,499	10,528					
Alta Partners ⁽³⁾		344,406	146,414	176,604	106,280	63,940	1,460
ARCH Venture Partners ⁽⁴⁾		143,589	371,900	203,502	240,352	170,045	163,473
Sprout Group ⁽⁵⁾		478,466	99,172	207,814	58,861	64,741	660
MPM Capital ⁽⁶⁾	87,899				784,825	130,802	
W Capital Partners Ironworks, L.P. ⁽⁷⁾				326,620	52,004	54,836	
Vector Fund					98,103		196,168
Vulcan Ventures	14,650			108,873	130,804	130,804	

⁽¹⁾See Principal stockholders for more details on shares held by these purchasers.

⁽²⁾Includes shares held in trust.

⁽³⁾Dr. Deleage is managing director of Alta Partners.

⁽⁴⁾Mr. Nelsen is a managing director of entities affiliated with ARCH Venture Partners.

⁽⁵⁾Dr. Curry is a consultant of Sprout Group.

⁽⁶⁾Dr. Henner is a general partner of MPM Capital.

⁽⁷⁾Mr. Wertheimer is a managing director of W Capital Partners.

In connection with our acquisition of all the outstanding capital stock of CellGenEx, we issued warrants to purchase 66,983 shares of Series A preferred stock at \$5.23 per share in August 1997. In addition, in connection with our Series D preferred stock private placement, we issued warrants to purchase 205,858 shares of common stock at \$1.65 per share in August 2000. In connection with our Series E preferred stock private placement, we issued warrants to purchase 470,205 shares of common stock at \$0.055 per share in November 2001. In connection with our Series F preferred stock private placement, we issued warrants to purchase 439,932 shares of common stock at \$0.055 per share in February and March 2002.

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The following table summarizes the number of shares of common stock and preferred stock issuable pursuant to warrants granted to 5% stockholders, directors, executive officers and entities affiliated with our executive officers and directors in private placement transactions:

Investor ⁽¹⁾	Shares of common stock underlying warrants	Shares of Series A preferred stock underlying warrants
Alta Partners ⁽²⁾	47,509	
ARCH Venture Partners ⁽³⁾	208,500	50,237
Sprout Group ⁽⁴⁾	42,196	
MPM Asset Management LLC ⁽⁵⁾	71,214	
W Capital Partners Ironworks, L.P. ⁽⁶⁾	35,679	
Vector Fund	125,011	
Vulcan Ventures	71,215	

⁽¹⁾See Principal stockholders for more details on shares held by these purchasers.

⁽²⁾Dr. Deleage is managing director of Alta Partners.

⁽³⁾Mr. Nelsen is a managing director of entities affiliated with ARCH Venture Partners.

⁽⁴⁾Dr. Curry is a consultant of Sprout Group.

⁽⁵⁾Dr. Henner is a general partner of MPM Capital.

⁽⁶⁾Mr. Wertheimer is a managing director of W Capital Partners.

In July 1999, we entered into a License Agreement with Genecraft LLC, or Genecraft, of which Dr. Jeffrey Ledbetter, our former Chief Scientific Officer and one of our scientific founders, is a principal founder. Under this agreement, in return for royalties we granted an exclusive sublicense to Genecraft for the rights to several pending patent applications that we are not using in the field of *in vivo* activation of T cells.

We have entered into indemnification agreements with our officers and directors containing provisions which require us, among other things, to indemnify our officers and directors against liabilities that may arise by reason of their status or service as officers or directors (other than liabilities arising from willful and other misconduct) and to advance their expenses incurred as a result of any proceeding against them as to which they could be indemnified. See Management Limitations on liability and indemnification of officers and directors.

We maintain key person life insurance, under which we are the beneficiary, on Dr. Berenson in the amount of \$2 million.

In connection with our acquisition of all of the outstanding capital stock of CellGenEx, Inc., we reserved an aggregate of 287,698 shares of our common stock in a milestone pool for issuance to our scientific founders, Drs. Jeffrey Bluestone, Carl June, Jeffrey Ledbetter and Craig Thompson, upon the achievement of scientific milestones determined by a milestone committee. In February 2001, we entered into a settlement agreement with each of Drs. Bluestone, June and Thompson to terminate the milestone pool, and no option grants were made pursuant to the Milestone Pool. In addition, we entered into a consulting agreement with each of Drs. Bluestone, June and Thompson under which each agreed to consult with us and to continue to serve on our Scientific Advisory Board. In exchange for these services, each consultant was awarded non-statutory stock options for an aggregate of 22,727 shares of our common stock, consisting of one option to purchase 9,090 shares of our common stock at an exercise price of \$2.75 per share and a second option to purchase 13,636 shares of our common stock at an exercise price of \$5.50 per share. The 13,636 shares vest in equal monthly installments (284 shares per month) over the 48 month term of the agreement. Dr. Ledbetter, our former Chief Scientific Officer, waived his rights to the milestone pool in connection with his resignation in March 1999.

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Dr. Frohlich's employment agreement, dated August 27, 2001, provides that we will forgive over four years from the date of the agreement a \$50,000 home loan made to him by the Company in connection with commencement of his employment.

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Pursuant to a clinical trial agreement dated November 25, 2003, James R. Berenson, M.D., a brother of our President and Chief Executive Officer, has acted as and will continue to act as a principal investigator for some of our clinical trials run by a site management organization called Oncotherapeutics.

In October 2003, we issued and sold convertible promissory notes in an aggregate amount of approximately \$12.7 million to investors, including, but not limited to, Alta Partners, ARCH Venture Partners, MPM Capital, The Sprout Group, Vector Partners, Vulcan Ventures and W Capital Partners Ironworks. These convertible promissory notes will be converted into approximately 1,339,943 shares of our common stock (as of December 31, 2003) upon completion of this offering.

In October 2003, in connection with the sale of convertible promissory notes, we issued to participants warrants to purchase shares of preferred stock issued in our next equity financing at the then applicable price per share. However, if we have not closed a qualifying equity financing, and we have not completed this initial public offering, on or before the maturity date of the convertible promissory notes, then the warrants will instead be exercisable for our Series F Preferred Stock at an exercise price of \$15.29 per share (adjusted for stock splits and similar transactions). If we complete our initial public offering prior to the earlier of the next equity financing or April 2004, these warrants will not be exercisable on or prior to completion of this offering and will terminate upon completion of this offering.

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PRINCIPAL STOCKHOLDERS

The following table shows information known to us with respect to the beneficial ownership of our common stock as of January 31, 2004 by:

- each of our directors;
- each named executive officer;
- each person or group of affiliated persons known by us to beneficially own more than 5% of our common stock; and
- all of our directors and executive officers as a group.

Beneficial ownership and percentage ownership are determined in accordance with the rules of the SEC. In computing the number of shares beneficially owned by a person and the percentage ownership of that person, shares of common stock underlying options and warrants that are exercisable within 60 days of January 31, 2004 are considered to be outstanding. To our knowledge, except as indicated in the footnotes to the following table and subject to community property laws where applicable, the persons named in this table have sole voting and investment power with respect to all shares of our common stock shown as beneficially owned by them.

The following table reflects the conversion of all 6,781,814 shares of our preferred stock outstanding as of January 31, 2004 into an aggregate of 6,781,814 shares of our common stock, which will become effective at the closing of this offering. This table is based on 8,328,438 shares of our common stock outstanding as of January 31, 2004 and 12,328,438 shares outstanding immediately after this offering. The address for those individuals for which an address is not otherwise indicated is: c/o Xcyte Therapies, Inc., 1124 Columbia Street, Suite 130, Seattle, Washington 98104.

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Name and address of beneficial owner	Number of shares owned ⁽¹⁾	Number of shares underlying options or warrants	Percent of shares beneficially owned	
			Before this offering	After this offering
Directors and named executive officers				
Ronald J. Berenson, M.D. ⁽²⁾	442,025	44,695	5.8%	3.9%
Stewart Craig, Ph.D.		63,028	*	*
Mark Frohlich, M.D.		20,634	*	*
Kathi L. Cordova, C.P.A. ⁽³⁾	13,636	12,665	*	*
Joanna S. Black, J.D.		10,226	*	*
Jean Deleage, Ph.D. ⁽⁴⁾	839,196	52,963	10.6	7.2
c/o Alta Partners				
One Embarcadero Center				
Suite 4050				
San Francisco, CA 94111				
Peter Langecker, M.D., Ph.D.		5,454	*	*
Robert T. Nelsen ⁽⁵⁾	1,292,811	258,737	18.1	12.3
c/o ARCH Venture Partners				
8725 W. Higgins Road, Suite 290				
Chicago, IL 60631				
Robert E. Curry, Ph.D. ⁽⁶⁾	909,705	42,196	11.4	7.7
c/o The Sprout Group				
3000 Sand Hill Road				
Building 1, Suite 170				
Menlo Park, CA 94025				
Dennis Henner, Ph.D. ⁽⁷⁾	1,003,526	71,214	12.8	8.6
c/o MPM Asset Management LLC				
111 Huntington Avenue				
31st Floor				
Boston, MA 02199				
Stephen N. Wertheimer ⁽⁸⁾	433,460	35,679	5.6	3.7
c/o W Capital Partners				
245 Park Avenue				
39th Floor				
New York, NY 10167				

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Robert M. Williams, Ph.D.	36,363	8,181	*	*
All executive officers and directors as a group (13 persons)	4,970,721	640,094	62.6%	43.3
5% stockholders				
Alta Partners ⁽⁴⁾	839,196	52,963	10.6	7.2
One Embarcadero Center				
Suite 4050				
San Francisco, CA 94111				
Arch Venture Partners ⁽⁵⁾	1,292,811	258,737	18.1	12.3
8725 W. Higgins Road, Suite 290				
Chicago, IL 60631				
The Sprout Group ⁽⁶⁾	909,705	42,196	11.4	7.7
3000 Sand Hill Road				
Building 1, Suite 170				
Menlo Park, CA 94025				
MPM Capital ⁽⁷⁾	1,003,526	71,214	12.8	8.6
c/o MPM Asset Management LLC				
111 Huntington Avenue				
31st Floor				
Boston, MA 02199				
W Capital Partners Ironworks, L.P. ⁽⁸⁾	433,460	35,679	5.6	3.7
245 Park Avenue				
39th Floor				
New York, NY 10167				
Ronald J. Berenson, M.D. ⁽²⁾	442,027	44,695	5.8	3.9
Vector Fund ⁽⁹⁾	333,510	125,011	5.4	3.7
1751 Lake Cook Road				
Suite 350				
Deerfield, IL 60015				
Vulcan Ventures ⁽¹⁰⁾	385,131	71,215	5.4	3.7
505 Orion Station				
505 Fifth Avenue South				
Suite 900				
Seattle, WA 98104				

* Represents beneficial ownership of less than 1%.

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- (1) Shares of preferred stock are shown on an as-converted basis.
- (2) Includes 393,141 shares of common stock, 30,207 of which are subject to repurchase, and 10,526 shares of Series A preferred stock held by Dr. Berenson; and 38,358 shares of common stock held by the Irrevocable Intervivos Trust Agreement of Ronald J. Berenson and Cheryl L. Berenson.
- (3) Includes 13,636 shares of common stock.
- (4) Includes 334,561 shares of Series A preferred stock, 143,144 shares of Series B preferred stock, 172,660 shares of Series C preferred stock, 103,907 shares of Series D preferred stock and 63,941 shares of Series E preferred stock held by Alta California Partners, L.P.; 46,449 shares of common stock issuable upon the exercise of immediately exercisable warrants held by Alta California Partners, L.P.; 9,936 shares of Series A preferred stock, 3,270 shares of Series B preferred stock, 3,944 shares of Series C preferred stock, 2,373 shares of Series D preferred stock and 1,460 shares of Series F preferred stock held by Alta Embarcadero Partners, L.L.C.; 1,060 shares of common stock issuable upon the exercise of immediately exercisable warrants held by Alta Embarcadero Partners, L.L.C.; and 5,454 shares of common stock issuable upon the exercise of immediately exercisable options held by Dr. Deleage, none of which are subject to a repurchase right. Dr. Deleage is a general partner of each of these partnerships, shares voting and dispositive power with respect to the shares held by each of these entities and disclaims beneficial ownership of the shares in which he has no pecuniary interest.
- (5) Includes 114,832 shares of Series A preferred stock and 66,115 shares of Series B preferred stock held by ARCH Venture Fund II, L.P.; 28,707 shares of Series A preferred stock, 305,785 shares of Series B preferred stock, 203,502 shares of Series C preferred stock, 240,352 shares of Series D preferred stock and 170,045 shares of Series E preferred stock; 50,237 shares of Series A preferred stock and 119,498 shares of common stock issuable upon the exercise of immediately exercisable warrants held by ARCH Venture Fund III, L.P.; and 163,473 shares of Series F preferred stock and 89,002 shares of common stock issuable upon the exercise of immediately exercisable warrants held by Healthcare Focus Fund, L.P. Mr. Nelsen is a managing director of the general partner of the general partner of the general partner of ARCH Venture Fund II, L.P. Mr. Nelsen is a managing director of the general partner of ARCH Venture Fund III, L.P. Mr. Nelsen is a managing director of the general partner of the general partner of the Healthcare Focus Fund, L.P. Mr. Nelsen shares voting and dispositive power with respect to the shares held by each of these entities and disclaims beneficial ownership of the shares in which he has no pecuniary interest.
- (6) Includes 9,569 shares of Series A preferred stock, 1,983 shares of Series B preferred stock, 4,156 shares of Series C preferred stock, 1,177 shares of Series D preferred stock and 1,308 shares of Series E preferred stock held by DLJ Capital Corporation; 843 shares of common stock issuable upon the exercise of immediately exercisable warrants held by DLJ Capital Corporation; 47,846 shares of Series A preferred stock, 9,917 shares of Series B preferred stock, 20,780 shares of Series C preferred stock, 5,886 shares of Series D preferred stock and 6,540 shares of Series E preferred stock held by DLJ First ESC, L.P.; 4,219 shares of common stock issuable upon the exercise of immediately exercisable warrants held by DLJ First ESC, L.P.; 416,217 shares of Series A preferred stock, 86,270 shares of Series B preferred stock, 180,770 shares of Series C preferred stock, 51,204 shares of Series D preferred stock and 56,893 shares of Series E preferred stock held by Sprout Capital VII, L.P.; 36,709 shares of common stock issuable upon the exercise of immediately exercisable warrants held by Sprout Capital VII, L.P.; 4,834 shares of Series A preferred stock, 1,002 shares of Series B preferred stock, 2,099 shares of Series C preferred stock, 594 shares of Series D preferred stock and 660 shares of Series F preferred stock held by the Sprout CEO Fund, L.P.; and 425 shares of common stock issuable upon the exercise of immediately exercisable warrants held by the Sprout CEO Fund, L.P. Robert L. Curry is a consultant to an affiliate of DLJ Capital Corporation. DLJ Capital Corporation is the managing general partner of Sprout Capital VII, L.P., and the general partner of Sprout CEO Fund, L.P. Dr. Curry is a limited partner of DLJ Associates VII, L.P., a general partner of Sprout Capital VII, L.P. Robert L. Curry is a consultant to an affiliate of DLJ LBO Plans Management Corp. and DLJ LBO Plans Management Corp. II, which are the general partners of DLJ First ESC, L.P. and Sprout Plan Investors, L.P., respectively. Dr. Curry disclaims beneficial ownership of shares held by these entities except to the extent of his pecuniary interest therein.
- (7) Includes 1,362 shares of common stock, 12,164 shares of Series D preferred stock and 2,027 shares of Series E preferred stock held by MPM Asset Management Investors 2000 B, LLC; 1,103 shares of common stock issuable upon the exercise of immediately exercisable warrants held by MPM Asset Management Investors 2000 B, LLC; 20,832 shares of common stock, 186,004 shares of Series D preferred stock and 31,000 shares of Series E preferred stock held by MPM Bioventures GMBH & Co. Parallel-Beteiligungs KG; 16,878 shares of common stock issuable upon the exercise of immediately exercisable warrants held by MPM Bioventures GMBH & Co. Parallel-Beteiligungs KG; 6,531 shares of common stock, 58,312 shares of Series D preferred stock and 9,718 shares of Series E preferred stock held by MPM Bioventures II, L.P.; 5,291 shares of common stock issuable upon the exercise of immediately exercisable warrants held by MPM Bioventures II, L.P.; 59,174 shares of common stock, 528,345 shares of Series D preferred stock and 88,057 shares of Series E preferred stock held by MPM Bioventures II-QP, L.P.; and 47,942 shares of common stock issuable upon the exercise of immediately exercisable warrants held by MPM Bioventures II-QP, L.P. Dr. Henner is a general partner of an entity affiliated with these entities, shares voting and dispositive power with respect to the shares held by each of these entities and disclaims beneficial ownership of the shares in which he has no pecuniary interest.
- (8) Includes 326,620 shares of Series C preferred stock, 52,004 shares of Series D preferred stock and 54,836 shares of Series E preferred stock held by W Capital Partners Ironworks, L.P., and 35,679 shares of common stock issuable upon the exercise of immediately exercisable warrants held by W Capital Partners Ironworks, L.P. Mr. Wertheimer is the managing director of W Capital Partners Ironworks, L.P., shares voting and dispositive power with respect to this partnership and disclaims beneficial ownership of the shares in which he has no pecuniary interest.
- (9) Includes 98,103 shares of Series D preferred stock, 147,126 shares of Series F preferred stock and 91,089 shares of common stock issuable upon the exercise of immediately exercisable warrants held by Vector Later-Stage Equity Fund II (QP) LP.; 32,701 shares of Series D preferred stock, 49,042 shares of Series F preferred stock and 30,362 shares of common stock issuable upon the exercise of immediately exercisable warrants held by Vector Later-Stage Equity Fund II L.P.; and 6,538 shares of Series F preferred stock and 3,560 shares of common stock issuable upon the exercise of immediately exercisable warrants held by Palivacinni Partners, LLC. The general partner of Vector Later-Stage Equity Fund II, L.P. and Vector Later-Stage Equity Fund II (QP) L.P. is Vector Fund Management, L.L.C., which has appointed Vector Fund Management, L.P. as the manager of the shares. There is no single person at the funds that exercises voting or investment control over the shares held by the funds. Voting and investment control over the shares is held by an internal investment committee of Vector Fund Management, L.P.
- (10) Includes 14,650 shares of common stock, 108,873 shares of Series C preferred stock, 130,804 shares of Series D preferred stock and 130,804 shares of Series E preferred stock held by Vulcan Ventures, Inc.; and 71,215 shares of common stock issuable upon the exercise of immediately exercisable warrants held by Vulcan Ventures, Inc. Paul G. Allen has investment and voting control over of these shares.

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DESCRIPTION OF CAPITAL STOCK

General

Upon the closing of this offering our authorized capital stock will consist of 100,000,000 shares of common stock, par value \$0.001 per share, and 5,000,000 shares of preferred stock, par value \$0.001 per share. The rights and preferences of the preferred stock may thereafter be established from time to time by our board of directors. As of December 31, 2003, 1,546,624 shares of common stock were issued and outstanding and 6,781,814 shares of preferred stock convertible into 6,781,814 shares of common stock upon the completion of this offering were issued and outstanding. As of December 31, 2003, we had 81 common stockholders of record and 44 preferred stockholders of record.

Immediately after the closing of this offering, we will have approximately 14,565,378 shares of common stock outstanding, which is based on 10,565,378 shares of our common stock outstanding as of December 31, 2003, after giving effect to:

- the conversion of all 6,781,814 shares of our preferred stock outstanding as of December 31, 2003 into 6,781,814 shares of our common stock, which will become effective at the closing of this offering;
- the net exercise of warrants outstanding as of December 31, 2003, which will expire at the closing of this offering, to purchase 907,316 shares of our common stock with a weighted average exercise price of \$0.30 per share, resulting in the issuance of 873,764 shares of common stock, assuming an initial public offering price of \$8 per share;
- the conversion of shares of our preferred stock issuable upon the net exercise of warrants outstanding as of December 31, 2003, which will expire at the closing of this offering, to purchase 66,983 shares of our preferred stock with a weighted average exercise price of \$5.23 per share, resulting in the issuance of 23,233 shares of common stock, assuming an initial public offering price of \$8 per share; and
- the conversion of the convertible promissory notes we issued in October 2003 for net proceeds of approximately \$12.7 million into approximately 1,339,943 shares of our common stock, which includes the conversion of approximately \$177,000 in accrued interest as of December 31, 2003, and the recognition of approximately \$12.4 million in interest expense associated with the discount on the notes, which will become effective upon the closing of this offering.

The description below gives effect to the filing of our amended and restated certificate of incorporation and the adoption of our amended and restated bylaws and is qualified in its entirety by reference to these documents, copies of which are filed as exhibits to the registration statement of which this prospectus is a part.

Common Stock

Each holder of common stock is entitled to one vote for each share on all matters to be voted upon by the stockholders, and there are no cumulative voting rights. Subject to preferences to which holders of preferred stock issued after the sale of the common stock being offered may be entitled, holders of common stock are entitled to receive ratably those dividends, if any, that may be declared from time to time by our board of directors out of funds legally available for the payment of dividends. In the event of a liquidation, dissolution or winding up of us, holders of

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our common stock would be entitled to share in our assets remaining after the payment of liabilities and the satisfaction of any liquidation preference that may be granted to holders of any outstanding shares of preferred stock. Holders of our common stock have no preemptive or conversion rights or other subscription rights, and there are no redemption or sinking fund provisions applicable to our common stock. All outstanding shares of common stock are, and the shares of common stock offered by us in this offering, when issued and paid for, will be, fully paid and nonassessable. The rights, preferences and privileges of the holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock which we may designate in the future.

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Preferred Stock

Upon the closing of this offering, our board of directors will be authorized, subject to any limitations prescribed by law, without stockholder approval, to issue from time to time up to an aggregate of 5,000,000 shares of preferred stock in one or more series. Each series of preferred stock will have the rights and preferences, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, as our board of directors determines. The issuance of preferred stock could adversely affect the voting power of holders of our common stock and the likelihood that holders of our common stock will receive dividend payments and payments upon liquidation. In addition, the issuance of preferred stock could have the effect of making it more difficult for a third party to acquire, or of discouraging a third party from attempting to acquire, a majority of our outstanding voting stock. We have no present plans to issue any shares of preferred stock.

Warrants

As of December 31, 2003, the following warrants were outstanding:

- warrants that expire between July 2006 and February 2009 to purchase at a weighted average exercise price of \$7.94 per share an aggregate of 46,607 shares of our preferred stock, which shares are convertible into an aggregate of 46,607 shares of common stock;
- warrants that will expire upon the closing of this offering to purchase an aggregate of 66,983 shares of our preferred stock at a weighted average exercise price of \$5.23 per share;
- warrants that will expire upon the closing of this offering to purchase 19,744 shares of our preferred stock at a weighted average exercise price of \$14.60 per share; and
- warrants that will expire upon the closing of this offering to purchase an aggregate of 907,316 shares of our common stock at a weighted average exercise price of \$0.30 per share.

Registration Rights

We and the holders of our preferred stock, certain holders of warrants to purchase our preferred stock and certain holders of our common stock entered into an investor rights agreement, dated May 25, 2000, as amended on August 8, 2000, October 18, 2000, November 13, 2001, February 5, 2002, May 22, 2002 and October 9, 2003. This investors rights agreement provides these holders with customary demand and piggyback registration rights with respect to the shares of common stock held by them and common stock to be issued upon conversion or exercise of preferred stock and warrants held by them. In addition, the holders of our preferred stock are entitled to receive quarterly and annual financial statements, subject to certain conditions and limitations.

Demand Registration

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According to the terms of the investor rights agreement, assuming the exercise of all warrants that terminate upon the closing and including the issuance of approximately 1,339,943 shares of our common stock (as of December 31, 2003) pursuant to convertible promissory notes, the holders of 9,143,313 shares of our common stock or warrants to purchase shares of our common stock have the right to require us to register their shares with the SEC for resale to the public. To demand such a registration, holders who hold together an aggregate of at least 50% of the shares having registration rights must request a registration statement to register shares for an aggregate offering price of at least \$10 million, net of underwriting discounts and commissions. We are not required to effect more than two demand registrations. We have currently not effected, or received a request for, any demand registrations. We may defer the filing of a demand registration statement for a period of up to 90 days once in any 12-month period.

Piggyback Registration

If we file a registration statement for a public offering of any of our securities solely for cash, other than a registration statement relating solely to our stock plans, the holders of demand registration rights will have the right to include their shares in the registration statement.

Form S-3 Registration

At any time after we become eligible to file a registration statement on Form S-3, holders of shares of common stock having demand and piggyback registration rights may require us to file a Form S-3 registration statement.

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We are obligated to file only one Form S-3 registration statement in any six-month period. Furthermore, the aggregate offering proceeds of the requested Form S-3 registration, before deducting underwriting discounts and expenses, must be at least \$500,000. We may defer one registration request for 120 days in any 12-month period.

These registration rights are subject to certain conditions and limitations, including the right of the underwriters of an offering to limit the number of shares of common stock to be included in the registration. We are generally required to bear the expenses of all registrations, except underwriting discounts and commissions. However, we will not pay for any expenses of any demand registration if the request is subsequently withdrawn by the holders of a majority of the securities to be registered unless such holders forfeit their right to one demand registration. The investors rights agreement also contains our commitment to indemnify the holders of registration rights for losses attributable to statements or omissions by us incurred with registrations under the agreement. The registration rights terminate five years after the closing of this offering.

Anti-Takeover Effects of Provisions of Our Amended and Restated Certificate of Incorporation and Bylaws and Delaware and Washington Law

Upon the closing of this offering, provisions of our amended and restated certificate of incorporation and bylaws may have the effect of making it more difficult for a third party to acquire, or of discouraging a third party from attempting to acquire, control of us. These provisions could limit the price that investors might be willing to pay in the future for shares of our common stock. Our amended and restated bylaws and certificate of incorporation eliminate the right of stockholders to call special meetings of stockholders or to act by written consent without a meeting and require advance notice for stockholder proposals and director nominations, which may preclude stockholders from bringing matters before an annual meeting of stockholders or from making nominations for directors at an annual meeting of stockholders. The authorization of undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change control of us. These and other provisions may have the effect of deterring hostile takeovers or delaying changes in control of us or our management. In addition, we are subject to Section 203 of the Delaware General Corporation Law, which, subject to certain exceptions, generally prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years following the time that such stockholder became an interested stockholder, unless:

- prior to the business combination, our board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of our voting stock outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding (but not the shares owned by the interested stockholder):
 - shares owned by persons who are directors and also officers; and
 - shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- at or after the time of the business combination, the business combination is:
 - approved by our board of directors; and

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- authorized at an annual or special meeting of our stockholders, and not by written consent, by the affirmative vote of at least 66²/₃% of our outstanding voting stock which is not owned by the interested stockholder.

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In general, the Delaware General Corporation Law defines an interested stockholder to be an entity or person that beneficially owns 15% or more of the outstanding voting stock of the corporation or any entity or person that is an affiliate or associate of such entity or person.

The Delaware General Corporation Law generally defines business combination to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, lease, exchange, mortgage, pledge, transfer or other disposition of 10% or more of the assets of the corporation or its majority-owned subsidiary that involves interested stockholder;
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- subject to certain exceptions, any transaction involving the corporation that has the effect of increasing the interested stockholder's proportionate share of the stock of any class or series of the corporation; and
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

The laws of the State of Washington, where our principal executive offices are located, impose restrictions on certain transactions between certain foreign corporations and significant stockholders. Chapter 23B.19 of the Washington Business Corporation Act, or the WBCA, generally prohibits a target corporation, with certain exceptions, from engaging in certain significant business transactions with an acquiring person for a period of five years after the acquiring person first became an acquiring person, unless the transaction or the purchase of shares by the acquiring person is approved by a majority of the members of the target corporation's board of directors prior to the time the acquiring person first became an acquiring person. An acquiring person is generally a person or group of persons who beneficially owns 10% or more of the voting securities of the target corporation. Prohibited transactions include, among other things:

- a merger or consolidation with, disposition of assets to, or issuance or redemption of stock to or from, the acquiring person;
- termination of 5% or more of the employees of the target corporation as a result of the acquiring person's acquisition of 10% or more of the shares of the target corporation; and
- allowing the acquiring person to receive a disproportionate benefit as a stockholder;

After the five-year period, a significant business transaction may take place as long as it complies with certain fair price provisions of the statute. A target corporation includes a foreign corporation if:

- the corporation has a class of voting shares registered pursuant to Sections 12 or 15 of the Securities Exchange Act of 1934, as amended;

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- the corporation's principal executive office is located in Washington;
- the corporation has either:
 - more than 10% of its stockholders of record resident in Washington;
 - more than 10% of its shares owned of record by Washington residents; or
 - 1,000 or more stockholders of record resident in Washington;
- a majority of the corporation's employees are Washington residents or more than 1,000 Washington residents are employees of the corporation; and
- a majority of the corporation's tangible assets are located in Washington or the corporation has more than \$50 million of tangible assets located in Washington.

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Because a corporation may not opt out of this statute, we anticipate this statute will apply to us. Depending on whether we meet the definition of a target corporation, Chapter 23B.19 of the WBCA may have the effect of delaying, deterring or preventing a change in control of us.

Nasdaq National Market Listing

We have applied to have our common stock approved for quotation on The Nasdaq National Market under the symbol XCYT.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is American Stock Transfer and Trust Company. Its address is 59 Maiden Lane, New York, NY 10038, and its telephone number is (212) 936-5100.

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SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our common stock. Future sales of substantial amounts of our common stock in the public market, or the perception that these sales could occur, could adversely affect the price of our common stock.

Based on the number of shares outstanding as of December 31, 2003, we will have approximately 14,565,378 shares of our common stock outstanding after the completion of this offering (approximately 15,165,378 shares if the underwriters exercise their overallotment option in full). Of those shares, the 4,000,000 shares of common stock sold in this offering (4,600,000 shares if the underwriters exercise their overallotment option in full) will be freely transferable without restriction, unless purchased by our affiliates. The remaining 10,565,378 shares of common stock to be outstanding immediately following the completion of this offering, which are restricted securities under Rule 144 of the Securities Act of 1933, or Rule 144, as well as any other shares held by our affiliates, may not be resold except pursuant to an effective registration statement or an applicable exemption from registration, including an exemption under Rule 144.

All of our officers and directors, and substantially all security holders have entered into lock-up agreements pursuant to which they have generally agreed, subject to certain exceptions, not to offer or sell any shares of common stock or securities convertible into or exchangeable or exercisable for shares of common stock for a period of 180 days from the date of this prospectus without the prior written consent of Piper Jaffray & Co. See Underwriting.

After the offering, the holders of 9,143,313 shares of our common stock will be entitled to registration rights. For more information on these registration rights, see Description of capital stock Registration rights.

In general, under Rule 144, as currently in effect, an affiliate of ours who beneficially owns shares of our common stock that are not restricted securities, or a person who beneficially owns for more than one year shares of our common stock that are restricted securities, may generally sell, within any three-month period, a number of shares that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately 145,653 shares immediately after this offering; and
- the average weekly trading volume of our common stock on The Nasdaq National Market during the four preceding weeks.

Sales under Rule 144 are also subject to requirements with respect to manner of sale, notice and the availability of current public information about us. Generally, a person who was not our affiliate at any time during the three months before the sale, and who has beneficially owned shares of our common stock that are restricted securities for at least two years, may sell those shares without regard to the volume limitations, manner of sale restrictions, notice requirements or the requirements with respect to availability of current public information about us.

Generally, an employee, officer, director or consultant who purchased shares of our common stock before the effective date of the registration statement of which this prospectus is a part, or who holds options as of that date, pursuant to a written compensatory plan or contract may rely on the resale provisions of Rule 701 under the Securities Act. Under Rule 701, these persons who are not our affiliates may generally sell their eligible securities, commencing 90 days after the effective date of the registration statement of which this prospectus is a part, without having to

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comply with the public information, holding period, volume limitation or notice provisions of Rule 144. These persons who are our affiliates may generally sell their eligible securities under Rule 701, commencing 90 days after the effective date of the registration statement of which this prospectus is a part, without having to comply with Rule 144's one-year holding period restriction.

Neither Rule 144 nor Rule 701 supersedes the contractual obligations of our security holders set forth in the lock-up agreements described above.

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The 10,565,378 shares of our common stock that were outstanding on December 31, 2003 as adjusted to reflect the conversion of our preferred stock in connection with this initial public offering will become eligible for sale, pursuant to Rule 144 or Rule 701, without registration approximately as follows:

- 9,143,677 shares of common stock will be immediately eligible for sale in the public market without restriction;
- 64,963 shares of common stock will be eligible for sale in the public market under Rule 144 or Rule 701, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, subject to the volume, manner of sale and other limitations under those rules; and
- the remaining 1,356,738 shares of common stock will become eligible under Rule 144 for sale in the public market from time to time after the effective date of the registration statement of which this prospectus is a part upon expiration of their respective holding periods.

The above does not take into consideration the effect of the lock-up agreements described above.

Stock Options

We have reserved an aggregate of 1,163,636 shares of our common stock for issuance under our 1996 Stock Option Plan, 636,363 shares of our common stock for issuance under our 2003 Stock Plan, 90,909 shares of our common stock for issuance under our 2003 Directors' Stock Option Plan and 109,090 shares of our common stock for issuance under our 2003 Employee Stock Purchase Plan. As of December 31, 2003, we had outstanding options under our 1996 Stock Option Plan to purchase 717,615 shares of our common stock. We intend to register the shares subject to these plans and the options on a registration statement under the Securities Act of 1933 on Form S-8 following this offering. Subject to the lock-up agreements, the restrictions imposed under the 1996 Stock Option Plan, the 2003 Stock Plan, the 2003 Directors' Stock Option Plan, the 2003 Employee Stock Purchase Plan and related option agreements, shares of common stock issued under these plans or agreements after the effective date of any registration statement on Form S-8 will be available for sale in the public market without restriction to the extent that they are held by persons who are not our affiliates.

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UNDERWRITING

We are offering the shares of our common stock described in this prospectus through the underwriters named below. Piper Jaffray & Co., RBC Capital Markets Corporation, Wells Fargo Securities, LLC and JMP Securities LLC are the representatives of the underwriters. We have entered into an underwriting agreement with the representatives. Subject to the terms and conditions of the underwriting agreement, each of the underwriters has severally agreed to purchase the number of shares of common stock listed next to its name in the following table:

Underwriters	Number of shares
Piper Jaffray & Co.	
RBC Capital Markets Corporation	
Wells Fargo Securities, LLC	
JMP Securities LLC	
Total	

The underwriting agreement provides that the underwriters must buy all of the shares if they buy any of them. However, the underwriters are not required to take or pay for the shares covered by the underwriters' over-allotment option described below.

Our common stock is offered subject to a number of conditions, including:

- receipt and acceptance of our common stock by the underwriters; and
- the underwriters' right to reject orders in whole or in part.

In connection with this offering, certain of the underwriters or securities dealers may distribute prospectuses electronically.

Over-Allotment Option

We have granted the underwriters an option to buy up to an aggregate of 600,000 additional shares of our common stock. The underwriters may exercise this option solely for the purpose of covering over-allotments, if any, made in connection with this offering. The underwriters have 30 days from the date of this prospectus to exercise this option. If the underwriters exercise this option, they will each purchase additional shares approximately in proportion to the amounts specified in the table above.

Commissions and Discounts

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Shares sold by the underwriters to the public will initially be offered at the offering price set forth on the cover of this prospectus. Any shares sold by the underwriters to securities dealers may be sold at a discount of up to \$ per share from the public offering price. Any of these securities dealers may resell any shares purchased from the underwriters to other brokers or dealers at a discount of up to \$ per share from the public offering price. If all the shares are not sold at the public offering price, the representatives may change the offering price and the other selling terms. Sales of shares made outside of the United States may be made by affiliates of the underwriters.

The underwriters have informed us that they do not expect discretionary sales to exceed 5% of the shares of common stock to be offered.

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The following table shows the per share and total underwriting discounts and commissions we will pay to the underwriters assuming both no exercise and full exercise of the underwriters' option to purchase up to an additional _____ shares.

	<u>No exercise</u>	<u>Full exercise</u>
Per share	\$	\$
Total	\$	\$

We estimate that the total expenses of this offering payable by us, not including the underwriting discounts and commissions, will be approximately _____.

No Sales of Similar Securities

We, our executive officers and directors and substantially all of our existing stockholders have entered into lock-up agreements with the underwriters. Under these agreements, we and each of these persons generally may not, without the prior written approval of Piper Jaffray & Co., offer, sell, contract to sell or otherwise dispose of directly or indirectly or hedge our common stock or securities convertible into or exchangeable for or exercisable for our common stock, subject to certain exceptions. These restrictions will be in effect for a period of 180 days after the date of this prospectus. At any time and without public notice, Piper Jaffray & Co. may, in their sole discretion, release some or all of the securities from these lock-up agreements.

Indemnification and Contribution

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act. If we are unable to provide this indemnification, we will contribute to payments the underwriters may be required to make in respect of those liabilities.

Nasdaq National Market Quotation

We have applied to have our common stock approved for quotation on The Nasdaq National Market under the trading symbol XCYT.

Price Stabilization, Short Positions

In connection with this offering, the underwriters may engage in activities that stabilize, maintain or otherwise affect the price of our common stock, including:

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- stabilizing transactions;
- short sales;
- purchases to cover positions created by short sales;
- imposition of penalty bids; and
- syndicate covering transactions.

Stabilizing transactions consist of bids or purchases made for the purpose of preventing or retarding a decline in the market price of our common stock while this offering is in progress. These transactions may also include making short sales of our common stock, which involve the sale by the underwriters of a greater number of shares of common stock than they are required to purchase in this offering and purchasing shares of common stock in the open market to cover positions created by short sales. Short sales may be covered short sales, which are short positions in an amount not greater than the underwriters' over-allotment option referred to above, or may be naked short sales, which are short positions in excess of that amount.

The underwriters may close out any covered short position by either exercising their over-allotment option, in whole or in part, or by purchasing shares in the open market. In making this determination, the underwriters will

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consider, among other things, the price of shares available for purchase in the open market compared to the price at which they may purchase shares through the over-allotment option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market that could adversely affect investors who purchased in this offering.

The underwriters also may impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of that underwriter in stabilizing or short covering transactions.

As a result of these activities, the price of our common stock may be higher than the price that otherwise might exist in the open market. If these activities are commenced, they may be discontinued by the underwriters at any time. The underwriters may carry out these transactions on The Nasdaq National Market, in the over-the-counter market or otherwise.

Determination of Offering Price

Prior to this offering, there was no public market for our common stock. The initial public offering price will be determined by negotiation by us and the representatives of the underwriters. The principal factors to be considered in determining the initial public offering price include:

- the information set forth in this prospectus and otherwise available to representatives;
- our history and prospects and the history of, and prospects for, the industry in which we compete;
- our past and present financial performance and an assessment of our management;
- our prospects for future earnings and the present state of our development;
- the general condition of the securities markets at the time of this offering;
- the recent market prices of, and demand for, publicly traded common stock of generally comparable companies; and
- other factors deemed relevant by the underwriters and us.

Directed Share Program

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At our request, certain of the underwriters have reserved up to 5% of the common stock being offered by this prospectus for sale at the initial public offering price to our directors, officers, employees and other individuals associated with us and members of their families. The sales will be made by Piper Jaffray & Co. through a directed share program. We do not know if these persons will choose to purchase all or any portion of these reserved shares, but any purchases they do make will reduce the number of shares available to the general public. These persons must commit to purchase no later than the close of business on the day following the date of this prospectus. Any employees or other persons purchasing these reserved shares will be prohibited from disposing of or hedging the shares for a period of at least 180 days after the date of this prospectus.

Affiliations

Certain of the underwriters and their affiliates have in the past provided and may from time to time provide certain commercial banking, financial advisory, investment banking and other services for us for which they were and will be entitled to receive separate fees.

The underwriters and their affiliates may from time to time in the future engage in transactions with us and perform services for us in the ordinary course of their business.

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LEGAL MATTERS

The validity of the common stock we are offering will be passed upon for us by Heller Ehrman White & McAuliffe LLP, Seattle, Washington. Cooley Godward LLP, Palo Alto, California, is counsel for the underwriters in connection with this offering. As of the date of this prospectus, an investment partnership affiliated with Cooley Godward LLP beneficially owns an aggregate of 4,784 shares of our Series A preferred stock. These shares of Series A preferred stock will convert into 4,784 shares of our common stock upon completion of this offering. Both an investment entity affiliated with Heller Ehrman White & McAuliffe LLP and individual attorneys of Heller Ehrman White & McAuliffe LLP beneficially own an aggregate of 201 shares of our common stock, 2,942 shares of our Series D preferred stock and warrants to purchase 292 shares of our common stock. These shares of Series D preferred stock will convert into 2,942 shares of our common stock upon completion of this offering.

EXPERTS

The financial statements of Xcyte Therapies, Inc. at December 31, 2002 and 2003, and for each of the three years in the period ended December 31, 2003 and for the period from inception (January 5, 1996) to December 31, 2003, appearing in this prospectus and registration statement have been audited by Ernst & Young LLP, independent auditors, as set forth in their report thereon (which contains an explanatory paragraph describing conditions that raise substantial doubt about the Company's ability to continue as a going concern as described in Note 1 to the financial statements) appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act of 1933 with respect to the shares of common stock we are offering. This prospectus does not contain all of the information in the registration statement and the exhibits to the registration statement. For further information with respect to us and our common stock, we refer you to the registration statement and to the exhibits to the registration statement. Statements contained in this prospectus about the contents of any contract or any other document are not necessarily complete, and, in each instance, we refer you to the copy of the contract or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference.

You may read and copy the registration statement of which this prospectus is a part at the SEC's Public Reference Room, which is located at 450 Fifth Street, N.W., Washington, D.C. 20549. You can request copies of the registration statement by writing to the SEC and paying a fee for the copying cost. Please call the SEC at 1-800-SEC-0330 for more information about the operation of the SEC's Public Reference Room. In addition, the SEC maintains an Internet website, which is located at www.sec.gov, that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC. You may access the registration statement of which this prospectus is a part at the SEC's Internet website. Upon completion of this offering, we will be subject to the information reporting requirements of the Securities Exchange Act of 1934, and we will file reports, proxy statements and other information with the SEC.

We maintain an Internet website at www.xcytetherapies.com. We have not incorporated by reference into this prospectus the information on our website, and you should not consider it to be a part of this prospectus.

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This prospectus includes statistical data that were obtained from industry publications. These industry publications generally indicate that the authors of these publications have obtained information from sources believed to be reliable but do not guarantee the accuracy and completeness of their information. While we believe these industry publications to be reliable, we have not independently verified their data.

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REPORT OF ERNST & YOUNG LLP, INDEPENDENT AUDITORS

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, 2002 and 2003, and the related statements of operations, stockholders' deficit and cash flows for each of the three years in the period ended December 31, 2003 and for the period from inception (January 5, 1996) to December 31, 2003. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Xcyte Therapies, Inc. (a development stage company) at December 31, 2002 and 2003, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2003 and for the period from inception (January 5, 1996) to December 31, 2003, in conformity with accounting principles generally accepted in the United States.

As discussed in Note 1 to the financial statements, the Company's recurring losses from operations and net capital deficiency raise substantial doubt about its ability to continue as a going concern. Management's plans as to these matters are also described in Note 1. The 2003 financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Ernst & Young LLP

Seattle, Washington

January 23, 2004,

except for the first paragraph of Note 13,

as to which the date is March 4, 2004

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XCYTE THERAPIES, INC.
(a development stage company)

BALANCE SHEETS

	<u>December 31,</u>		Pro forma
	<u>2002</u>	<u>2003</u>	stockholders equity at December 31, 2003 (Note 13) (unaudited)
(in thousands, except share and per share data)			
Assets			
Current assets:			
Cash and cash equivalents	\$ 3,728	\$ 2,241	
Short-term investments	13,616	11,299	
Prepaid expenses and other current assets	598	519	
	<u> </u>	<u> </u>	
Total current assets	17,942	14,059	
Property and equipment, net	2,613	2,767	
Deposits and other assets	879	1,672	
	<u> </u>	<u> </u>	
Total assets	\$ 21,434	\$ 18,498	
	<u> </u>	<u> </u>	
Liabilities and stockholders equity (deficit)			
Current liabilities:			
Accounts payable	\$ 595	\$ 954	
Accrued compensation and related benefits	339	405	
Other accrued liabilities	721	856	
Convertible promissory notes		11,652	
Current portion of equipment financings	717	845	
	<u> </u>	<u> </u>	
Total current liabilities	2,372	14,712	
Equipment financings, less current portion	1,052	993	
Other liabilities	462	562	
Commitments and contingencies			
Redeemable convertible preferred stock, Issued and outstanding 6,773,298 and 6,781,814 shares as of December 31, 2002 and December 31, 2003, respectively (no shares, pro forma)			
Aggregate preference in liquidation \$76,475 and \$76,520 at December 31, 2002 and December 31, 2003, respectively			
	64,540	64,604	
Redeemable convertible preferred stock warrants	1,133	2,467	
Stockholders equity (deficit):			
Preferred stock, \$0.001 par value per share			
Authorized 42,000,000 shares (5,000,000 shares, pro forma)			
Designated redeemable and convertible 41,909,976 shares (no shares issued and outstanding pro forma)			
			\$
Common stock, par value \$0.001 per share			
Authorized 70,000,000 shares (100,000,000 shares, pro forma)			
Issued and outstanding 1,523,867 and 1,546,624 shares as of December 31, 2002 and December 31, 2003, respectively (9,668,390 shares, pro forma)			
	2	2	10

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Additional paid-in capital	21,887	24,532	115,830
Deferred stock compensation	(1,880)	(2,774)	(2,774)
Accumulated other comprehensive income (loss)	4	(5)	(5)
Deficit accumulated during the development stage	(68,138)	(86,595)	(99,001)
	<u> </u>	<u> </u>	<u> </u>
Total stockholders' equity (deficit)	\$ (48,125)	\$ (64,840)	\$ 14,060
	<u> </u>	<u> </u>	<u> </u>
Total liabilities and stockholders' equity (deficit)	\$ 21,434	\$ 18,498	
	<u> </u>	<u> </u>	

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

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XCYTE THERAPIES, INC.
(a development stage company)

STATEMENTS OF OPERATIONS

	Year ended December 31,			Period from inception (January 5, 1996) to December 31, 2003
	2001	2002	2003	
	(in thousands, except per share data)			
Revenue:				
License fee	\$	\$	\$	\$ 100
Collaborative agreement			170	170
Government grant	30			144
Total revenue	30		170	414
Operating expenses:				
Research and development	14,701	14,663	13,685	66,825
General and administrative	5,204	4,979	4,322	21,451
Total operating expenses	19,905	19,642	18,007	88,276
Loss from operations	(19,875)	(19,642)	(17,837)	(87,862)
Other income (expense):				
Interest income	698	467	149	3,472
Interest expense	(260)	(267)	(768)	(2,010)
Loss on sale of equipment	(75)	(11)	(1)	(195)
Other income (expense), net	363	189	(620)	1,267
Net loss	(19,512)	(19,453)	(18,457)	(86,595)
Accretion of preferred stock	(8,411)	(8,001)		(16,412)
Net loss applicable to common stockholders	\$ (27,923)	\$ (27,454)	\$ (18,457)	\$ (103,007)
Basic and diluted net loss per common share	\$ (22.14)	\$ (19.34)	\$ (12.40)	
Shares used in computation of basic and diluted net loss per common share	1,261,089	1,419,755	1,488,218	

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

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XCYTE THERAPIES, INC.

(a development stage company)

STATEMENTS OF CHANGES IN STOCKHOLDERS DEFICIT

	Common stock		Additional paid-in capital	Deferred stock compensation	Accumulated other comprehensive income (loss)	Deficit accumulated during the development stage	Total
	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)				