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	**2834**	**91-1707622**
(State or Other Jurisdiction of Incorporation or Organization)	**(Primary Standard Industrial Classification Code Number)**	**(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

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)

Copies to:

Sonya F. Erickson	**Joanna S. Black**	**Laura A. Berezin**
Heller Ehrman White	**General Counsel & Vice President**	**Cooley Godward LLP**
& McAuliffe LLP	**Xcyte Therapies, Inc.**	**Five Palo Alto Square**
701 Fifth Avenue, Suite 6100	**1124 Columbia Street, Suite 130**	**3000 El Camino Real**
Seattle, Washington 98104	**Seattle, Washington 98104**	**Palo Alto, CA 94306-2155**
(206) 447-0900	**(206) 262-6200**	**(650) 843-5000**

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

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

	Per Share	Total
Public offering price	$	$
Underwriting discount	$	$
Proceeds, before expenses, to Xcyte Therapies, Inc.	$	$

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

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 trails 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;

- 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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SUMMARY FINANCIAL DATA

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)	

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;

- 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 commercialibility 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.

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.

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.

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:

- 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,

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, Favrille, 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 many 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.

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

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.

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;

- 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;

- 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

- 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.

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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.

	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;

- 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

General and administrative expenses represented approximately 25% and 26% or 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

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):

		Payments due by period			
Contractual obligations	**Total**	**Less than 1 year**	**1 to 3 years**	**4 to 5 years**	**After 5 years**
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.

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,

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.