XCYTE THERAPIES INC
Form S-1/A
October 21, 2004
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As filed with the Securities and Exchange Commission on October 21, 2004

Registration No. 333-119585

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

AMENDMENT NO. 1

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)

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

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

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, 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, 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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The 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 it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED OCTOBER 21, 2004

1,500,000 Shares

XCYTE THERAPIES, INC.

% Convertible Exchangeable Preferred Stock

(Cumulative Dividend, Liquidation Preference $10 Per Share)

- Xcyte Therapies, Inc. is offering 1,500,000 shares of % convertible exchangeable preferred stock, which is referred to in this prospectus as convertible preferred stock.
- Dividends will be cumulative from the date of original issue at the annual rate of % of the liquidation preference of the convertible preferred stock, payable quarterly on the day of , , , and , commencing , 2005. Any dividends must be declared by our board of directors and must come from funds that are legally available for dividend payments.
- You may convert each share of the convertible preferred stock into shares of our common stock based on the initial conversion price of $, subject to certain adjustments.
- We may elect to automatically convert the convertible preferred stock into our common stock if the closing price of our common stock has exceeded $, which is 150% of the conversion price of the convertible preferred stock, for at least 20 trading days during any 30-day trading period, ending within five trading days prior to notice of automatic conversion.
- If we elect to automatically convert, or you elect to voluntarily convert, some or all of the convertible preferred stock into our common stock prior to , 2007, we will make an additional payment on the convertible preferred stock equal to the aggregate amount of dividends that would have been payable on the convertible preferred stock through and including , 2007, less any dividends already paid on the convertible preferred stock.
- We may elect to redeem the convertible preferred stock after , 2007 on the terms described in this prospectus.
- At our option, we may exchange the convertible preferred stock in whole, but not in part, on any dividend payment date beginning on , 2005 for our % convertible subordinated debentures. If we elect to exchange the convertible preferred stock for debentures, the exchange rate will be $10 principal amount of debentures for each share of the convertible preferred stock. The debentures, if issued upon exchange of the convertible preferred stock, will mature 25 years after the exchange date and will have terms substantially similar to those of the preferred stock.
- The convertible preferred stock has no maturity date and no voting rights prior to conversion into common stock, except under limited circumstances.
- Shares of our common stock are listed on the Nasdaq National Market under the symbol XCYT. The last reported sale price of our common shares on October 20, 2004 was $2.74 per share. We have applied to list the convertible preferred stock on the Nasdaq National Market under the symbol XCYTP.

This investment involves risk. See Risk Factors beginning on page 9.

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

The underwriters have a 30-day option to purchase up to 225,000 additional shares of convertible preferred stock from us to cover over-allotments, if any.

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

Piper Jaffray **JMP Securities**

The date of this prospectus is , 2004.

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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.

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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 the convertible preferred stock, which we discuss under Risk Factors beginning on page 9, 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 have submitted the findings on the increase in quantity of T cells to the FDA and plan to submit additional data in our next annual report. We believe we can efficiently manufacture Xcellerated T Cells for therapeutic applications. We expect Xcellerated T Cells may be used alone or in combination with other complementary treatments.

Our clinical trials and independent clinical trials using an earlier version of our technology, to date, have involved small numbers of patients and we have not designed nor been required to design such trials to produce statistically significant results as to efficacy. These trials have neither been randomized nor blinded to ensure that the results are due to the effects of Xcellerated T Cells. Success in early clinical trials neither ensures that large-scale trials will be successful nor predicts 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 12 of 17 (71%) patients for whom data was available as of September 27, 2004. In addition, there was a 50% or greater reduction in spleen size as measured below the rib cage by physical examination in 10 of the 13 patients (77%) with enlarged spleens. These findings were submitted to the FDA in the Information Packet for a Type B End of Phase II meeting held on September 23, 2004. At this meeting we discussed with the FDA our plans for a Phase II/III clinical trial of Xcellerated T Cells in patients with CLL who have been previously treated with chemotherapy and have failed treatment with Campath, an FDA-approved drug used to treat CLL. Based on feedback from the FDA during this meeting, we intend to modify our planned protocol for this Phase II/III clinical trial to

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provide the FDA with data we believe will address the FDA s concerns regarding the subcutaneous route of Campath administration and the dose and schedule of Xcellerated T Cells. While we believe these modifications will be responsive to the FDA s requests, we cannot be certain that this protocol will satisfy the FDA with respect to the issues raised at the FDA s September 23, 2004 meeting. We are also continuing to discuss issues related to chemistry, manufacturing and controls for the Xcellerated T Cells with the FDA. We have begun preparation for this Phase II/III clinical trial and expect to enroll our first patient by the end of the second quarter of 2005, subject to the FDA accepting our protocol and our proposals on chemistry, manufacturing and controls related matters.

- ***Multiple myeloma.*** In our ongoing Phase I/II clinical trial, we have shown that treatment with Xcellerated T Cells led to rapid recovery of T cells and lymphocytes in all 36 treated patients with multiple myeloma following treatment with high-dose chemotherapy and 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 of our clinical trial show that, of the 35 patients evaluable for tumor responses, 18 patients (51%) had a greater than 90% decrease in the tumor marker used to measure disease. We have submitted these data to the FDA and will submit additional data in our next annual report. Additional follow-up will be required to determine the therapeutic effects of Xcellerated T Cells after transplant. In independent clinical trials, a greater than 90% decrease in the tumor marker has been associated with increased survival in multiple myeloma patients. We are also conducting a Phase II trial to treat patients who have advanced disease with Xcellerated T Cells without other anti-tumor therapy and expect to complete this trial by the end of the second quarter of 2005.

- ***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 follow-up of 33 months. These data were derived from an independent clinical trial, which we did not control and which was not designed to produce statistically significant results as to efficacy or to ensure the results were due to the effects of T cells activated using an earlier version of our proprietary technology. We have been advised that these data have been submitted to the FDA for review. We are also conducting a Phase II clinical trial in patients with low-grade non-Hodgkin s lymphoma who have failed prior therapies. We plan to enroll a total of 40 patients in this trial with most of the common forms of low-grade non-Hodgkin s lymphoma, including small lymphocytic, follicular, marginal zone and mantle cell types. We expect to complete this trial by the end of 2005.

- ***HIV.*** In an independent clinical trial in HIV patients with low T cell counts, conducted by one of our scientific founders under a physician-sponsored IND, treatment with T cells activated using an earlier version of our proprietary technology increased the patient population s average T cell count to within normal levels and maintained this normal count for at least one year following therapy. These data were derived from an independent clinical trial, which we did not control and which was not designed to produce statistically significant results as to efficacy or to ensure the results were due to the effects of T cells activated using

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an earlier version of our proprietary technology. We have been advised that these data have been submitted to the FDA for review. The results of this study were published in a peer- reviewed journal, *Nature Medicine*, in January 2002. In several independent clinical studies, increased levels of T cells have been shown to correlate with increased patient survival and improved clinical outcome. Our collaborative partner, Fresenius Biotech GmbH, is conducting a Phase I clinical trial to treat HIV patients with genetically-modified T cells produced using our Xcellerate Technology. In addition, we are currently conducting laboratory studies in HIV and if these laboratory studies are successful, we plan to initiate a clinical trial using Xcellerated T Cells in patients with HIV.

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 9. 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 $24.4 million for the six months ended June 30, 2004, and our deficit accumulated during the development stage was approximately $111.0 million as of June 30, 2004. We have no commercial products for sale, and we anticipate that we will incur substantial and increasing losses over the next several years as we expand our research, development and clinical trial activities, acquire or license technologies, scale up and improve our manufacturing operations, seek regulatory approval and, if we receive FDA approval, commercialize our products. Because of the numerous risks and uncertainties associated with our product development efforts, we are unable to predict whether or when we will achieve profitability. Our clinical trials and independent clinical trials using an earlier version of our technology, to date, have involved small numbers of patients, and we have not designed nor been required to design such trials to produce statistically significant results as to efficacy. These trials have neither been randomized nor blinded to ensure that the results are due to the effects of the Xcellerated T Cells. The results reported are preliminary and success in early clinical trials

neither ensures that large-scale trials will be successful nor predicts 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

Securities Offered	1,500,000 shares of % convertible exchangeable preferred stock, par value $0.001 per share (1,725,000 shares of convertible preferred stock if the underwriters exercise their over-allotment option in full).
Dividends	Dividends will be cumulative from the date of original issue at the annual rate of % of the liquidation preference of the convertible preferred stock, payable quarterly on the day of , , , and , commencing , 2005. Any dividends must be declared by our board of directors and must come from funds which are legally available for dividend payments.
Conversion Rights	Unless we redeem or exchange the convertible preferred stock, the convertible preferred stock can be converted at your option at any time into shares of our common stock at an initial conversion price of $ (equivalent to a conversion rate of approximately shares of common stock for each share of convertible preferred stock). The initial conversion price with respect to the convertible preferred stock is subject to adjustment in certain events, including a non-stock fundamental change or a common stock fundamental change, which are explained in more detail under the section entitled Description of Convertible Preferred Stock Conversion Conversion Price Adjustment Merger, Consolidation or Sale of Assets.
Automatic Conversion	Unless we redeem or exchange the convertible preferred stock, we may elect to automatically convert some or all of the convertible preferred stock into shares of our common stock if the closing sale price of our common stock has exceeded 150% of the conversion price for at least 20 out of 30 consecutive trading days ending within five trading days prior to the notice of automatic conversion.
Dividend Make-Whole Payment	If we elect to automatically convert, or you voluntarily convert, some or all of the convertible preferred stock into shares of our common stock prior to , 2007, we will make an additional payment on the convertible preferred stock equal to the aggregate amount of cumulative

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	dividends that would have accrued and become payable on the convertible preferred stock from the date of original issue through and including , 2007, less any dividends already paid on the convertible preferred stock. This additional payment is payable by us in cash or, at our option, in shares of our common stock, or a combination of cash and shares of our common stock.
Liquidation Preference	In the event of our voluntary or involuntary dissolution, liquidation or winding up, you will be entitled to be paid a liquidation preference equal to $10 per share of convertible preferred stock, plus accrued and unpaid dividends before any distribution of assets may be made to holders of capital stock ranking junior to the convertible preferred stock.
Optional Redemption	On or after , 2007, we may redeem the convertible preferred stock, in whole or in part, at our option at the redemption prices set forth in this prospectus, together with accrued dividends to, but excluding, the redemption date. See the section entitled Description of Convertible Preferred Stock Optional Redemption below.
Voting Rights	Except as provided by law and in other limited situations described in this prospectus, you will not be entitled to any voting rights. However, you will, among other things, be entitled to vote as a separate class to elect two directors if we have not paid the equivalent of six or more quarterly dividends, whether or not consecutive. These voting rights will continue until we pay the full accrued but unpaid dividends on the convertible preferred stock.
Exchange Provisions	At our option, we may exchange the convertible preferred stock in whole, but not in part, on any dividend payment date beginning on , 2005 for our % convertible subordinated debentures. If we elect to exchange the convertible preferred stock for debentures, the exchange rate will be $10 principal amount of debentures for each share of convertible preferred stock.

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Debentures	The debentures, if issued upon exchange of the convertible preferred stock, will have the following terms:
Interest Rate	The debentures will have an interest rate of % per year. Interest will be payable on and of each year, beginning on the first interest payment date after the exchange date.
Redemption	On or after , 2007 we may redeem the debentures at the redemption prices listed in this prospectus, plus accrued interest.
Maturity	The debentures will mature 25 years after the exchange date.
Conversion	The debentures may be converted at any time by the holder prior to maturity into shares of our common stock at the same conversion price applicable to the convertible preferred stock, subject to adjustment upon certain events.
Automatic Conversion	We may automatically convert the debentures into shares of our common stock at any time prior to maturity under the same terms applicable to the convertible preferred stock.
Interest Make-Whole Payment	If you voluntarily convert or we elect to automatically convert some or all of the debentures into shares of our common stock prior to , 2007, we will also make an additional payment on the debentures equal to the aggregate amount of interest that would have accrued and been payable from date of the original issuance of the debentures pursuant to the exchange through and including , 2007, less any interest paid with respect to such debentures. This additional payment is payable by us, in cash or, at our option, in shares of our common stock, or a combination of cash and shares of our common stock.

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Subordination	The debentures are subordinated to all existing and future senior indebtedness and are effectively subordinated to all of the indebtedness and other liabilities (including trade and other payables, but excluding intercompany liabilities) of us and our subsidiaries. As of June 30, 2004, we had approximately $2.2 million of indebtedness outstanding that would have constituted senior indebtedness and approximately $4.6 million of indebtedness and other liabilities outstanding to which the debentures would have been effectively subordinated (including trade and other payables, but excluding intercompany liabilities). The indenture governing the debentures does not limit the amount of indebtedness, including senior indebtedness, that we and our subsidiaries may incur. See the section entitled Description of Debentures Subordination below.
Use of Proceeds	We expect to use the net proceeds of this offering for working capital and general corporate purposes, including clinical trial, manufacturing and preclinical research and development activities, capital expenditures and complementary technology acquisitions.
Nasdaq National Market Symbol for our Common Stock	Our common stock is traded on the Nasdaq National Market under the symbol XCYT.
Nasdaq National Market Symbol for our Convertible Preferred Stock	We have applied to list the convertible preferred stock on the Nasdaq National Market under the symbol XCYTP.
Listing of Debentures	It is a condition to our ability to exchange the convertible preferred stock for debentures that the debentures be listed on one of the following markets: the Nasdaq National Market, Nasdaq SmallCap Market, American Stock Exchange or New York Stock Exchange or another similar national securities exchange.
Risk Factors	An investment in the convertible preferred stock involves a high degree of risk. See the section entitled Risk Factors beginning on page 9 for a discussion of certain factors that should be considered in evaluating an investment in the convertible preferred stock.

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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. The following summary financial data for the six-month periods ended June 30, 2003 and 2004, and the summary balance sheet data as of June 30, 2004 have been derived from our unaudited condensed financial statements. The unaudited condensed financial statements have been prepared on a basis consistent with our audited financial statements and include all adjustments we consider necessary for the fair presentation of the information. Operating results for the six months ended June 30, 2004 are not necessarily indicative of the results that may be expected for the entire year ending December 31, 2004. 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,					Six months ended June 30,	
	1999	2000	2001	2002	2003	2003	2004
	(in thousands, except per share data)					(unaudited)	
Statement of Operations Data							
Total revenue	$ 16	$ 98	$ 30	$	$ 170	$ 72	$ 36
Operating expenses:							
Research and development	5,471	11,257	14,701	14,663	13,685	7,029	8,601
General and administrative	1,654	2,403	5,204	4,979	4,322	2,194	3,297
Total operating expenses	7,125	13,660	19,905	19,642	18,007	9,223	11,898
Loss from operations	(7,109)	(13,562)	(19,875)	(19,642)	(17,837)	(9,151)	(11,862)
Other income (expense), net	162	621	363	189	(620)	(38)	(12,508)
Net loss	(6,947)	(12,941)	(19,512)	(19,453)	(18,457)	(9,189)	(24,370)
Accretion of preferred stock			(8,411)	(8,001)			(8,973)
Net loss applicable to common stockholders	$ (6,947)	$ (12,941)	$ (27,923)	$ (27,454)	$ (18,457)	$ (9,189)	$ (33,343)
Basic and diluted net loss per common share	$ (6.32)	$ (11.86)	$ (22.14)	$ (19.34)	$ (12.40)	$ (6.21)	$ (3.66)
Shares used in basic and diluted net loss per share calculation	1,100	1,091	1,261	1,420	1,488	1,481	9,107

The following table contains a summary of our balance sheet as of June 30, 2004:

- on an actual basis; and

- on an as adjusted basis to reflect the sale of 1,500,000 shares of the convertible preferred stock we are offering at an assumed public offering price of $10 per share, after deducting underwriting discounts and commissions and estimated offering expenses to be paid by us.

	As of June 30, 2004	
	Actual	As adjusted
	(unaudited, in thousands)	
Balance Sheet Data		
Cash, cash equivalents and short-term investments	$ 33,730	$ 47,315
Working capital	30,838	44,423
Total assets	39,860	53,445
Long-term obligations, less current portion	2,594	2,594
Total stockholders equity	33,097	46,682

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RISK FACTORS

Investing in the convertible preferred 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 the convertible preferred 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 the convertible preferred stock and 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 $24.4 million for the six months ended June 30, 2004, and we may never become profitable. As of June 30, 2004, we had a deficit accumulated during the development stage of approximately $111.0 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 and convertible preferred stock will likely decline.

We will need to raise substantial additional capital to fund our operations, and our failure to obtain funding when needed may force us to delay, reduce or eliminate our product development programs or collaboration efforts.

Developing products and conducting clinical trials for the treatment of cancer and infectious diseases require substantial amounts of capital. To date, we have raised capital through private equity financings, an initial public offering, the sale of convertible promissory notes and equipment leases. Currently, we anticipate that our cash, cash equivalents and investments will be adequate to satisfy our capital needs through at least the end of the second quarter of 2005 if we do not raise capital in this offering. If we are unable to obtain additional funding in a timely fashion, we may never conduct required clinical trials to demonstrate safety and clinical efficacy of Xcellerated T Cells, and we may never obtain FDA approval or commercialize any of our products. We will need to raise additional capital to, among other things:

- fund our clinical trials;
- expand our research and development activities;

- scale up and improve our manufacturing operations;
- finance our general and administrative expenses;
- acquire or license technologies;
- prepare, file, prosecute, maintain, enforce and defend our patent and other proprietary rights;

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- pursue regulatory approval and commercialization of Xcellerated T Cells and any other products that we may develop; and
- develop and implement sales, marketing and distribution capabilities.

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

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

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

Due to our limited resources and access to capital, we must prioritize our development programs and may choose to pursue programs that never receive regulatory approval or prove to be profitable.

Because we have limited resources and access to capital to fund our operations, our management must make significant prioritization decisions on which programs to pursue and how much of our resources to allocate to each program. We are currently focusing our research and development efforts on the use of Xcellerated T Cells to treat CLL, multiple myeloma, non-Hodgkin s lymphoma 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.

If we are unable to protect our proprietary rights, we may not be able to compete effectively.

Our success depends in part on obtaining, maintaining and enforcing our patents and in-licensed and proprietary rights throughout the world. We believe we own, or have rights under licenses to, issued patents and pending patent applications that are necessary to commercialize Xcellerated

T Cells. However, the patents on which we rely may be challenged and invalidated, and our patent applications may not result in issued patents. Moreover, our patents and patent applications may not be sufficiently broad to prevent others from practicing our technologies or developing competing products. We also face the risk that others may independently develop similar or alternative technologies or may design around our proprietary and patented technologies.

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

Third parties may successfully challenge the validity of our patents. We will only be able to protect our technologies from unauthorized use by third parties to the extent that valid and enforceable patents or other

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

In addition, it is possible that others may infringe upon our patents or successfully avoid them through design innovation. We may initiate litigation to police unauthorized use of 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 parties 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 grounds that their activities do not infringe upon our patents. Because protecting our intellectual property is difficult and expensive, we may be unable to prevent misappropriation of our proprietary rights.

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

The clinical and commercial utility of our Xcellerate Technology is uncertain and may never be realized.

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

Although we have observed few serious side effects in patients infused with Xcellerated T Cells in clinical trials conducted to date, we may not ultimately be able to provide the FDA with satisfactory data to support a claim of clinical safety and efficacy sufficient to enable the FDA to approve Xcellerated T Cells for commercialization. This may be because later clinical trials may fail to reproduce favorable data we may have obtained in earlier clinical trials, because the FDA may disagree with how we interpret the data from these clinical trials or because the FDA may not accept these therapeutic effects as valid endpoints in pivotal trials necessary for market approval. For example, although our studies to date have indicated that our Xcellerate Technology can lead to increased T cell and lymphocyte counts, the FDA will not accept increased T cell and lymphocyte counts as a valid endpoint in pivotal studies necessary for market approval. Instead, we would be required to show that Xcellerated T Cells lead to a significant clinical benefit. We will also need to demonstrate that Xcellerated T Cells are safe. We do not have data on possible harmful long-term effects of Xcellerated T Cells and will not

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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.

Our ability to initiate a pivotal trial in patients with CLL on our proposed protocol and timeline is uncertain and highly dependent on the FDA.

We cannot be sure that the FDA will accept the Phase II/III clinical trial protocol we plan to submit in the fourth quarter of 2004 for Xcellerated T Cells in patients with CLL, who have been previously treated with chemotherapy and have failed treatment with Campath. The FDA may conclude that we have not adequately addressed the issues they raised in our initial meeting on September 23, 2004 or they may propose additional modifications to address new concerns they have with our protocol. If the FDA does not accept the Phase II/III clinical trial protocol we plan to submit in the fourth quarter of 2004 or if the FDA requires us to conduct a separate clinical trial to address their concerns, then our plan to initiate a pivotal trial by the end of the second quarter of 2005 could be significantly delayed. Our clinical development plan for CLL is premised upon the continued existence of an unmet medical need in this population. FDA approval of another drug or biologic to treat Campath-refractory CLL could result in the FDA requiring that we conduct larger, controlled studies in more patients.

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

Our ability to initiate a pivotal trial by the end of the second quarter of 2005, or at any other time, will also depend on our ability to address comments received from the FDA related to chemistry, manufacturing and controls issues for the Xcellerated T Cells. We plan to provide further information and have further discussions with the FDA concerning these issues. We cannot be sure that the FDA will accept our proposals.

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

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

Conducting clinical trials is uncertain and expensive and often takes many years to complete. The results from preclinical testing and early clinical trials are often not predictive of results obtained in later clinical trials. In conducting clinical trials, we may fail to establish the effectiveness of Xcellerated T Cells for the targeted indication or we may discover unforeseen side effects. Moreover, clinical trials may require

the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit. Clinical trials are also often subject to unanticipated delays. Also, patients participating in the trials may die before completion of the

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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. In addition, we have developed a custom bioreactor system in our manufacturing process, and we will not be able to obtain FDA approval to commercialize Xcellerated T Cells without the FDA s acceptance of our manufacturing process using this bioreactor system.

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

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

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

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

We have limited manufacturing experience and may not be able to manufacture Xcellerated T Cells on a large scale or in a cost-effective manner.

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 have recently renovated for the manufacture of Xcellerated T Cells for our planned clinical trials and, if we receive FDA approval, initial commercialization. However, we may encounter difficulties in obtaining the approvals for validating and operating this manufacturing facility. We may also be unable to hire the qualified personnel that we will require to accommodate the expansion of our operations and

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manufacturing capabilities. If we relocate our manufacturing activities to a new facility during or after a pivotal clinical trial, we will be required to demonstrate to the FDA similarity of the Xcellerated T Cells manufactured in the new facility to the Xcellerated T Cells manufactured in the prior facility to obtain FDA approval. If we cannot adequately demonstrate similarity to the FDA, we could be required to repeat clinical trials, which would be expensive and substantially delay regulatory approval.

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

We are the only manufacturer of Xcellerated T Cells. Although we are considering third-party manufacturing options, we expect that we will conduct most of our manufacturing in our own facility for the next several years. Furthermore, because we are the only manufacturer of Xcellerated T Cells and we currently use only one manufacturing facility, any damage to or destruction of our manufacturing facility or our equipment, prolonged power outage, contamination of our facility or shutdown by the FDA or other regulatory authority could significantly impair or curtail our ability to produce Xcellerated T Cells. In addition, we store our patients cells in freezers at our manufacturing facility. If these cells are damaged at our facility, including by the loss or malfunction of these freezers or our back-up power systems, we would need to collect replacement patient cells, which would delay our patients treatments. If we are unable to collect replacement cells from our patients, we could incur liability and our business could suffer.

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.

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We rely on third parties to conduct some of the clinical trials for Xcellerated T Cells, and their failure to timely and successfully perform their obligations to us, or their defective performance, could significantly harm our product development programs and our business.

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

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

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

Xcellerated T Cells may never achieve market acceptance even if we obtain regulatory approvals.

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

- our ability to provide acceptable evidence of safety and efficacy;
- convenience and ease of administration;
- prevalence and severity of adverse side effects;
- availability of alternative and competing treatments;
- cost effectiveness;

- effectiveness of our marketing and distribution strategy and the pricing of any product that we may develop;
- publicity concerning our products or competitive products; and
- our ability to obtain sufficient third-party coverage or reimbursement.

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

Even if we obtain regulatory approvals for Xcellerated T Cells, those approvals and ongoing regulation of our products may limit how we manufacture and market our products, which could prevent us from realizing the full benefit of our efforts.

If we obtain regulatory approvals, Xcellerated T Cells, our Xcellerate Technology and our manufacturing facilities will be subject to continual review, including periodic inspections, by the FDA and other U.S. and foreign

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regulatory authorities. In addition, regulatory authorities may impose significant restrictions on the indicated uses or marketing of Xcellerated T Cells or other products that we may develop. These and other factors may significantly restrict our ability to successfully commercialize Xcellerated T Cells and our Xcellerate Technology.

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

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

We rely on third parties to administer Xcellerated T Cells to patients, and our business could be harmed if these third parties administer Xcellerated T Cells incorrectly.

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

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

There are risks inherent in our business that may subject us to potential product liability suits and other claims, which may require us to engage in expensive and time-consuming litigation or pay substantial damages and may harm our reputation and reduce the demand for our product.

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

Certain aspects of how Xcellerated T Cells are processed and administered may increase our exposure to liability. Our Xcellerate Technology requires us to activate a patient s T cells *ex vivo,* or outside of the body, using blood collected from the patient. Third-party physicians or other medical personnel initially collect a patient s blood through a process called leukapheresis, which may pose risks, such as bleeding and infection. The blood that we collect from our patients may contain infectious agents that may infect medical personnel or others with whom the blood comes in contact. Medical personnel administer Xcellerated T Cells to patients intravenously in an outpatient

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procedure. This procedure poses risks to the patient similar to those occurring with infusions of other frozen cell products, such as stem cells, including blood clots, infection and mild to severe allergic reactions.

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

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

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

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

If Xcellerated T Cells or components of our Xcellerate Technology alone or in combination with complementary treatments cause unforeseen harmful side effects, physicians may not use our products and/or we may incur significant product liability, which will adversely affect our ability to operate our business.

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

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

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

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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.

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.

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

Although these and other suppliers have produced our components with acceptable quality, quantity and cost in the past, they may be unable or unwilling to timely meet our future demands. They may also increase the prices they charge us. Obtaining similar components from other suppliers and validating these components may be difficult and expensive. If we have to switch to a replacement supplier, we could face additional regulatory delays, which could interrupt the manufacture and delivery of our product for an extended period. In addition,

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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.

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. In addition, as we expand our clinical trial sites, we may need to make modifications to the shipping process to ship internationally, such as requiring third parties to freeze the patient s white blood cells prior to shipment to us for processing, which may reduce our control over the production of Xcellerated T Cells. Furthermore, shipping blood products internationally will subject us to foreign import laws and customs regulations, which complicate, and could delay, shipment of components to and from us and delay the development, production and infusion of Xcellerated T Cells.

We use hazardous materials and must comply with environmental, health and safety laws and regulations, which can be expensive and restrict how we do business.

Our research and development and manufacturing processes involve the controlled storage, use and disposal of hazardous materials, including biological hazardous materials. We are subject to federal, state and local regulations governing the use, manufacture, storage, handling and disposal of materials and waste products.

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Although we believe that our safety procedures for handling and disposing of these hazardous materials comply with the standards prescribed by law and regulation, we cannot completely eliminate the risk of accidental contamination or injury from hazardous materials. In the event of an accident, we could be held liable for any damages that result, and any liability could exceed the limits or fall outside the coverage of our insurance. We may not be able to obtain insurance on acceptable terms, if at all. We could incur significant costs to comply with current or future environmental laws and regulations.

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

In some circumstances we plan to rely on collaborators to commercialize Xcellerated T Cells. If our current collaborators do not perform as expected or if future collaborators do not commit adequate resources to their collaboration with us, our product development and potential for profitability may suffer.

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

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

We may be unable to establish sales, marketing and distribution capabilities necessary to successfully commercialize our products.

We currently have only limited marketing capabilities and no direct or third-party sales or distribution capabilities. We currently plan to develop an internal sales force to serve certain North American markets and pursue strategic partnerships to obtain development and marketing support for territories outside North America. However, we may be unable to establish marketing, sales and distribution capabilities necessary to commercialize and gain market acceptance for our potential products. In addition, developing a sales force, or

entering into co-promotion agreements with third parties, is expensive and time-consuming and could delay any product launch. Co-promotion or other marketing arrangements with third parties to commercialize potential products may also not be successful and could significantly limit the revenues we derive from Xcellerated T Cells.

We face competition in our industry, and many of our competitors have substantially greater experience and resources than we have.

Even if our Xcellerate Technology proves successful, we might not be able to remain competitive because of the rapid pace of technological development in the biotechnology field. We are currently aware of several companies developing *ex vivo* cell-based immunotherapy products as a method of treating cancer and infectious diseases. These competitors include Antigenics, Inc., CancerVax Corporation, Cell Genesys, Inc., CellExSys, Inc. (recently sold to Chromos Molecular Systems, Inc.), Dendreon Corporation, Favrille, Inc., Genitope Corporation, IDM, S.A. and Kirin Pharmaceutical. 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.

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. However, we currently have no commitments or agreements, and are not involved in any negotiations,

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

Changes in the value of the British pound and Euro relative to the U.S. dollar may adversely affect us.

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

Under our agreements with Lonza to purchase antibodies, we must make payments denominated in British pounds. As a result, from time to time, we are exposed to currency exchange risks related to the British pound. Accordingly, if the British pound strengthens against the U.S. dollar, our payments to Lonza will increase in U.S. dollar terms. We have paid a total of $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. Assuming development and supply services are completed as scheduled under our agreements with Lonza, our remaining payments will be approximately $1.6 million through the end of 2005.

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

If we do not achieve our projected development goals in the time frames we announce and expect, the commercialization of our products may be delayed and, as a result, our stock price may decline.

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

If the use of our technologies conflicts with the rights of others, we could be subject to expensive litigation or be required to obtain licenses from others to develop or market Xcellerated T Cells.

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

We may be unaware that the use of our technology conflicts with pending or issued patents. Because patent applications can take many years to issue, there may be currently pending applications, unknown to us, that may later result in issued patents upon which our Xcellerate Technology or Xcellerated T Cells may infringe. There could also be existing patents of which we are unaware upon which our Xcellerate Technology or Xcellerated T Cells may infringe. In addition, if third parties file patent applications or obtain patents claiming technology also claimed by us in pending applications, we may have to participate in interference proceedings in the U.S. Patent and Trademark Office to determine priority of invention. If third parties file oppositions in foreign

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countries, we may also have to participate in opposition proceedings in foreign tribunals to defend the patentability of the filed foreign patent applications. We may have to participate in interference proceedings involving our issued patents or our pending applications.

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

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

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

Our rights to use antibodies and technologies licensed to us by third parties are not within our control, and we may not be able to implement our Xcellerate Technology without these antibodies and technologies.

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

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

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

If we violate the terms of our licenses, or otherwise lose our rights to these antibodies, patents or patent applications, we may be unable to continue development of our Xcellerate Technology. Our licensors or others may dispute the scope of our rights under any of these licenses. Additionally, the licensors under these licenses might breach the terms of their respective agreements or fail to assist in the prevention of infringement of the

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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

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 44.0% of our common stock following this offering, and approximately % of our common and convertible preferred stock taken together on an as-converted to common stock basis. This significant concentration of share ownership may adversely affect the trading price of our common stock because investors often perceive disadvantages in owning stock in companies with controlling stockholders. These stockholders, acting together, 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. Since the convertible preferred stock has very limited voting rights prior to conversion, you will have little or no ability to control matters requiring approval of our stockholders.

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

After this offering, based on shares outstanding as of September 27, 2004, we will have approximately 14,826,970 shares of common stock outstanding and 1,500,000 shares of convertible preferred stock outstanding that are convertible into shares of our common stock. The 1,500,000 shares of convertible preferred stock sold in this offering, or 1,725,000 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 and convertible preferred stock outstanding after this offering will be available for public sale subject in some cases to volume, lock-up and other limitations.

If our common or convertible preferred stockholders sell substantial amounts of our stock in the public market, or the market perceives that such sales may occur, the market price of our common and convertible preferred stock could fall. After this offering, according to the terms of our investors rights agreement, the holders of approximately 8,992,108 shares of our common stock and warrants 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.

Upon the expiration of a 90-day lock-up agreement, a substantial number of shares of our common stock will become available for sale in the public market which may cause the market price of our preferred and common stock to decline.

On , 2005, which is 90 days after the date of this offering, lock-up agreements covering approximately 5.5 million shares of our common stock held by existing stockholders will expire and those shares will become available for sale. If these stockholders sell substantial amounts of our common stock in the public market at concentrated times, the market price of our common and, in turn our convertible preferred stock, could fall. These sales also might make it more difficult for us to sell equity or equity-related securities in the future at a time and price acceptable to us.

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An active, liquid trading market for the convertible preferred stock and debentures may never develop.

Prior to this offering, there was no public market for the convertible preferred stock. An active trading market for the convertible preferred 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 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 public offering price. In addition, if we exchange the convertible preferred stock for debentures, we are required to list the debentures on an exchange but there can be no assurances that a market in the debentures will develop. Our ability to list and continue to list the convertible preferred stock on the Nasdaq National Market will depend on our ability to meet the Nasdaq National Market listing requirements for both the convertible preferred stock and our common stock.

Our common and convertible preferred stock may experience extreme price and volume fluctuations, which could lead to costly litigation for us and make an investment in us less appealing.

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

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

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

Our amended and restated certificate of incorporation and bylaws may delay or prevent a change in our management.

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

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

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

We may have limited ability to pay cash dividends on the convertible preferred stock.

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

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

We expect to use the net proceeds of this offering for working capital and general corporate purposes, including clinical trial, manufacturing and preclinical research and development activities, as well as capital expenditures and complementary technology acquisitions. 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.

If we exchange the convertible preferred stock for debentures, the exchange will be taxable but we will not provide any cash to you to pay any tax liability you may incur.

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

If we automatically convert the convertible preferred stock, you should be aware that there is a substantial risk of fluctuation in the price of our common stock from the date we elect to automatically convert to the conversion date.

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

You will suffer immediate and substantial dilution.

The offering price of the convertible preferred stock is substantially higher than the book value per share of our outstanding common stock. Accordingly, investors purchasing shares of convertible preferred stock in this offering will pay a price per share of the common stock into which such preferred stock is convertible that substantially exceeds the value of our assets after subtracting liabilities.

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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 More Information.

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USE OF PROCEEDS

We estimate that the net proceeds to us from the sale of the 1,500,000 shares of convertible preferred stock we are offering will be approximately $13.6 million, assuming public offering price of $10 per share, after deducting underwriting discounts and commissions and the estimated offering expenses.

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, multiple myeloma, and non-Hodgkin s lymphoma, and our plans to initiate a new Phase II/III clinical trial in CLL in patients treated with Campath, as well as a new Phase II clinical trial in patients with HIV;
- 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 our new manufacturing facilities; and
- complementary technology acquisitions.

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 2005. See Management s Discussion and Analysis of Financial Condition and Results of Operations Liquidity and Capital Resources.

DIVIDEND POLICY

We currently intend to pay cash dividends on the convertible preferred stock. Dividends on the convertible preferred stock are cumulative, meaning that if they are not paid they continue to accrue and must be paid prior to the payment of any dividends on our common stock. For a discussion of dividends payable on the convertible preferred stock, please see Description of Convertible Preferred Stock Dividends.

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

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RATIO OF EARNINGS TO FIXED CHARGES AND PREFERRED STOCK DIVIDENDS

Our ratio of earnings to fixed charges and preferred stock dividends for each of the periods indicated as follows:

	Fiscal Year Ended December 31,					Six Months Ended June 30,	
	1999	2000	2001	2002	2003	2003	2004
Ratio of earnings to fixed charges and preferred stock dividends[1]							

[1] For the fiscal years ended December 31, 1999, 2000, 2001, 2002 and 2003, and for the six months ended June 30, 2003 and 2004, earnings were insufficient to cover fixed charges by $6.9 million, $12.9 million, $19.5 million, $19.5 million, $18.5 million, $9.2 million and $24.4 million, respectively. For this reason, no ratios are provided.

PRICE RANGE OF COMMON STOCK

Our common stock began trading March 16, 2004 and is traded on the Nasdaq National Market under the symbol XCYT. We have applied to list the convertible preferred stock on the Nasdaq National Market under the symbol XCYTP. The following table sets forth, for the calendar periods indicated, the high and low sale prices per share of the common stock as reported on the Nasdaq National Market:

	High	Low
2004		
First Quarter (Beginning March 16, 2004)	$ 8.50	$ 6.51
Second Quarter	$ 7.45	$ 4.00
Third Quarter	$ 5.04	$ 2.99
Fourth Quarter (Through October 20, 2004)	$ 3.70	$ 2.52

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CAPITALIZATION

The following table sets forth our cash, cash equivalents and short term investments and capitalization as of June 30, 2004:

- on an actual basis;
- on an as adjusted basis to further reflect sale of 1,500,000 shares of our convertible preferred stock we are offering at an assumed public offering price of $10 per share, after deducting underwriting discounts and commissions and estimated offering expenses to be paid by us.

	As of June 30, 2004	
	Actual	As adjusted
	(unaudited, in thousands, except share and per share data)	
Cash, cash equivalents and short-term investments	$ 33,730	$ 47,315
Long-term obligations, less current portion	$ 2,594	$ 2,594
Stockholders equity:		
Preferred stock, $0.001 par value per share; 5,000,000 shares authorized; no shares issued, actual; 1,725,000 shares designated % convertible exchangeable preferred stock, as adjusted; 1,500,000 shares issued and outstanding, as adjusted		2
Common stock, par value $0.001 per share; 70,000,000 shares authorized, actual; 100,000,000 shares authorized, as adjusted; 14,826,573 shares issued and outstanding, actual and as adjusted	15	15
Additional paid-in capital	146,511	160,094
Deferred stock compensation	(2,404)	(2,404)
Accumulated other comprehensive loss	(60)	(60)
Deficit accumulated during the development stage	(110,965)	(110,965)
Total stockholders equity	33,097	46,682
Total capitalization	$ 35,691	$ 49,276

The table above should be read in conjunction with our financial statements and related notes included in this prospectus. This table is based on 14,826,573 shares of our common stock outstanding as of June 30, 2004 and excludes the following:

- shares of our common stock issuable upon conversion of the convertible preferred stock;

- 46,607 shares of our common stock issuable upon the exercise of warrants outstanding as of June 30, 2004 at a weighted average exercise price of $7.94 per share;

- 933,045 shares of our common stock issuable upon the exercise of stock options outstanding as of June 30, 2004 under our 1996 Stock Option Plan at a weighted average exercise price of $5.10 per share;

- 21,143 shares of our common stock reserved for future issuance under our 1996 Stock Option Plan as of June 30, 2004; 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 June 30, 2004.

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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. The statement of operations data for the six-month periods ended June 30, 2003 and 2004 and the balance sheet data as of June 30, 2004 have been derived from our unaudited condensed financial statements included elsewhere in this prospectus. The unaudited condensed financial statements have been prepared on a basis consistent with that of our audited financial statements and include all adjustments we consider necessary for the fair presentation of the information. Operating results for the six months ended June 30, 2004 are not necessarily indicative of the results that may be expected for the entire year ending December 31, 2004.

	Years ended December 31,					Six months ended June 30,	
	1999	2000	2001	2002	2003	2003	2004
	(in thousands, except per share data)					(unaudited)	
Statement of Operations Data							
Revenue:							
License fee	$	$	$	$	$	$	$ 12
Collaborative agreement					170	72	24
Government grant	16	98	30				
Total revenue	16	98	30		170	72	36
Operating expenses:							
Research and development	5,471	11,257	14,701	14,663	13,685	7,029	8,601
General and administrative	1,654	2,403	5,204	4,979	4,322	2,194	3,297
Total operating expenses	7,125	13,660	19,905	19,642	18,007	9,223	11,898
Loss from operations	(7,109)	(13,562)	(19,875)	(19,642)	(17,837)	(9,151)	(11,862)
Other income (expense), net	162	621	363	189	(620)	(38)	(12,508)
Net loss	(6,947)	(12,941)	(19,512)	(19,453)	(18,457)	(9,189)	(24,370)
Accretion of preferred stock			(8,411)	(8,001)			(8,973)
Net loss applicable to common stockholders	$ (6,947)	$ (12,941)	$ (27,923)	$ (27,454)	$ (18,457)	$ (9,189)	$ (33,343)
Basic and diluted net loss per common share	$ (6.32)	$ (11,86)	$ (22.14)	$ (19.34)	$ (12.40)	$ (6.21)	$ (3.66)
Shares used in basic and diluted net loss per common share calculation	1,100	1,091	1,261	1,420	1,488	1,481	9,107

	As of December 31,	As of June 30,
		2004

	1999	2000	2001	2002	2003	
			(in thousands)			(unaudited)
Balance Sheet Data						
Cash, cash equivalents and short-term investments	$ 7,363	$ 23,926	$ 21,098	$ 17,344	$ 13,540	$ 33,730
Working capital	6,100	21,785	19,135	15,570	(653)	30,838
Total assets	10,055	28,479	24,727	21,434	18,498	39,860
Long-term obligations, less current portion	854	952	1,046	1,514	1,555	2,594
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)	(110,965)
Total stockholders equity (deficit)	(15,804)	(25,384)	(36,260)	(48,125)	(64,840)	33,097

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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 June 30, 2004, our deficit accumulated during the development stage was $111.0 million. Our operating expenses consist of research and development expenses and general and administrative expenses.

We have recognized revenues from inception through June 30, 2004 of approximately $450,000 from license fees, payments under a collaborative agreement and income from a National Institutes of Health Phase I Small Business Innovation Research, or SBIR, grant in chronic lymphocytic leukemia. We currently do not market any products and will not for several years, if at all. Accordingly, we do not expect to have any product sales or royalty revenue for a number of years. Our net losses are primarily a result of research and development and general and administrative expenses incurred to support our operations. We anticipate incurring net losses over at least the next several years as we complete our clinical trials, apply for regulatory approvals, continue development of our technology and expand our operations.

Research and Development

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

- payroll and personnel-related expenses;

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

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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 June 30, 2004, we incurred research and development expenses of approximately $75.4 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.

Prior to our initial public offering, we determined the fair value of our common stock for purposes of these calculations based on our review of the primary business factors underlying the value of our common stock on the date these option grants were made or revalued, viewed in light of our initial public offering and the initial public offering price per share. Subsequent to our initial public offering, the fair value is determined

based on the price of the common stock as reported by the Nasdaq National Market in *The Wall Street Journal*.

Revenue Recognition

To date, we have generated no revenues from sales of products. Revenues relate to fees received for licensed technology, cost reimbursement contracts and a SBIR grant awarded to us by the National Institutes of Health.

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We recognize revenue associated with up-front license fees and research and development funding payments ratably over the relevant periods specified in the agreement, which generally is the period we are obligated to perform services. We recognize revenue under research and development cost-reimbursement agreements as the related costs are incurred. We recognize revenue related to grant agreements as the related research and development expenses are incurred.

Cash, Cash Equivalents and Investments

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

Results of Operations

Six Months Ended June 30, 2004 and 2003

Revenue

Revenue was approximately $36,000 and $72,000 for the six months ended June 30, 2004 and 2003, respectively. This consisted of revenue recognized related to the amortization of license fees received and reimbursements of our costs incurred under a collaboration agreement.

Research and Development

Research and development expenses represented approximately 72% and 76% of our operating expenses for the six months ended June 30, 2004 and 2003, respectively. Research and development expenses increased 22%, from $7.0 million for the six months ended June 30, 2003 to $8.6 million for the six months ended June 30, 2004. The increase was primarily the result of amounts charged to expense for contractual obligations relating to developing our bead technology, in addition to increases in clinical trial costs, laboratory supplies, salary and other personnel-related expenses and non-cash stock compensation expense. Expenses associated with developing our bead technology totaled $500,000 for the six months ended June 30, 2004, with no such costs incurred for the six months ended June 30, 2003. Clinical trial and laboratory supplies costs have increased as we continue to advance and expand our clinical testing. As of June 30, 2004 we had 71 employees in research and development and manufacturing operations compared to 53 employees in research and development and manufacturing operations as of June 30, 2003. In addition, our non-cash stock compensation expense increased from $399,000 for the six months ended June 30, 2003 to $603,000 for the six months ended June 30, 2004. These increases were partially offset by a reduction of $1.2 million in contractual payments relating to developing our antibody technology. The higher level of expense in the first half of 2003, related to our antibody technology, resulted from obligations to the third-party manufacturer 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. We anticipate that research and development expenses will continue to grow in the foreseeable future as we expand our research, development and clinical trial activities.

General and Administrative

General and administrative expenses represented approximately 28% and 24% of our operating expenses for the six months ended June 30, 2004 and 2003, respectively. General and administrative expenses increased 50%,

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from $2.2 million for the six months ended June 30, 2003 to $3.3 million for the six months ended June 30, 2004. The rise was due primarily to increases in professional fees, insurance costs, salary and other personnel-related expenses and non-cash stock compensation expense. Non-cash stock compensation expense increased from $326,000 for the six months ended June 30, 2003 to $614,000 for the six months ended June 30, 2004. We anticipate that general and administrative expenses will increase in the foreseeable future as we support our growth and incur costs related to being a public company.

Other Income (Expense)

Other expense, comprised primarily of interest expense and interest income, totaled $38,000 for the six months ended June 30, 2003, compared to $12.5 million for the six months ended June 30, 2004. Interest income increased 57%, from $94,000 for the six months ended June 30, 2003 to $148,000 for the six months ended June 30, 2004, due to increased average cash and investment balances upon which interest is earned. Interest expense increased from $131,000 for the six months ended June 30, 2003 to $12.7 million for the six months ended June 30, 2004, due to interest expense associated with the convertible promissory notes issued in October 2003. Upon consummation of our initial public offering and conversion of the notes to common stock, we recognized $11.3 million in interest expense, which represented the beneficial conversion feature of the notes. We also recognized an additional $1.1 million in interest expense associated with the discount on the notes, representing the value of the proceeds allocated to the warrants received by the note holders.

Accretion of Preferred Stock

For the six months ended June 30, 2004, we recognized $9.0 million in accretion of preferred stock to arrive at our net loss applicable to common stockholders. No such accretion was recognized for the six months ended June 30, 2003. This accretion represented the remaining discount associated with our Series E and F preferred stock, which was recognized when the preferred stock was converted into common stock upon the closing of our initial public offering.

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.

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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 $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

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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, 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.

Quarterly Financial Data

For information relating to our quarterly financial data, see Note 13 Quarterly Financial Data in our financial statements included elsewhere in this prospectus.

Stock-Based Compensation

During the years ended December 31, 2003, 2002 and 2001, we recorded deferred stock-based compensation totaling $2.4 million, $3.2 million and $1.7 million, respectively. During the six months ended June 30, 2004, we recorded deferred stock-based compensation totaling $811,000. We amortize the deferred stock-based compensation to expense using the graded vesting method. As of June 30, 2004, there was $2.4 million of deferred stock-based compensation to be amortized in future periods as follows: $978,000 for the six months ending December 31, 2004, $942,000 in 2005, $397,000 in 2006 and $86,000 in 2007. During the years ended December 31, 2003, 2002 and 2001, we granted non-employee stock options and warrants to purchase 24,543, 6,363 and 71,814 shares of our common stock, respectively. No such stock options or warrants were granted during the six months ended June 30, 2004. 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 $360,000, $65,000 and $1.1 million for the years ended December 31, 2003, 2002 and 2001, respectively. Total stock-based compensation expense for non-employees was $39,000 for the six months ended June 30, 2004.

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 June 30, 2004, we had cash, cash equivalents and short-term investments of $33.7 million, with cash equivalents being held in highly liquid money market accounts with financial institutions. Cash, cash equivalents

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and short-term investments were $13.5 million, $17.3 million and $21.1 million as of December 31, 2003, 2002 and 2001, respectively.

In March 2004, we raised net proceeds of approximately $29.7 million from the sale of 4,200,000 shares of common stock in our initial public offering. In connection with the initial public offering, all of our outstanding shares of redeemable convertible preferred stock and all of our outstanding convertible promissory notes, including interest accrued thereon through the closing date of the offering, were converted into 6,781,814 and 1,357,357 shares of our common stock, respectively.

We have financed our operations since inception through private and public placements of securities, grant revenue, license fees, payments under a collaborative agreement, equipment financings and interest income earned on cash, cash equivalents and investments. From inception through June 30, 2004, we have raised net proceeds of $75.6 million from private equity financings, $29.7 million from our initial public offering and $12.7 million from the sale of convertible promissory notes. Since our inception to June 30, 2004, we have received $450,000 in revenue, $6.9 million in equipment financings and $3.6 million in interest income.

Since our inception, investing activities, other than purchases and maturities of investments, have consisted primarily of purchases of property and equipment. As of June 30, 2004, our investment in property and equipment was $7.5 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 $8.0 million for each of the six-month periods ended June 30, 2004 and 2003. Net cash used in operating activities was $15.5 million, $15.2 million and $15.1 million for the years ended December 31, 2003, 2002 and 2001, respectively. Expenditures in these periods were generally a result of research and development expenses and general and administrative expenses in support of our operations.

We have entered into agreements to develop bead and antibody technology that required significant cash expenditures, including an agreement with Dynal under which we agreed to make payments totaling $3.0 million upon the accomplishment of bead development activities. Additionally, we have two agreements with Lonza under which we agreed to make payments to develop and produce cGMP-grade antibodies totaling $6.6 million. As of June 30, 2004, we have paid the entire $3.0 million to Dynal and $4.9 million to Lonza. We anticipate that the remaining payments to Lonza will be made in 2005. 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**	**1-3 years**	**3-5 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.

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, we have issued common stock warrants to these lenders. At December 31, 2003, we had two financing

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arrangements. Under the first arrangement, with General Electric Capital Corporation, we could borrow up to $1.7 million. At June 30, 2004, we had $728,000 available under the outstanding arrangement, which was replaced by a new arrangement with General Electric Capital Corporation in July 2004. This new arrangement provides for borrowings up to $3.0 million, subject to credit approval, and expires in July 2005 unless renewed. Under the second arrangement, with Oxford Finance Corporation, we could borrow up to $2.5 million. At June 30, 2004, we had $1.7 million available under the outstanding arrangement, which was replaced by a new arrangement with Oxford Finance Corporation in July 2004. This new arrangement provides for borrowings up to $3.0 million, subject to credit approval, and expires in December 2005 unless renewed. Outstanding borrowings under the current and previous financing arrangements were $1.9 million and $1.8 million at years ended December 31, 2002 and 2003, respectively, and $2.3 million at June 30, 2004. Outstanding borrowings require monthly principal and interest payments and mature at various dates through 2008. Interest rates applicable to the outstanding borrowings at December 31, 2003 ranged from 9.18% to 14.11%. The weighted average interest rates for borrowings outstanding during the years ended December 31, 2001, 2002 and 2003 and the six months ended June 30, 2004 were 12.66%, 11.09%, 10.27% and 9.72%, respectively. 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 acquisitions 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 2005. We will likely seek additional financing prior to that time to, among other things, support our continuing product development, manufacturing and clinical trials for Phase II or Phase III clinical trials in future periods. Furthermore, we expect to require additional funding before we are able to generate revenue, if at all, from our potential products. Additional financing may not be available on favorable terms, if at all. If we are unable to raise additional funds when we need them, we may have to delay, reduce or eliminate some or all of our development programs or our clinical trials. We also may have to license our technologies to others, including technologies that we would prefer to develop internally, to raise capital.

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 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. 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.

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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 June 30, 2004 consisted of $18.0 million in corporate bonds, $4.6 million in federal agency obligations, and $2.3 million in municipal bonds with contractual maturities of one year or less. Due to the short-term nature of our investments, we believe that our exposure to market interest rate fluctuations is minimal. The corporate bonds in which we invest are rated A or better by both Moody s and Standard and Poor s. Our cash and cash equivalents are held primarily in highly liquid money market accounts. A hypothetical 10% change in short-term interest rates from those in effect at June 30, 2004 would not have a significant impact on our financial position or our expected results of operations. We do not currently hold any derivative financial instruments.

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

Foreign Currency Risk

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

For antibody development and supply services provided by Lonza, we must make payments denominated in British pounds. As a result, from time to time, we are exposed to currency exchange risks related to the British pound. If the British pound strengthens against the U.S. dollar, our payments to Lonza will increase in U.S. dollar terms. Assuming development and supply services are completed as scheduled under our agreements with Lonza, our remaining payments will be approximately $1.6 million through the end of 2005. A hypothetical 10% change in the British pound from the rate in effect at June 30, 2004 would not have a significant impact on our financial position or our expected results of operations.

The terms of our license agreement with Fresenius include the receipt of potential royalties on net sales as well as potential milestone payments to us denominated in Euro. As a result, we are exposed to currency exchange risks related to the Euro. If the Euro weakens against the U.S. dollar, payments received from Fresenius will decrease in U.S. dollar terms. A hypothetical 10% change in the Euro from the rate in effect at June 30, 2004 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 have submitted the findings on the increase in quantity of T cells to the FDA and plan to submit additional data in our next annual report. We believe we can efficiently manufacture Xcellerated T Cells for therapeutic applications. We expect Xcellerated T Cells may be used alone or in combination with other complementary treatments. We and other clinical investigators have completed or are conducting clinical trials in the following indications:

- ***Chronic lymphocytic leukemia, or CLL.*** In our ongoing Phase I/II clinical trial in CLL, treatment with Xcellerated T Cells resulted in a 50% to 100% reduction in the size of enlarged lymph nodes in 12 of 17 (71%) patients for whom data was available as of September 27, 2004. In addition, there was a 50% or greater reduction in spleen size as measured below the rib cage by physical examination in 10 of the 13 patients (77%) with enlarged spleens. These findings were submitted to the FDA in the Information Packet for a Type B End of Phase II meeting held on September 23, 2004. At this meeting we discussed with the FDA our plans for a Phase II/III clinical trial of Xcellerated T Cells in patients with CLL who have been previously treated with chemotherapy and have failed treatment with Campath, an FDA-approved drug used to treat CLL. Based on feedback from the FDA during this meeting, we intend to modify our planned protocol for this Phase II/III clinical trial to provide the FDA with data we believe will address the FDA s concerns regarding the subcutaneous route of Campath administration and the dose and schedule of Xcellerated T Cells. While we believe these modifications will be responsive to the FDA s requests, we cannot be certain that this protocol will satisfy the FDA with respect to the issues raised at the FDA s September 23, 2004 meeting. We are also continuing to discuss issues related to chemistry, manufacturing and controls for the Xcellerated T Cells with the FDA. We have begun preparation for this Phase II/III clinical trial and expect to enroll our first patient by the end of the second quarter of 2005, subject to the FDA accepting our protocol and our proposals on chemistry, manufacturing and controls related matters.

- ***Multiple myeloma.*** In our ongoing Phase I/II clinical trial, we have shown that treatment with Xcellerated T Cells led to rapid recovery of T cells and lymphocytes in all 36 treated patients with multiple myeloma following treatment with high-dose chemotherapy and autologous stem cell transplantation. Previous independent clinical studies have demonstrated a correlation between patient survival and the speed of recovery of lymphocytes following treatment with chemotherapy and stem cell transplantation. Preliminary clinical results of our clinical trial show that, of the 35 patients evaluable for tumor responses, 18 patients (51%) had a greater than 90% decrease in the tumor marker, which is used to measure disease. We have submitted some of these findings to the FDA, and will submit additional data in our next annual report. Additional follow-up will be required to determine the therapeutic effects of Xcellerated T Cells after transplant. In independent clinical trials, a greater than 90% decrease in the tumor marker has been associated with increased survival in multiple myeloma patients. We are also conducting a Phase II trial to treat patients who have advanced disease with Xcellerated T Cells without other anti-tumor therapy.

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- ***Non-Hodgkin s lymphoma.*** In an independent clinical trial, conducted by one of our scientific founders under a physician-sponsored investigational new drug application, or IND, 16 non- Hodgkin s lymphoma patients undergoing high-dose chemotherapy and autologous stem cell transplantation were treated with T cells activated with an earlier version of our proprietary technology. As reported in the peer-reviewed journal, *Blood*, in September 2003, 8 out of these 16 patients with a very poor prognosis were still alive with a median follow-up of 33 months. These data were derived from an independent clinical trial, which we did not control and which was not designed to produce statistically significant results as to efficacy or to ensure the results were due to the effects of T cells activated using an earlier version of our proprietary technology. We have been advised that these data have been submitted to the FDA. We are also conducting a Phase II clinical trial in patients with low-grade non-Hodgkin s lymphoma who have failed prior therapies. We plan to enroll a total of 40 patients in this trial with most of the common forms of low-grade non-Hodgkin s lymphoma, including small lymphocytic, follicular, marginal zone and mantle cell types. We expect to complete this trial by the end of 2005.

- ***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 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. The results of this study were published in a peer-reviewed journal, *Nature Medicine,* in January 2002. In several independent clinical studies, increased levels of T cells have been shown to correlate with increased patient survival and improved clinical outcome. Our collaborative partner, Fresenius Biotech GmbH, is conducting a Phase I clinical trial to treat HIV patients with genetically-modified T cells produced using our Xcellerate Technology. In addition, we are currently conducting laboratory studies in HIV and if these laboratory studies are successful, we plan to initiate a clinical trial using Xcellerated T Cells in patients with HIV.

In clinical trials, we have observed few side effects in most patients. As of September 27, 2004, in over 156 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 neither been randomized nor blinded to ensure that the results are due to the effects of the Xcellerated T Cells. Success in early clinical trials neither ensures that large-scale trials will be successful nor predicts final results.

Based on these clinical results, we believe there are several important clinical opportunities for Xcellerated T Cells. We plan to initially focus our development efforts in those clinical indications that we believe have significant commercial opportunities and offer the most rapid path to regulatory approval. We believe hematological malignancies, including CLL, multiple myeloma and non-Hodgkin s lymphoma, represent major potential markets for Xcellerated T Cells. In addition, these types of cancer are generally incurable, which means that Xcellerated T Cells may qualify for fast track approval by the FDA, which could shorten the time to potential regulatory approval and commercialization. We plan to initiate one or more pivotal clinical trials in these hematological malignancies in 2005.

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Background

T Cells and the Immune System

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

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

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

Activation of T Cells

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

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

When a T cell becomes activated, it produces a number of different molecules to carry out its many functions. Some of these molecules, known as cytokines, are secreted by the T cell while other molecules are expressed on the surface of the T cell. Many of these molecules activate other cellular elements of the immune system. The activated T cell also produces several toxic substances that are responsible for directly killing pathogens. Several different molecules that a T cell produces in proper amounts work together to generate an effective immune response. Many of these molecules are extremely potent and would be extremely toxic if they were administered

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intravenously or by other routes that allow them to circulate throughout the body. The activated T cell is able to control the production and site of delivery of these molecules in order to generate a safe immune response that is concentrated at the site of disease.

The Dangers of T Cell Deficiencies

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

- ***Quantity.*** A variety of treatments for cancer and autoimmune diseases destroy T cells, including chemotherapy, radiation and some monoclonal antibodies. In addition, many diseases, such as HIV and several kinds of primary immunodeficiencies, are associated with low numbers of T cells. When the number of T cells decreases significantly, the human immune system is less able to defend the body against cancer and infectious diseases.

- ***Quality.*** In many diseases, such as cancer and HIV, T cells have a reduced ability to generate effective immune responses. Many chemotherapy drugs and immunosuppressive agents also depress the activity and function of T cells. Defective T cells may not be able to respond to normal signals required for an effective immune response. These T cells may produce insufficient numbers of molecules required either to mark tumor cells for destruction or to directly destroy them.

- ***Diversity.*** A decreased diversity of T cell receptors is observed in many diseases, including cancer, HIV and autoimmune diseases. This decreased spectrum of T cell receptors narrows the ability of T cells to recognize a broad array of antigens. This may reduce a patient s ability to respond to and eliminate cancer and infectious diseases.

In many patients, decreases in the quantity, quality and diversity of T cells occur together. This puts patients at an increased risk of developing serious and often life-threatening infectious diseases as well as cancer. For example, patients with autoimmune diseases treated with immunosuppressive drugs have an increased risk of infections. Additionally, transplant patients treated with similar drugs have an increased risk of infections and non- Hodgkin s lymphoma. Patients with HIV have an increased risk of developing non-Hodgkin s lymphoma and multiple myeloma. Patients with certain types of primary immunodeficiencies have an increased risk of developing infections as well as non-Hodgkin s lymphoma and gastric cancer. In each of these medical conditions, patients often have poorly functioning T cells that are reduced in number and have limited diversity, which makes these patients particularly susceptible to infection and cancer.

Conversely, the presence of a sufficient number of healthy T cells is associated with improved therapeutic outcome in patients with cancer, HIV and autoimmune diseases. At the time of diagnosis, patients with non-Hodgkin s lymphoma who have higher lymphocyte counts have better survival. Several recent independent

clinical studies have shown that cancer patients who experience more rapid and complete recovery of lymphocytes after chemotherapy have improved survival and clinical outcome. Improved prognosis has been well documented in HIV patients whose T cell counts significantly increased after anti-HIV therapy. These patients demonstrate improvements in T cell function as well as in T cell receptor repertoire diversity after successful treatment. Restoring healthy T cell diversity has also been associated with remission of disease in patients with certain autoimmune diseases.

Current Approaches to Activate the Immune System and Their Limitations

There has been a major clinical focus on developing therapeutic agents to strengthen and activate a patient s immune system. Many of these agents are used to activate the patient s T cells inside the body. These therapeutic agents include:

- ***Cytokines.*** Cytokines, such as IL-2, are potent chemical messengers produced by the immune system that stimulate T cells and generate an immune response. Although cytokines have demonstrated therapeutic effects in cancer and infectious diseases, they are associated with serious and sometimes life-threatening side effects when administered to patients. In order to reduce adverse effects, these drugs are often given at decreased doses, which may compromise their therapeutic effects.

- ***Monoclonal antibodies.*** A variety of different monoclonal antibodies are being developed that target molecules expressed on the surface of T cells. Some of these target molecules activate T cells, while others inhibit T cell activation. By blocking the molecules that inhibit T cell activation, T cell activity can be increased. These antibodies have demonstrated limited therapeutic activity, and some of these molecules have been associated with serious side effects due to overactive T cells.

- ***Adjuvants.*** Other therapeutic agents known as adjuvants have also been developed to stimulate immune responses. Some of the most potent adjuvants are derived from bacteria that make a variety of molecules that stimulate immune responses. Adjuvants are used for some clinical applications, but their use is limited due to toxicity. Recently, several of the molecules produced by bacteria that activate the immune system have been identified, and some are being developed as immunotherapeutic agents. However, it is unclear whether these individual molecules will retain the therapeutic effects of whole adjuvants.

- ***Vaccines.*** A number of different vaccines are under development to treat cancer and HIV. These vaccines are made up of antigens expressed by tumor cells or HIV and are often administered with adjuvants. Patients are treated with the goal of stimulating T cells to respond to antigens, so that the T cells become activated and destroy the cancer or virus. However, many patients with cancer or HIV have deficiencies in the quantity, quality or diversity of their T cells, which may limit their ability to generate an effective response to the vaccine. This may be one reason vaccines have been ineffective in treating cancer and HIV.

- ***Dendritic cells.*** Cells of the immune system known as dendritic cells are being used to stimulate immune responses in patients with cancer. In healthy individuals, dendritic cells deliver both Signal 1 and Signal 2, which activate T cells. For most clinical applications, a patient s own dendritic cells are grown outside of the body and then administered back to the patient. However, the ability to generate dendritic cells varies from patient to patient. Recently, it has been documented that dendritic cells under some circumstances may also make molecules that inhibit T cell responses. In addition, many patients with cancer or HIV have T cell deficiencies, which may limit their ability to respond to dendritic cells. Accordingly, dendritic cells may be limited in their ability to activate patients T cells and generate effective immune responses.

- ***Activated T cells generated using other methods.*** To overcome the limitations of activating T cells inside of the body, researchers have attempted to activate and grow patients T cells *ex vivo,* or outside of the body, before administering them for therapeutic applications. The development of monoclonal antibodies, which are proteins derived from a single clone of antibody-producing cells

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that bind to well-defined targets, made it possible to develop reagents that bind to the CD3 molecule and deliver Signal 1 to T cells. These antibodies are used to activate and grow T cells outside of the body. However, the process generates only one of the two signals required to activate T cells. Without Signal 2, this results in limited activity, growth and survival of T cells in the laboratory as well as after their administration into patients. Some recent approaches use antigens to target T cell receptors to generate antigen-specific T cells. However, these approaches result in a restricted T cell response that may not be effective for many clinical applications requiring broader T cell responses.

Our Solution

Our Therapeutic Approach

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

Our patented Xcellerate Technology is used in a process that employs magnetic beads, which are plastic-coated magnetic microspheres, densely covered with two monoclonal antibodies that deliver Signal 1 and Signal 2 to activate T cells. One of the monoclonal antibodies delivers Signal 1 to T cells by binding directly to the CD3 molecule. Our Xcellerate Technology also uses another monoclonal antibody that binds to the CD28 molecule to deliver Signal 2 to T cells. We attach both of these monoclonal antibodies to the surface of magnetic beads. When T cells bind to the monoclonal antibodies on these magnetic beads, they become activated and significantly increase in number. We believe these magnetic beads can provide the signals required to activate and grow a broad spectrum of T cells characterized by a diverse T cell receptor repertoire. These Xcellerated T Cells are then administered to the patient with the goal of restoring the health of the patient s immune system and ability to eliminate cancer and infectious diseases.

To produce Xcellerated T Cells, white blood cells, a rich source of T cells, are first collected from a patient s blood in an outpatient clinical setting using a standard procedure called leukapheresis. These cells are sent to our

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cGMP manufacturing facility, where they are frozen and stored. When needed, the cells are thawed and processed in a closed system to avoid exposure to the outside environment, reducing the risk of microbial contamination. In this process, the patient s white blood cells are mixed with our microscopic magnetic beads and then placed in a sterile, custom disposable bioreactor containing a solution of nutrients and a low level of IL-2 that sustains the growth of the T cells. These beads are covered with our two monoclonal antibodies, which deliver Signal 1 and Signal 2 to activate the T cells in the solution. During an approximate 10-13 day period after the application of the beads, the T cells become activated and rapidly increase in number. At the end of this period, the antibody-coated magnetic beads are substantially removed with a magnetic device. The Xcellerated T Cells are then frozen for increased shelf life. We have documented that we can store the Xcellerated T Cells in a frozen state for at least 12 months without significant loss of activity. When requested by the physician, the frozen Xcellerated T Cells are shipped to the outpatient clinic where they are thawed and administered by intravenous infusion in approximately two hours.

For purposes of safety and regulatory compliance, we have established procedures designed to track patients cells during the manufacture and shipment of Xcellerated T Cells. Each patient receives a unique identifying number that also contains a code for the clinical site where they are being treated. This unique identifying number is used to track, monitor and record all documentation, labels and materials relating to the production of the patient s Xcellerated T Cells from blood collection through infusion of the final product. Before the product is shipped to the clinical site, we conduct quality control procedures in our laboratory. These procedures are designed to assure that Xcellerated T Cells meet strict quality control criteria such as T cell purity, dosage, potency, safety and sterility.

Benefits of Xcellerated T Cells

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

- ***Increased T cell quantity.*** Using our Xcellerate Technology, we have documented the activation and growth of more than 100 billion T cells, representing a 100-fold to 300-fold increase in T cells

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

- ***Prolonged T cell survival.*** In an independent clinical trial, T cells activated using an earlier version of our proprietary technology have been documented to survive in the body for more than a year after their administration. We have been advised that these data have been submitted to the FDA for review. We believe the prolonged survival of Xcellerated T cells may enable less frequent administration than existing therapeutic products for cancer and infectious diseases.

- ***Improved T cell quality.*** We have documented that Xcellerated T Cells produce a broad spectrum of cytokines and express many important surface molecules required to generate an effective immune response. We have submitted these data to the FDA for review. In laboratory studies, our Xcellerate Technology has been used to restore healthy immune responses in T cells from patients with leukemia activated and grown using our Xcellerate Technology. These Xcellerated T Cells have been shown in the laboratory to mark patients leukemic cells for destruction by the immune system. We have also observed that the Xcellerated T Cells can directly kill the patients tumor cells. In our ongoing Phase I/II clinical trial in CLL, treatment with Xcellerated T Cells resulted in a 50% to 100% reduction in the size of enlarged lymph nodes in 12 of 17 patients (71%) evaluated and a 50% or greater reduction in spleen size as measured below the ribcage by physical examination in 10 of the 13 patients (77%) with enlarged spleens. We have submitted these findings to the FDA for review.

- ***Increased numbers of white blood cells, red blood cells and platelets.*** In our ongoing Phase I/II trial in CLL, we have observed that the infusion of Xcellerated T Cells results in increased numbers of white blood cells including T cells, neutrophils and natural killer cells, which may help fight infections and cancer, increased numbers of red blood cells, as measured by hemoglobin levels, which carry oxygen to tissues, and increased numbers of platelets, which prevent bleeding. We have submitted these findings to the FDA for review.

- ***Favorable side effect profile.*** Xcellerated T Cells are produced from T cells originating from the patient. We believe that using a patient s own cells may result in a safer product than chemotherapy drugs. Xcellerated T Cells and T cells generated using an earlier version of our proprietary technology have been administered to over 204 patients in clinical trials. We have observed few side effects in most patients. The side effects associated with administration of Xcellerated T Cells are typically minor and similar to those observed with infusions of other kinds of cells, such as red blood cells or frozen cell products. To date, there have been only two serious adverse events reportable to the FDA that were judged as possibly or probably related to the therapy, both of which were resolved. The first of these was a rash that resolved following treatment. The second of these was congestive heart failure in a patient with pre-existing severe anemia that resolved approximately two hours following treatment. We subsequently amended our protocols to identify patients with anemia prior to administering Xcellerated T Cells.

- ***Complementary to other therapies.*** Based on our clinical observations to date, we believe Xcellerated T Cells may be complementary to current therapies, such as chemotherapy, radiation and monoclonal antibodies. Xcellerated T Cells may help repair the damage to the immune system

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caused by chemotherapy or other drugs that suppress the immune system. In addition, we believe Xcellerated T Cells may be combined with anti-viral drugs as well as therapies that activate the immune system, such as cancer vaccines. We and other clinical investigators have performed both preclinical animal studies as well as laboratory studies using patients tissues demonstrating the feasibility of using this approach to improve the potential efficacy of combining T cells activated with our proprietary technology with cancer vaccines.

Benefits of Our Xcellerate Technology

We believe our Xcellerate Technology may have the following benefits:

- ***Ex vivo process.*** We designed our Xcellerate Technology to be used *ex vivo*, or outside of the body. This allows us to grow and monitor Xcellerated T Cells in a controlled environment where we can provide optimal conditions for the activation and growth of T cells.

- ***Broad clinical applications.*** Based on recent clinical trials, we believe our Xcellerate Technology can be applied to a variety of diseases. We have demonstrated in the laboratory as well as in our cGMP manufacturing facility that our Xcellerate Technology can be used to activate and grow T cells from patients with a variety of cancers, including kidney cancer, prostate cancer, non-Hodgkin s lymphoma, multiple myeloma and leukemia. Other clinical investigators have used an earlier version of our proprietary technology to activate and grow T cells from HIV patients for clinical applications. In addition, we have entered into a collaboration under which Fresenius Biotech GmbH has treated ten HIV patients with genetically-modified T cells produced using our Xcellerate Technology. Recently, we have demonstrated in the laboratory that we can use our Xcellerate Technology to activate and grow T cells from patients with autoimmune diseases, including rheumatoid arthritis, systemic lupus erythematosus and scleroderma. In addition, we have demonstrated that we can modify our Xcellerate Technology for potential application in other areas of immunotherapy, including vaccines and antigen-specific T cell approaches. These findings were recently published in the peer-reviewed *Journal of Immunotherapy* in September 2004.

- ***Ease of administration.*** We initially collect a patient s white blood cells, a rich source of T cells, in a standard outpatient procedure called leukapheresis. After our process is completed, Xcellerated T Cells are administered in approximately two hours using a routine intravenous procedure in an outpatient clinic. This is similar to what is performed today in most oncology practices where chemotherapy, monoclonal antibodies and red blood cell transfusions are administered intravenously.

- ***Reproducible and cost-effective manufacturing.*** We use the same standardized process to produce Xcellerated T Cells for all patients. Other than our proprietary components, our Xcellerate Technology incorporates commercially available products and standard clinical and blood bank supplies, which enables us to efficiently manufacture Xcellerated T Cells. We do not require materials that must be obtained by surgery, such as samples of the patient s tumor. We can freeze the cells we initially collect from our patients as well as freeze the Xcellerated T Cells we generate from those cells. We have documented storage of Xcellerated T Cells in our facility for at least 12 months without significant loss of activity. Freezing may enable us to generate several Xcellerated T Cell treatments from one manufacturing procedure. In addition, we believe freezing should allow us to supply Xcellerated T Cells to patients throughout the United States from a central manufacturing site.

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Our Strategy

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

- ***Maximize speed to market.*** We plan to initiate one or more pivotal clinical trials in CLL, multiple myeloma or non-Hodgkin s lymphoma in 2005. We believe these clinical indications provide the most rapid and cost-effective commercialization strategy for Xcellerated T Cells. We believe that focusing on life-threatening diseases can facilitate rapid entry into the market for Xcellerated T Cells. The FDA has adopted fast track approval and priority trial procedures for therapies that address life-threatening diseases, and we may apply for fast track designation.

- ***Expand the therapeutic applications of Xcellerated T Cells.*** In addition to cancer and HIV, we believe Xcellerated T Cells can be used to treat patients with other illnesses, including infectious diseases, such as hepatitis. In addition, we are studying the potential therapeutic benefits of Xcellerated T Cells in patients with autoimmune diseases treated with immunosuppressive drugs and in patients with compromised immune systems, such as those with primary immunodeficiencies. We may also expand the application of Xcellerated T Cells to other types of cancer. We are also exploring the use of Xcellerated T Cells in patients with autoimmune diseases who have been treated with immunosuppressive drugs. In addition to our own clinical trials, our scientific founders are conducting a number of independent clinical studies using an earlier version of our proprietary technology for additional clinical applications. Based on the results of their studies, we may pursue some of these clinical opportunities using Xcellerated T Cells.

- ***Leverage complementary technologies and therapies.*** Xcellerated T Cells may be effective in combination with current treatments for cancer and infectious diseases, such as chemotherapy. We believe Xcellerated T Cells may help ameliorate the effects of immunosuppression associated with treatment of autoimmune diseases. We also intend to explore opportunities to combine complementary technologies and therapies, such as cancer vaccines and monoclonal antibodies, with Xcellerated T Cells. In addition, we may supplement our internal efforts by acquiring or licensing technologies and product candidates that complement our Xcellerate Technology.

- ***Retain selected U.S. commercialization rights in cancer.*** We intend to retain marketing and commercialization rights in North America for products in specialized markets, such as cancer. We may seek development and marketing support for clinical indications that have broader patient populations in North America. In addition, we plan to pursue strategic partnerships with biopharmaceutical companies to obtain development and marketing support for territories outside North America, such as Europe and Asia.

- ***Enhance our manufacturing capabilities.*** We have a major focus on developing an efficient and cost-effective process to manufacture Xcellerated T Cells. We currently produce T cells for clinical trials using a cost-effective process that is readily scaleable. We intend to make additional improvements to our manufacturing procedures and components, which should further reduce the costs of manufacturing. In addition, we plan to optimize our manufacturing process for other disease indications in the future.

- ***Expand and enhance our intellectual property.*** We have a portfolio of issued patents and patent applications that we own or exclusively license, which we believe provides patent coverage for our Xcellerate Technology. As we continue to improve our Xcellerate Technology, including developing process improvements and improving the activity and the specificity of Xcellerated T Cells, we intend to file patents to protect these improvements.

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Clinical Applications

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

Disease and indication	Clinical trial status	Sponsor
Cancer Hematological malignancies		
Chronic Lymphocytic Leukemia		
• Progressive disease	Ongoing Phase I/II	Xcyte
• Post-Campath	Planned Phase II/III	Xcyte
Multiple myeloma		
• Post-autologous stem cell transplant	Ongoing Phase I/II	Xcyte
	Ongoing Phase I/II	Physician
• Relapsed	Ongoing Phase II	Xcyte
Non-Hodgkin s lymphoma	Completed Phase I	Physician
	Ongoing Phase II	Xcyte
HIV	Completed Phase I	Physician
	Ongoing Phase I	Fresenius
	Ongoing Phase II	Physician
	Planned Phase II	Xcyte
Cancer Solid tumors		
Kidney cancer	Completed Phase I/II	Xcyte
Prostate cancer	Completed Phase I/II	Xcyte

Cancer Hematological Malignancies

Hematological malignancies are cancers of the blood or bone marrow. The American Cancer Society estimates that there will be approximately 110,960 new cases of hematological malignancies in the United States in 2004. Hematological malignancies include leukemia, non-Hodgkin s lymphoma, multiple myeloma and Hodgkin s lymphoma. Because hematological malignancies have usually spread throughout the body by the time of diagnosis, they typically require treatment with chemotherapy. Recently, immune-based therapeutic products have been developed to treat some hematological malignancies. Most kinds of hematological malignancies, including CLL, multiple myeloma and the vast majority of non-Hodgkin s lymphomas, are cancers of lymphocytes known as B cells. In healthy individuals, T cells control the proliferation of B cells. However, in patients with B cell malignancies, T cells are abnormal, and this may contribute to uncontrolled B cell proliferation and tumor progression.

Chronic Lymphocytic Leukemia

According to third-party sources, approximately 75,000 patients have CLL in the United States, and there will be 8,190 new cases of CLL and 4,800 deaths due to this disease in the United States in 2004. The disease is characterized by proliferation of malignant lymphocytes in the bone marrow, lymph nodes and spleen, which leads to an increase in white blood cell counts, as well as enlarged lymph nodes and spleens in most patients. A number of chemotherapy drugs can be used to treat leukemia. Recently, the FDA approved two drugs, fludarabine, a chemotherapy agent, and Campath, a monoclonal antibody, to treat CLL. These drugs are effective in some patients but do not cure the disease. Both fludarabine and Campath are powerful drugs that destroy all lymphocytes. Consequently, patients treated with these drugs suffer from severe T cell deficiencies, which increase the risk of infection.

In 2003, we began treating patients with CLL with a single infusion of Xcellerated T Cells with no other therapy in a Phase I/II clinical trial. We treated a minimum of three patients at each of three different dose levels of 10, 30 and 60-100 billion Xcellerated T Cells. Serious injury has sometimes occurred with other therapeutic agents used to treat CLL due to rapid destruction of leukemic cells. To reduce this risk, we started with a low dose in

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this trial and have gradually increased the dose of Xcellerated T Cells. A total of 17 patients have been treated as of September 27, 2004. We have observed few side effects in most patients. As of September 27, 2004, we have reported one serious adverse event to the FDA for this trial, which involved a patient who developed an abnormal heart rhythm 17 days following treatment. In the judgment of the attending physician, the event was unlikely related to the therapy. In addition, we have documented a 50% to 100% reduction in the size of enlarged lymph nodes in 12 of 17 patients (71%) evaluated and a 50% or greater reductions in spleen size as measured below the ribcage by physical examination in 10 of the 13 patients (77%) with enlarged spleens. To date, we have not observed any significant decrease in leukemia counts in the blood of these patients. We have also documented increases in white blood cells including T cells, neutrophils and natural killer T cells, which may help fight infections and cancer, increases in platelets, which prevent bleeding, and increases in red blood cells as measured by hemoglobin, which carry oxygen. These findings have been submitted to the FDA in the Information Packet for a Type B End of Phase II meeting held on September 23, 2004. In July 2004, we amended the protocol for the Phase I/II clinical trial to allow patients to receive a second infusion of Xcellerated T Cells and to enroll additional patients in this trial.

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

We plan to initiate a Phase II /III clinical trial in which patients who have previously received chemotherapy and who have failed treatment with Campath will be treated with Xcellerated T Cells. Use of Campath is a standard treatment for CLL but increases the risk of infection in part because Campath eradicates nearly all T cells for several months following treatment. In addition, although Campath can decrease leukemic cell counts in the blood, it has less therapeutic activity in the lymph nodes and spleens of CLL patients. Accordingly, we believe there is a strong clinical rationale for combining Xcellerated T Cells with Campath. We discussed our plans for this trial with the FDA at an End of Phase II meeting on September 23, 2004. Based on feedback from the FDA during this meeting, we intend to modify our planned protocol for this Phase II/III clinical trial to provide the FDA with data we believe will address the FDA s concerns regarding the subcutaneous route of Campath administration and the dose and schedule of Xcellerated T Cells. While we believe these modifications will be responsive to the FDA s requests, we cannot be certain that this protocol will satisfy the FDA with respect to the issues raised at the FDA s September 23, 2004 meeting. We are also continuing to discuss issues related to chemistry, manufacturing and controls for the Xcellerated T Cells with the FDA. We have begun preparation for this Phase II/III clinical trial and expect to enroll our first patient by the end of the second quarter of 2005, subject to the FDA accepting our protocol and our proposals on chemistry, manufacturing and controls related matters.

Multiple Myeloma

Multiple myeloma is a form of cancer that usually originates in the bone marrow and has metastasized to multiple bone sites by the time of diagnosis. According to third-party sources, approximately 50,000 patients have multiple myeloma in the United States, approximately 15,270 new patients will be diagnosed with multiple myeloma and 11,070 patients will die of the disease in 2004. Chemotherapy has been the most common form of treatment for multiple myeloma. More recently, physicians started using drugs such as Velcade and thalidomide to treat this disease. These drugs can temporarily reduce the tumor load in patients with myeloma but only rarely eradicate the disease. The most effective therapeutic approach for treatment of multiple myeloma is high-dose chemotherapy followed by autologous stem cell transplantation. However, this therapy is not curative, and only approximately 25% of patients achieve a complete response. In addition, patients whose lymphocyte counts recover slowly after transplant have a poor clinical outcome. We believe that administering Xcellerated T Cells may be able to accelerate lymphocyte recovery and improve the clinical outcome of these patients.

We have completed treatment of all 36 of the planned patients in our ongoing Phase I/II clinical trial in patients with multiple myeloma. Patients received a single infusion of Xcellerated T Cells three days following high-dose chemotherapy and autologous stem cell transplantation. Treatment with Xcellerated T Cells has resulted in few side effects in most patients and two serious adverse events reportable to the FDA. Of these two events only one,

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which involved a patient who developed a rash after treatment that subsequently resolved, was judged to be possibly or probably related to the therapy. Lymphocyte recovery and T cell recovery in all 36 patients has been much more rapid than observed in a comparable group of patients who did not receive Xcellerated T Cells after stem cell transplantation. Rapid lymphocyte recovery has been correlated with improved prognosis and increased survival in previous independent clinical studies. We believe the improvements in the time to lymphocyte recovery may lead to a better clinical outcome in these patients. We are currently monitoring these patients for infections, days in hospital and other clinical parameters that may be associated with immune recovery. Preliminary results of our clinical trial show that, of the 35 patients evaluable for tumor responses, 18 patients (51%) had a greater than 90% decrease in the tumor marker used to measure disease. We have submitted these findings to the FDA and will submit additional data in our next annual report. Additional follow-up will be required to determine the therapeutic effects of Xcellerated T Cells after transplant. In independent clinical trials, a greater than 90% decrease in the tumor marker has been associated with increased survival in multiple myeloma patients.

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

We are conducting a Phase II clinical trial in multiple myeloma in which we plan to enroll approximately 30 patients who have failed prior therapies. Patients in this trial are randomized to treatment with either a single infusion of Xcellerated T Cells alone or treatment with the drug fludarabine followed by a single infusion of Xcellerated T Cells. This trial is designed to evaluate whether treatment with Xcellerated T Cells is effective as a stand-alone therapy and whether fludarabine can enhance the anti-tumor effects of Xcellerated T Cells in patients with multiple myeloma. As of September 27, 2004, we have treated 18 patients in this trial. Our clinical trials to date have involved small numbers of patients and we have not designed nor been required to design such trials to produce statistically significant results as to efficacy. These trials have neither been randomized nor blinded to ensure that the results are due to the effects of the Xcellerated T Cells. Success in early clinical trials neither ensures that large-scale trials will be successful nor predicts final results.

Non-Hodgkin s Lymphoma

Non-Hodgkin s lymphoma is a cancer that originates in the lymph nodes of the body. According to third-party sources, approximately 310,000 patients have non-Hodgkin s lymphoma, and approximately 54,370 new patients will be diagnosed with this disease in the United States in 2004. About 60% of newly diagnosed patients have an aggressive disease course, while approximately 40% of patients have a slow growing, low-grade form of the disease. Chemotherapy and radiation are used to treat patients with non-Hodgkin s lymphoma. More recently, immune-based therapeutic products, such as the monoclonal antibody Rituxan, have increasingly been used alone or in combination with chemotherapy. Patients with low-grade lymphoma often respond to Rituxan treatment, but they cannot be cured with any form of therapy. These patients eventually become refractory to all forms of therapy and die from their disease. Patients with aggressive non-Hodgkin s lymphoma may be cured with chemotherapy treatment. However, most patients relapse or fail to respond to therapy and have a poor prognosis. Some of these patients may be treated with high-dose chemotherapy followed by an autologous stem cell transplant, but there are few patients with long-term survival.

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

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significant results as to efficacy or to ensure the results were due to the effects of T cells activated using an earlier version of our proprietary technology. We have been advised that these data have been submitted to the FDA for review.

We believe administration of Xcellerated T Cells may increase the lymphocyte counts of patients with low-grade lymphoma. Recent studies have demonstrated a correlation between lymphocyte counts in patients with low-grade lymphoma and their survival. In addition, low-grade lymphoma has many similar characteristics to CLL. However, in contrast to CLL, tumor cells are rarely found on routine examination of the blood in patients with lymphoma. The primary site of disease in patients with low-grade lymphoma is the lymph nodes. There is one type of low-grade lymphoma, known as small lymphocytic lymphoma, which is classified as the same disease as CLL, except for the absence of tumor cells in the blood. Because of similarities between some of these low-grade lymphomas and CLL and the effects that we have documented in the lymph nodes in patients with CLL, we have initiated a Phase II clinical trial to test whether Xcellerated T Cells can be used to treat patients with the most common forms of low-grade lymphomas, including small lymphocytic, follicular, marginal zone and mantle cell types. As of September 27, 2004, we had treated 9 patients in this clinical trial. Our clinical trials to date have involved small numbers of patients, and we have not designed nor been required to design such trials to produce statistically significant results as to efficacy. These trials have neither been randomized nor blinded to ensure that the results are due to the effects of the Xcellerate Technology. Success in early clinical trials neither ensures that large-scale trials will be successful nor predicts final results.

HIV

According to third-party sources, there are estimated to be approximately 950,000 individuals infected with HIV in the United States. HIV patients are at increased risk of infections and cancer. In HIV, patients T cells become infected with the virus, leading to low numbers of T cells and an extremely narrow T cell receptor repertoire. According to independent clinical studies, it has been shown that increasing T cell count and restoring T cell repertoire are associated with improved clinical outcome. Patients with HIV are currently treated with combinations of anti-viral drugs known as highly active antiretroviral therapy, or HAART. Although HAART is effective in suppressing the virus and delaying the onset of acquired immunodeficiency syndrome, or AIDS, HAART often ceases to be effective in a significant number of patients over time. HAART is also associated with serious side effects.

One of our scientific founders independently demonstrated in the laboratory that T cells activated using an earlier version of our proprietary technology were resistant to infection with HIV. In an independent clinical trial conducted by one of our scientific founders under a physician-sponsored IND with the FDA, eight HIV patients were administered T cells activated using an earlier version of our proprietary technology. The results were published in the medical journal *Nature Medicine* in January 2002, where it was reported that the treatment increased the average of the patient population s T cell counts to within the normal range for at least one year following initiation of therapy. We have been advised that these data have been submitted to the FDA. In laboratory studies, the investigators also demonstrated that they were able to restore a broad T cell receptor diversity in the T cells that were produced using this technology.

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

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

Cancer Solid Tumors

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

Kidney Cancer

The American Cancer Society estimates that approximately 35,710 patients will be diagnosed with kidney cancer in the United States in 2004. Approximately one-third of the patients with kidney cancer will develop metastatic disease. Once patients develop metastatic disease, they have a very poor prognosis with an average survival of approximately one year. According to third-party sources, the five-year survival for patients with metastatic kidney cancer is less than 5%, and approximately 12,000 deaths were expected to occur in the United States in 2003. The only drug currently approved by the FDA for treating metastatic kidney cancer is IL-2, a cytokine that activates T cells and increases lymphocyte counts. However, the FDA-approved regimen requires extremely high doses of IL-2, which are associated with serious and life-threatening side effects. Several recent clinical studies have demonstrated a strong correlation between the increase in lymphocyte counts that occurs with IL-2 therapy and clinical outcome in patients with metastatic kidney cancer. We believe administration of Xcellerated T Cells may improve the clinical outcome in these patients by boosting lymphocyte counts.

In February 2003, we completed a Phase I/II clinical trial of Xcellerated T Cells in 25 patients with metastatic kidney cancer. In this clinical trial, patients were treated with two infusions of Xcellerated T Cells approximately four weeks apart. After each infusion of Xcellerated T Cells, patients were treated with low doses of IL-2. We observed few side effects in most patients and no serious adverse events reportable to the FDA related to the therapy. We also observed the complete elimination of detectable bone metastases in two patients. Furthermore, there was a statistically significant increase in lymphocyte counts with treatment, and there was an increase in post-infusion survival in patients achieving higher lymphocyte counts. The median survival in these patients was 21 months. Several independent clinical trials have shown that the median survival in patients with metastatic kidney cancer is approximately 12 months. The results of our clinical trial were reported in the medical journal *Clinical Cancer Research* in September 2003, and have been submitted to the FDA for review.

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

Prostate Cancer

Prostate cancer is the most common form of cancer in men in the United States. The American Cancer Society estimates that there will be 230,110 new cases and approximately 29,900 patients will die of prostate cancer in

the United States in 2004. Patients with prostate cancer can be cured by surgery if the disease is localized. However, once the disease spreads to other organs, it cannot be cured with current standard treatments, either hormonal therapy or chemotherapy.

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

Potential Future Applications in Autoimmune Diseases

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

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

Research and Development

As of September 27, 2004, we had a total of 26 employees dedicated to research and development, including 9 with advanced degrees. We spent approximately $14.7 million, $14.7 million and $13.7 million during the years ended December 31, 2001, 2002 and 2003, respectively, and $8.6 million during the six months ended June 30, 2004 on the research and development of our Xcellerate Technology and Xcellerated T Cells. Our internal research and development efforts are focused on:

- ***Improving our Xcellerate Technology.*** We intend to continuously evaluate and improve our Xcellerate Technology. We have developed methods that further simplify our Xcellerate Technology, allowing us to increase our production yield, reduce labor

and materials and lower the costs associated with the production of Xcellerated T Cells.

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- ***Increasing the therapeutic activity of Xcellerated T Cells.*** We intend to continuously evaluate and improve the therapeutic activity of Xcellerated T Cells. We are currently evaluating whether other molecules of the immune system or genes could be used to improve the therapeutic activity of Xcellerated T Cells. We are working with several groups to evaluate using Xcellerated T Cells in conjunction with recently discovered antigens to specifically target cancers and infectious diseases associated with those antigens. We have conducted laboratory studies demonstrating that we can generate large numbers of antigen-specific Xcellerated T Cells with anti-tumor activity in several types of cancer, including melanoma, breast cancer, kidney cancer and lung cancer. We expect that some of our collaborators will be conducting physician-sponsored clinical trials with these approaches in the near future.

- ***Developing additional clinical indications for Xcellerated T Cells.*** There are many medical conditions that are associated with deficiencies in T cells. We are currently studying the potential to use Xcellerated T Cells to treat these illnesses. For example, patients with autoimmune diseases are treated with immunosuppressive drugs that damage their immune systems. We have demonstrated in laboratory studies that we can activate and grow T cells and restore a normal T cell repertoire in patients with several of these diseases. In addition, we may study the use of Xcellerated T Cells in patients with primary immunodeficiencies. Finally, we are interested in exploring the potential therapeutic use of Xcellerated T Cells in the elderly, who often have weakened immune systems.

Manufacturing and Supply

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

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

In June 2000, we entered into two service agreements with Lonza, which were subsequently amended, for the cGMP-grade manufacture of the two monoclonal antibodies for use with our antibody-coated beads. Under the terms of these agreements, we are obligated to make certain payments to Lonza. We have paid $4.9 million as of June 30, 2004. Assuming development and supply services under our agreements with Lonza are completed as scheduled under our agreements with Lonza, our remaining payments will be approximately $1.6 million through the end of 2005. These agreements may be terminated by either party for breach or insolvency of the other party or in the event that the manufacturing services cannot be completed for scientific or technical reasons.

We use tissue culture media and a custom bioreactor in our manufacturing process. We currently do not have agreements with third parties to supply us with tissue culture media or bioreactors.

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Competition

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

There are numerous pharmaceutical and biotechnology companies that are developing therapies for cancer and infectious disease generally, and many of these companies are focused on activating the immune system using therapeutic agents, including monoclonal antibodies, cytokines, vaccines, adjuvants, dendritic cells, nucleotides and cells. We are currently aware of several companies developing *ex vivo* cell-based immunotherapy products as a method of treating cancer and infectious diseases. These competitors include Antigenics, Inc., CancerVax Corporation, Cell Genesys, Inc., CellExSys, Inc. (recently sold to Chromos Molecular Systems, Inc.), Dendreon Corporation, Favrille, Inc., Genitope Corporation, IDM, S.A. and Kirin Pharmaceutical. Even if our Xcellerate Technology proves successful, we might not be able to remain competitive in this rapidly advancing area of technology. Some of our potential competitors may have more financial and other resources, larger research and development staffs and more experienced capabilities in researching, developing and testing products. Some of these companies also have more experience than us in conducting clinical trials, obtaining FDA and other regulatory approvals and manufacturing, marketing and distributing medical products. Smaller companies may successfully compete with us by establishing collaborative relationships with larger pharmaceutical companies or academic institutions. Our competitors may succeed in developing, obtaining patent protection for or commercializing their products more rapidly than us. A competing company developing, or acquiring rights to, a more effective therapeutic product for the same diseases targeted by us, or one that offers significantly lower costs of treatment, could render our products noncompetitive or obsolete.

Intellectual Property

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

We have a portfolio of issued patents and patent applications, which we believe provides patent coverage for our Xcellerate Technology. As of October 1, 2004, we owned or held exclusive rights to six issued patents, six allowed patent applications and numerous pending patent applications in the United States in the field of or directed to *ex vivo* T cell stimulation. Three of the issued patents relate to methods of stimulating T cells utilized by our Xcellerate Technology, two of which expire in 2019 and one of which expires in 2021, while two other issued patents, which expire in 2016, relate to a method of stimulating T cells and an antibody that we are not currently using. Two additional issued patents expire in 2020 and are in the field of or directed to immunosuppression and the treatment and prevention of disorders related to T cells. These two issued patents are directed to the use of a specific compound for these applications, and one of these patents is directed specifically to compositions of matter including likely derivatives of this compound. The final issued patent expires in 2020 and relates to *ex vivo* T cell stimulation to improve uptake of exogenous nucleic acid molecules, thus having gene therapy applications. We also have licensed numerous currently pending foreign patent applications and seven issued foreign patents corresponding to our T cell stimulation technology.

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

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

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

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

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

Corporate Collaborations

Part of our strategy is to establish corporate collaborations with pharmaceutical, biopharmaceutical and biotechnology companies for the development and commercialization of our Xcellerate Technology. We focus our efforts on partnering our technologies in markets and diseases that we do not plan to pursue on our own. We target collaborators that have the expertise and capability to develop, manufacture, obtain regulatory approvals for and commercialize our Xcellerate Technology. In our corporate collaborations, we seek to cover our research and development expenses through research funding, milestone payments and technology or license fees. We also seek to retain significant downstream participation in product sales through either profit sharing or product royalties paid on annual net sales.

Fresenius Biotech GmbH

In November 2003, we licensed our Xcellerate Technology and some related improvements on an exclusive basis in the field of HIV retroviral gene therapy to Fresenius for research, development, and commercialization in Europe, with a right of first negotiation under some circumstances to expand their territory to include North America. Our agreement with Fresenius requires us to license our Xcellerate Technology, including methods for manufacturing Xcellerated T Cells, to Fresenius, transfer certain enabling technology and supply all proprietary magnetic beads, or Xcyte Dynabeads, ordered by Fresenius to support its development and commercialization efforts. If we do not supply the Xcyte Dynabeads, Fresenius has the right to manufacture such Xcyte Dynabeads on its own or through a third party, until such time that we are able to supply the quantity of Xcyte Dynabeads ordered by Fresenius. Fresenius has agreed to reimburse us for our expenses in transferring the technology and pay us for the Xcyte Dynabeads on a cost-plus basis. In addition, under the agreement Fresenius has granted us a perpetual, irrevocable, non-exclusive, fully paid worldwide license to technology invented by Fresenius that directly relates to our Xcellerate

Technology. This agreement includes royalties on net sales as well as up to 5.4 million Euros in potential milestone payments to us, less applicable sublicense fees payable by us to third parties, for each product developed under this agreement. Fresenius obligation to pay us royalties under this

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agreement terminates on a country-by-country basis upon the later of the last to expire of the licensed patents or 15 years after the first commercial sale of a product in the country. The agreement is also subject to earlier termination by Fresenius at any time if Fresenius determines it cannot develop a commercially viable product or complete a required manufacturing audit, at any time by Xcyte if Fresenius does not meet certain development and commercialization milestones and by either party for the material breach or insolvency of the other party. The agreement specifies that the termination of certain technology licenses, under which we obtained much of our Xcellerate Technology, is a breach of this agreement.

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

Technology Licenses

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

- ***Diaclone S.A.*** In October 1999, we entered into a license agreement with Diaclone. Under the agreement, Diaclone granted us an exclusive, worldwide license to make, use and sell products or services using the monoclonal antibody that binds to the CD28 molecule for all *ex vivo* uses involving therapeutic and research applications. We have an option and right of first refusal to expand our license to include *in vivo* therapeutic and research purposes. We are currently obligated to purchase all our requirements for this monoclonal antibody from Diaclone until we begin preparing for Phase III clinical trials of a product covered by this license. Under certain circumstances, we would be permitted to have the monoclonal antibody made by third parties or manufacture it ourselves. This agreement has a term of 15 years from the date of first approval by the FDA, or its foreign equivalent, of a therapeutic product containing a bead coated with the licensed antibody and may be terminated earlier by either party for material breach or insolvency of either party. We currently do not have FDA approval of any therapeutic products containing a bead coated with the licensed antibody. At the end of the term, we will have a perpetual, irrevocable, royalty-free, exclusive license. We paid initial non-refundable license fees totaling $75,000 to Diaclone and are required to pay royalties if our products are commercialized.

- ***Fred Hutchinson Cancer Research Center.*** In October 1999, we entered into a license agreement with the Fred Hutchinson Cancer Research Center. Under the agreement, the Fred Hutchinson Cancer Research Center granted us a non-exclusive, worldwide license to make, use and sell products or services using the monoclonal antibody that binds to the CD3 molecule for T cell stimulation for *ex vivo* therapeutic and research uses other than cell separation and selection. We paid a non-refundable up-front licensing fee of $25,000 to the Fred Hutchinson Cancer Research Center, and we are obligated to pay the Fred Hutchinson Cancer Research Center a royalty fee if we or our sublicensees commercialize products or services that use the licensed monoclonal antibody. We are also required to pay fees to Fred Hutchinson Cancer Research Center under certain circumstances if we sublicense these rights to third parties. We paid sublicense fees in connection with our Fresenius collaboration totaling $42,227 to the Fred Hutchinson Cancer Research Center. On December 1, 2000, we amended this license agreement to broaden the field of use to include any *ex vivo* use involving therapeutic and research applications in exchange for an additional non-refundable up-front fee of $25,000 and the issuance of 27,272 shares of our common stock to the Fred Hutchinson Cancer Research Center. Our obligation to pay royalties under this license agreement will remain in effect for 15 years following the first commercial sale of our product and

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may be terminated earlier by either party for material breach or by Fred Hutchinson Cancer Research Center for Xcyte s insolvency. Thereafter, our license will be fully-paid.

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

Governmental Regulation

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

In order to obtain approval of a new product from the FDA, we must, among other requirements, submit proof of safety and efficacy as well as detailed information on the manufacture, quality, composition and labeling of the product in a new drug application or a biologics license application. In most cases, this proof entails extensive laboratory tests and preclinical and clinical trials. This testing, the preparation of necessary applications, the processing of those applications by the FDA and review of the applications by an FDA advisory panel of outside experts are expensive and typically take many years to complete. Additionally, the FDA recently formed a new division that will regulate biologic products, such as Xcellerated T Cells. The processes and requirements associated with this new division may cause delays and additional costs in obtaining regulatory approval of our products or regulatory authorization for our clinical trials. The FDA may not act quickly or favorably in reviewing these applications, or may deny approval altogether, and we may encounter significant difficulties or costs in our efforts to obtain FDA approval, which could delay or preclude us from marketing any products we may develop. The FDA may also require post-marketing testing and surveillance to monitor the effects of approved products or place conditions on any approval that could restrict the commercial applications of these products. The FDA may withdraw product approval if we fail to comply with regulatory standards, if we encounter problems following initial marketing or if new safety or other issues are discovered regarding our products after approval. With respect

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to patented products or technologies, delays imposed by the governmental approval process may materially reduce or eliminate the period during which we will have the exclusive right to exploit the products or technologies.

In order to conduct research to obtain regulatory approval for marketing, we must submit information to the FDA on the planned research in the form of an investigational new drug application. The investigational new drug application must contain, among other things, an investigational plan for the therapy, a study protocol, information on the study investigators, preclinical data, such as toxicology data, and other known information about the investigational compound. An investigational new drug application generally must be submitted by a commercial sponsor who intends to collect data on the safety and efficacy of a new drug or biological product prior to conducting human trials and submitting an application for marketing approval. In certain circumstances, an investigational new drug application may also be submitted which allows physicians to gain an initial understanding of the compound through an expanded access program. Data from expanded access trials can generally be used to support the safety, but not the efficacy, of a product.

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

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

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

Because the FDA is regulating Xcellerated T Cells as a biologic, we must submit biologics license applications to the FDA to obtain approval of our products. A biologics license application requires data showing the safety, purity and potency of the product. In a process which generally takes several years or more, the FDA reviews this application and, when and if it decides that adequate data are available to show that the new compound is both safe and effective and that other applicable requirements have been met, approves the drug or biologic for marketing. Prior to issuing a denial or an approval, the FDA often will seek recommendations from one of its advisory committees of independent experts. The amount of time taken for this approval process is a function of a number of variables, including the quality of the submission and studies presented, the potential contribution that the compound will make in improving the treatment of the disease in question, the recommendations of the

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FDA advisory committee and the workload at the FDA. It is possible that our Xcellerate Technology will not successfully proceed through this approval process or that the FDA will not approve our applications in any specific period of time, or at all. Any approval, if obtained, could be limited or could be made contingent on burdensome post-approval commitments or could be otherwise restricted.

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

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

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

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

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

Before approving a new drug application or biologics license application, the FDA will also inspect the facilities where the product is manufactured and will not approve the product unless the manufacturing facilities are in

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compliance with cGMP. In addition, the manufacture, holding and distribution of a product must remain in compliance with cGMP following approval. Manufacturers must continue to expend time, money and effort in the area of production and quality control and record keeping and reporting to ensure full compliance with those requirements.

The labeling, advertising, promotion, marketing and distribution of a drug or biologic product must be in compliance with FDA regulatory requirements. Our distribution of pharmaceutical samples to physicians must comply with the Prescription Drug Marketing Act. In addition, manufacturers are required to report adverse events and errors and accidents in the manufacturing process. Changes to an approved product, or changes to the manufacturing process, may require the filing of a supplemental application for FDA review and approval. Failure to comply with applicable requirements can lead to the FDA demanding that production and shipment cease, and, in some cases, that the manufacturer recall products or to FDA enforcement actions that can include seizures, injunctions and criminal prosecution. These failures can also lead to FDA withdrawal of approval to market the product. Where the FDA determines that there has been improper promotion or marketing, it may require corrective communications such as Dear Doctor letters. Even if we comply with FDA and other requirements, new information regarding the safety or effectiveness of a product, or a change in the law or regulations, could lead the FDA to modify or withdraw a product approval.

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

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

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

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

In May 2000, we filed our initial Phase I investigational new drug application, or IND, involving Xcellerated T Cells to treat metastatic kidney cancer. The FDA allowed us to start the trial in June 2000. The trial was

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completed in February 2003. In September 2001, we amended the IND to add a Phase I study of Xcellerated T Cells to treat hormone refractory prostate cancer. The trial was completed in June 2003. In August 2002, we amended the IND to add a Phase I/II to treat multiple myeloma patients post autologous stem cell transplantation. This trial is ongoing. In November 2002, we amended the IND to add a Phase I/II study to treat CLL. This CLL study was subsequently amended in July 2004 to allow for additional patients and is still ongoing. In September 2003, we amended the IND to add a randomized Phase II study to treat multiple myeloma patients with and without fludarabine. We anticipate completion of the trial by the end of the second quarter of 2005. In December of 2003, we amended the IND to add a Phase II study to treat non-Hodgkin s lymphoma patients. We anticipate completion of the trial by the end of 2005.

Legal Proceedings

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

Employees

As of September 27, 2004, we had 98 employees, 26 of whom are directly involved in research and development and 38 of whom are involved in manufacturing operations. We consider our relations with our employees to be good.

Facilities

We currently lease a total of approximately 63,500 square feet of space at three facilities. We lease approximately 22,000 square feet of office and laboratory space and a cGMP manufacturing facility in Seattle, Washington, with monthly payments of approximately $49,000. The lease on this space expires in October 2006, and we have options to renew for two additional five-year terms. We sublease approximately 1,000 square feet of laboratory space and equipment in Seattle, Washington, with monthly payments of approximately $3,333. The sublease on this space expires in March 2005, and we have options to extend for additional six-month terms at the sublessor s discretion. We also lease approximately 40,500 square feet of space in Bothell, Washington, with monthly payments of approximately $77,000. We have renovated approximately 20,000 square feet of this facility for the manufacture Xcellerated T Cells for our planned clinical trials and, if we obtain regulatory approval, initial commercialization. The initial lease term on this space expires December 2010, and we have options to renew until December 2020. Under the terms of the lease, we also have rights to negotiate for further expansion space in the building. We believe that this facility has sufficient space to accommodate expansion of our operations.

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SCIENTIFIC ADVISORY BOARD

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

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

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

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

John Hansen, M.D., is a Member, Fred Hutchinson Cancer Research Center and Professor, Division of Medical Oncology, University of Washington.

Carl June, M.D., is one of our scientific founders and is Professor of Pathology and Laboratory Medicine at the University of Pennsylvania.

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

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

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

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

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

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

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MANAGEMENT

Executive Officers and Directors

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

Name	Age	Position(s)
Ronald J. Berenson, M.D.	52	President, Chief Executive Officer and Director
Robert L. Kirkman, M.D.	55	Chief Business Officer and Vice President
Stewart Craig, Ph.D.	43	Chief Operating Officer and Vice President
Mark Frohlich, M.D.	42	Medical Director and Vice President
Lawrence A. Romel, M.S.	47	Vice President, Clinical Operations and Project Management
Mark L. Bonyhadi, Ph.D.	50	Vice President of Research
Kathi L. Cordova, C.P.A.	44	Senior Vice President of Finance and Treasurer
Joanna S. Black, J.D.	31	General Counsel, Vice President and Secretary
Jean Deleage, Ph.D.	64	Director
Dennis Henner, Ph.D.	53	Director
Peter Langecker, M.D., Ph.D.	53	Director
Robert T. Nelsen, M.B.A.	41	Director
Daniel K. Spiegelman, M.B.A.	46	Director
Stephen N. Wertheimer, M.M.	53	Director
Robert M. Williams, Ph.D.	51	Director

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

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

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

Mark Frohlich, M.D., has served as our Medical Director since October 2001 and has served as our Vice President since January 2002. Dr. Frohlich is a board-certified medical oncologist with an appointment as

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Clinical Assistant Professor of Medicine at the University of Washington. From July 1998 to October 2001, Dr. Frohlich held the position of Assistant Adjunct Professor of Medicine at the University of California at San Francisco. From July 1994 to June 1998, Dr. Frohlich completed his fellowship in medical oncology at the University of California at San Francisco. Dr. Frohlich received a B.S. in electrical engineering and economics from Yale University and an M.D. from Harvard Medical School.

Lawrence A. Romel, M.S., has served as our Vice President of Clinical Operations and Project Management since July 2004. From June 2002 to July 2004, Mr. Romel served as Senior Director of Project Management, New Product Planning, and Clinical Operations at Cell Genesys, Inc., a cancer vaccine and oncolytic viral therapies company. From July 2000 to June 2002, Mr. Romel served as Vice President of Clinical Operations at SuperGen, Inc., an emerging pharmaceutical company. From August 1999 to July 2000, Mr. Romel served as Vice President Clinical Operations and Regulatory Affairs at Onyx Pharmaceuticals, Inc., a biotechnology company. Mr. Romel received a M.S. in Chemistry from the University of Illinois-Chicago.

Mark L. Bonyhadi, Ph.D., has served as our Vice President of Research since January 2003. Dr. Bonyhadi previously served as our Director of Research from January 2002 to January 2003, Director of Strategic Scientific Development from April 2001 to December 2001 and Director of Biological Research from May 1997 to March 2001. From September 1990 to April 1997, Dr. Bonyhadi served as Senior Scientist with SyStemix, Inc., a stem cell and gene therapy company. Dr. Bonyhadi received a B.A. in biology from Reed College and a Ph.D. in immunology from the University of California at Berkeley.

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

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

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

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

Peter Langecker, M.D., Ph.D., has served as one of our directors since January 2000. Since October 1999, Dr. Langecker has served as Chief Medical Officer and Vice President of Clinical Affairs of BioMedicines, Inc.,

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a biotechnology company. From July 1997 to September 1999, Dr. Langecker served as Vice President of Clinical Affairs and Regulatory Affairs of Sugen, Inc., a biotechnology company. From March 1995 to July 1997, Dr. Langecker served as Vice President of Clinical Affairs of Coulter Pharmaceuticals, Inc., a biotechnology company. Before that, Dr. Langecker held various medical positions at Ciba Geigy and Schering-Plough. Dr. Langecker received an M.D. and a Ph.D. in medical sciences from Ludwig Maximilians University in Munich.

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

Daniel K. Spiegelman , M.B.A., has served as one of our directors since September 2004. Since September 1999, Mr. Spiegelman has served as the Senior Vice President and Chief Financial Officer for CV Therapeutics, Inc. From January 1998 to September 1999, Mr. Spiegelman served as Vice President and Chief Financial Officer for CV Therapeutics, Inc. From July 1991 until January 1998, Mr. Spiegelman was employed by Genentech, Inc., a biotechnology company, holding the position of treasurer from January 1996 to January 1998, assistant treasurer from July 1992 to December 1996, and treasury manager from July 1991 to July 1992. Mr. Spiegelman holds a B.A. in economics from Stanford University and an M.B.A. from Stanford Graduate School of Business.

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

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

Board Composition

Our board of directors is currently comprised of eight directors. The board is divided into three classes, with each director serving a three-year term and one class being elected at each year s annual meeting of stockholders. Dr. Langecker and Dr. Williams will be in the class of directors whose initial term expires at the 2005 annual meeting of stockholders. Dr. Deleage, Dr. Henner and Mr. Wertheimer will be in the class of directors whose initial term expires at the 2006 annual meeting of stockholders. Dr. Berenson, Mr. Spiegelman and Mr. Nelsen will be in the class of directors whose initial term expires at the 2007 annual meeting of stockholders.

Board Committees

Our board of directors has established an audit committee, a compensation committee, a nominating committee and a stock option committee.

The audit committee consists of Dr. Deleage, Mr. Spiegelman and Mr. Wertheimer. Dr. Deleage serves as the chairperson of the committee. The audit committee is responsible for assuring the integrity of our financial control, audit and reporting functions and reviews with our management and our independent auditors the effectiveness of our financial controls and accounting and reporting practices and procedures. In addition, the audit committee reviews the qualifications of our independent auditors, is responsible for their appointment, compensation, retention and oversight and reviews the scope, fees and results of activities related to audit and non-audit services.

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The compensation committee consists of Mr. Nelsen, Dr. Langecker and Mr. Spiegelman. The compensation committee s principal responsibility is to administer our stock plans and to set the salary and incentive compensation, including stock option grants, for our Chief Executive Officer and other executive officers.

The nominating committee consists of Dr. Langecker, Mr. Wertheimer and Dr. Williams. The purpose of the nominating committee is to identify individuals qualified to serve as members of our Board, and recommend nominees for election.

The stock option committee consists of Dr. Berenson and Mr. Nelsen. The stock option committee s principal responsibility is to grant stock options under the our stock plans to newly hired non-executive officers in accordance with set parameters outlined by the Board.

Director Compensation

Our seven outside directors are compensated with cash and options to purchase our common stock pursuant to our 2003 Directors Stock Option Plan. Non-employee directors are entitled to an annual cash retainer of $20,000, and receive $1,000 for each board meeting attended in person, $500 for each board meeting participated in telephonically, and $500 for each committee meeting participated, in addition to reimbursement for out-of-pocket expenses incurred in connection with attending board and committee meetings.

In November 1996, Dr. Deleage and Dr. Williams were each awarded non-statutory options for 5,454 shares of our common stock. In November 1999, Dr. Langecker was awarded a non-statutory option for 5,454 shares of our common stock. These shares vest over a four-year period at a rate of 25% of the total number of shares one year after the date of grant, with the remaining shares vesting monthly in equal installments over the next 36 months. In November 2003, Dr. Williams was awarded non-statutory options for 2,727 fully vested shares of our common stock in connection with his service on our Scientific Advisory Board. In September 2004, in connection with his election to our board of directors, Mr. Spiegelman was granted an option to purchase 10,000 shares of our common stock under the amended 2003 Directors Stock Option Plan, which option is subject to stockholder approval and is not exercisable until such approval. Directors who are our employees are eligible to participate in our 1996 Stock Option Plan, our 2003 Stock Plan and 2003 Employee Stock Purchase Plan. Directors who are not our employees are eligible to participate in our 2003 Directors Stock Option Plan.

Pursuant to our 2003 Directors Stock Option Plan, each non-employee director joining our board after June 2, 2004 is automatically granted an option to purchase 10,000 shares of our common stock. In addition, on the date of each annual meeting of our stockholders, each non-employee director is granted an option to purchase 10,000 shares of common stock if, on that date, the director has served on our board of directors for at least six months. Furthermore, directors serving as the chairperson of a committee of our board, or as members of the audit committee of our board, are granted an option to purchase 2,500 shares of common stock on the date of each annual meeting of our stockholders. The total number of shares subject to options granted under this plan vests in equal monthly installments over two years. Although this plan is currently effective, prior to receiving stockholder approval, options granted under this plan will not be exercisable and will be contingent on such approval

Compensation Committee Interlocks and Insider Participation

Dr. Deleage, Mr. Nelsen, and Dr. Berenson served on our compensation committee in 2003. During 2003, none of our executive officers served as a director or member of the compensation committee of any other entity that had any executive officer who served on our board of directors or on our compensation committee.

Limitations on Liability and Indemnification of Officers and Directors

Our amended and restated certificate of incorporation limits the liability of our directors to the maximum extent permitted by Delaware law. Delaware law provides that a corporation may eliminate the personal liability of its

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directors for monetary damages for breach of their fiduciary duties as directors, except liability for any of the following acts:

- breach of their duty of loyalty to us or our stockholders;
- acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions; and
- any transaction from which the director derived an improper personal benefit.

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

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

Executive Compensation

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

Summary Compensation Table

		Annual compensation		Long-term compensation Securities underlying	
Name and principal position(s)	**Year**	**Salary**	**Bonus**	**options**	**All other compensation**

Ronald J. Berenson, M.D. President and Chief Executive Officer	2003 2002	$ 249,714 239,276	$ 35,000 25,051	$	$ 286[1] 595[1]
Stewart Craig, Ph.D. Chief Operating Officer and Vice President	2003 2002	215,176 205,714	 51		284[2] 527[2]
Kathi L. Cordova, C.P.A. Senior Vice President of Finance and Treasurer	2003 2002	150,547 139,588			286[3] 391[3]
Mark Frohlich, M.D Medical Director and Vice President	2003 2002	181,759 172,183	17,447 16,043		513[4] 534[4]
Lewis Chapman Chief Business Officer	2003 2002	201,488 100,403	35,000 40,051		380[5] 312[5]
Joanna S. Black, J.D. General Counsel and Vice President	2003 2002[7]	154,882 128,656	 51		264[6] 377[6]

Footnotes appear on following page

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(1) Dr. Berenson received other compensation consisting of the payment of insurance premiums for group term life benefits in the amount of $286 in 2003 and $595 in 2002.
(2) Dr. Craig received other compensation consisting of the payment of insurance premiums for group term life benefits in the amount of $284 in 2003 and $527 in 2002.
(3) Ms. Cordova received other compensation consisting of the payment of insurance premiums for group term life benefits in the amount of $286 in 2003 and $391 in 2002.
(4) Dr. Frohlich received other compensation consisting of the payment of insurance premiums for group term life benefits in the amount of $513 in 2003 and $534 in 2002.
(5) Mr. Chapman received other compensation consisting of the payment of insurance premiums for group term life insurance in the amount of $380 in 2003 and $312 in 2002. Mr. Chapman s employment with us ended in August 2003.
(6) Ms. Black received other compensation consisting of the payment of insurance premiums for group term life benefits in the amount of $264 in 2003 and $377 in 2002.
(7) Ms. Black joined Xcyte Therapies, Inc. in January 2002.

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

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

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

Option Grants in Fiscal Year 2003 [1]

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

Joanna S. Black, J.D. Lewis Chapman	13,636	6.35%	5.50	09/22/13	34,090	102,695	207,948

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

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

Aggregated Option Exercises During 2003 and Fiscal Year-End Option Values

Named executive officer		Shares acquired upon exercise	Value realized	Number of securities underlying unexercised options at December 31, 2003		Value of unexercised in-the-money options at December 31, 2003					
				Exercisable	Unexercisable						
						−32.25	9/5/2022	—	—	—	
	12/8/2010	(4)	—	—	—	—	35,625	1,558,950	—	—	
	7/21/2011	(7)	—	—	—	—	28,125	1,230,750	—	—	
	9/5/2012	(6)	—	—	—	—	—	—	12,000	525,120	

(1) The time-based vesting has been met and the option is fully-vested and exercisable.
(2) Option vests over a period of four years in equal monthly installments commencing on the grant date.
(3) 50% of the option vests on September 14, 2013 and the remaining 50% vests in equal monthly installments over two years thereafter, subject to continued service as Chief Executive Officer of the Company through each such vesting date.
(4) RSUs vest quarterly over four years from the vesting commencement date of December 15, 2010.
(5) RSUs vest quarterly over four years from the vesting commencement date of March 15, 2011 assuming the attainment of performance conditions, which were attained.
(6) RSUs vest quarterly over four years, assuming attainment of pre-defined financial results for fiscal year 2013, which were attained.
(7) RSUs vest quarterly over four years from the vesting commencement date of September 15, 2012.
(8) Options granted prior to 2012 contain an early exercise feature subject to the Company's right of repurchase.
(9) The amounts shown are based on a price of $43.76 per share, which was the closing price of our common stock as reported on NYSE on July 31, 2013.

Option Exercises and Stock Vested at Fiscal Year End - 2013

The following table presents certain information concerning the exercise of options by each of the Named Executive Officers during the fiscal year ended July 31, 2013, as well as information regarding stock awards that vested during the fiscal year.

Option Exercises and Stock Vested at Fiscal Year End - 2013

	Options Awards		Stock Awards	
Name	Number of Shares Acquired on Exercise (#)	Value Realized on Exercise ($) [1]	Number of Shares Acquired on Vesting (#) [2]	Value Realized on Vesting ($) [3]
Marcus S. Ryu	—	—	321,418	10,976,535
Karen Blasing	365,000	10,483,317	6,250	217,608
Priscilla Hung	102,500	3,281,580	28,750	1,001,002
Jeremy Henrickson	17,000	552,361	22,500	783,394
Alexander C. Naddaff	60,000	1,813,337	36,250	1,262,135

(1) The value realized upon the exercise of stock options is calculated by (a) subtracting the option exercise price from the market value on the date of exercise to get the realized value per share, and (b) multiplying the realized value per share by the number of shares underlying options exercised.
(2) Represents shares of common stock released during fiscal 2013.
(3) The value realized upon vesting of RSUs is calculated by multiplying the number of RSUs vested by the prior day's closing price of common stock on the vest date.

Pension Benefits and Non-qualified Deferred Compensation

We do not provide a pension plan for our employees and none of our Named Executive Officers participated in a non-qualified deferred compensation plan during the year ended July 31, 2013.

Post-Employment Compensation

Except for payments or benefits equal to or less than those described in this section, we do not have any agreements or other arrangements with any of our executive officers, including the Named Executive Officers, providing for payments or benefits in the event of a termination of employment or in connection with a change in control of the Company.

Involuntary Termination of Employment

In the event that the employment of Mr. Ryu, Ms. Blasing or Ms. Hung is terminated without cause (as defined in the executive agreements), and subject to such officer delivering a fully effective release of claims, he or she will be entitled to cash severance equal to one times in the case of Mr. Ryu and 0.5 times in the case of Mses. Blasing and Hung, the sum of such officer's then current base salary and target annual incentive compensation, payable over 12 months in the case of Mr. Ryu and six months in the case of Mses. Blasing and Hung, plus a monthly payment equal

to our contribution towards health insurance for 12 months in the case of Mr. Ryu and six months in the case of Mses. Blasing and Hung.

Involuntary Termination of Employment in Connection with a Change in Control

In the event that the employment of Mr. Ryu, Ms. Blasing or Ms. Hung is terminated without cause or for good reason (as defined in the executive agreements) in the two month period prior to or 18 month period after, in the case of Mr. Ryu, and 12 month period after, in the case of Mses. Blasing and Hung, a change in control, then in lieu of the severance described above, and subject to such officer delivering a fully effective release of claims, he or she will be entitled to cash severance equal to 1.5 times in the case of Mr. Ryu and one times in the case of Mses. Blasing and Hung, the sum of the officer's then current base salary and target annual incentive compensation, payable in a single lump sum, plus a monthly payment equal to our contribution towards health insurance for 18 months in the case of Mr. Ryu and 12 months in the case of Mses. Blasing and Hung. In addition, all stock options, RSUs and other stock based awards held by Mr. Ryu, the stock option granted to Ms. Blasing on July 28, 2009 (which have all vested as of July 1, 2013) and any stock options and

RSUs granted to Ms. Hung as of and prior to December 31, 2012 will immediately accelerate and become fully vested upon such termination, and all other stock options, RSUs and other stock based awards held by Mses. Blasing and Hung will be accelerated as if such executive had completed an additional 12 months of service with us.

The payments and benefits provided under the executive agreements in connection with a change in control may not be eligible for a federal income tax deduction for the Company pursuant to Section 280G of the Code. These payments and benefits also may be subject to an excise tax under Section 4999 of the Code. If the payments or benefits payable to Mr. Ryu, Ms. Blasing or Ms. Hung in connection with a change in control would be subject to the excise tax on golden parachutes imposed under Section 4999 of the Code, then those payments or benefits will be reduced if such reduction would result in a higher net after-tax benefit to such officer.

Potential Payments Upon Termination or Change in Control

The table below reflects, as applicable, cash severance, equity acceleration and continuation of health benefits payable to our Named Executive Officers in connection with (1) the termination of his or her employment relationship without cause or for "good reason" or in connection with an "involuntary termination," as applicable, (2) upon a change in control of our Company and (3) in connection with a termination of employment described in (1) above following a change in control, and assuming, in each case, that the applicable triggering event(s) occurred on July 31, 2013. Neither Mr. Henrickson nor Mr. Naddaff are contractually entitled to any payments upon a termination or change in control of our Company. See section entitled "Post-Employment Compensation."

Name	Benefit	Termination without Cause Not in Connection with a Change in Control ($) [1]		Change in Control ($)	Involuntary Termination in Connection with a Change in Control ($) [1]	
Marcus S. Ryu	Cash Severance	650,000	[2]	—	975,000	[3]
	Equity Acceleration	—		—	33,602,307	[4]
	Health Benefits	35,251	[5]	—	52,877	[6]
	Total	685,251		—	34,630,184	
Karen Blasing	Cash Severance	180,000	[7]	—	360,000	[8]
	Equity Acceleration	—		—	781,660	[9]
	Health Benefits	24,653	[10]	—	49,306	[5]
	Total	204,653		—	1,190,966	
Priscilla Hung	Cash Severance	155,000	[7]	—	310,000	[8]
	Equity Acceleration	—		—	4,078,222	[11]
	Health Benefits	7,851	[10]	—	15,703	[5]
	Total	162,851		—	4,403,925	

(1) The closing price of our common stock as reported on the NYSE on July 31, 2013 was $43.76.

(2) Represents 12 months continuation of Mr. Ryu's base salary and payment of 12 months of his target bonus opportunity.

(3) Represents 1.5 times Mr. Ryu's base salary and target bonus opportunity.

(4) Represents the value of the acceleration of 100% of Mr. Ryu's unvested RSUs and stock options.

(5) Represents 12 months of payment of COBRA premiums.

(6) Represents 18 months of payment of COBRA premiums.

(7) Represents 6 months continuation of base salary and payment of 6 months of target bonus opportunity.

(8) Represents one times base salary and target bonus opportunity.

(9) Represents the value of the acceleration of the portion of Ms. Blasing's RSUs and options that would have vested if Ms. Blasing had provided an additional 12 months of service.

(10) Represents 6 months of payment of COBRA premiums.

(11) Represents the value of the acceleration of (i) 100% of Ms. Hung's unvested option awards and RSUs granted prior to December 31, 2012 and (ii) the portion of Ms. Hung's RSUs and options that would have vested if Ms. Hung had provided an additional 12 months of service.

Employee Stock Plans

Prior to becoming a public company, we maintained several equity compensation plans. In connection with our initial public offering, we discontinued using those equity compensation plans and adopted our 2011 Stock Plan (the “2011 Plan”). We now grant all stock options, RSUs and other equity awards under the 2011 Plan.

As of July 31, 2013, we had reserved 11,760,350 shares of our common stock for the issuance of awards under the 2011 Plan. The 2011 Plan provides that the number of shares reserved and available for issuance under the plan will increase each January 1, by up to 5% subject to board of director approval of the outstanding number of shares of our common stock on the immediately preceding December 31. This number is subject to adjustment in the event of a stock split, stock dividend or other change in our capitalization.

The shares we issue under the 2011 Plan will be authorized but unissued shares or shares that we reacquire. The shares of common stock underlying any

awards under the 2011 Plan or our prior stock plans that are forfeited, canceled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, reacquired by us prior to vesting, satisfied without any issuance of stock, expire or are otherwise terminated (other than by exercise) are added back to the shares of common stock available for issuance under the 2011 Plan.

The 2011 Plan is administered by the Committee. The Committee has full power to select, from among the individuals eligible for awards, the individuals to whom awards will be granted, to make any combination of awards to participants, and to determine the specific terms and conditions of each award, subject to the provisions of the 2011 Plan. Persons eligible to participate in the 2011 Plan will be those employees, non-employee directors and consultants as selected from time to time by the Committee in its discretion.

The 2011 Plan permits the granting of both options to purchase common stock intended to qualify as incentive stock options under Section 422 of the Code and options that do not so qualify. The option exercise price of each option will be determined by the Committee but may not be less than 100% of the fair market value of the common stock on the date of grant. The term of each option will be fixed by the Committee and may not exceed ten years from the date of grant. The Committee will determine at what time or times each option may be exercised.

The Committee may award stock appreciation rights subject to such conditions and restrictions as it may determine. Stock appreciation rights entitle the recipient to shares of common stock equal to the value of the appreciation in our stock price over the exercise price. The exercise price is the fair market value of the common stock on the date of grant.

The Committee may award restricted shares of common stock and RSUs under the 2011 Plan subject to such conditions and restrictions as it may determine. These conditions and restrictions may include the achievement of certain performance goals and/or continued employment with us through a specified vesting period. The Committee may also grant shares of common stock that are free from any restrictions under the 2011 Plan. Unrestricted stock may be granted to participants in recognition of past services or other valid consideration and may be issued in lieu of cash compensation due to such participant.

The Committee may grant performance share awards to participants, which entitle the recipient to receive shares of common stock upon the achievement of certain performance goals and such other conditions as the Committee shall determine.

The Committee may grant cash-based awards under the 2011 Plan to participants, subject to the achievement of certain performance goals.

The Committee may grant awards of restricted stock, RSUs, performance shares or cash-based awards under the 2011 Plan that are intended to qualify as “performance-based compensation” under Section 162(m) of the Code. Those awards would only vest or become payable upon the attainment of performance goals that are established by the Committee and related to one or more performance criteria. The performance criteria that would be used with respect to any such awards include: earnings before interest, taxes, depreciation and amortization, net income (loss) (either before or after interest, taxes, depreciation and/or amortization), changes in the market price of our common stock, economic value-added, funds from operations or similar measure, sales or revenue, acquisitions or strategic transactions, operating income (loss), cash flow (including, but not limited to, operating cash flow and free cash flow), return on capital, assets, equity, or investment, stockholder returns, return on sales, gross or net profit levels, productivity, expense, margins, operating efficiency, customer satisfaction, working capital, earnings (loss) per share of stock, sales or market shares, number of customers, number of new customers or customer references, operating income and net annual recurring revenue, any of which may be measured either in absolute terms or as compared to any incremental increase or as compared to results of a peer group. Stock options and stock appreciation rights with respect to no more than 2,500,000 shares of common stock may be granted to any individual grantee during any one calendar year period.

The 2011 Plan provides that upon the effectiveness of a “change in control” as defined in the 2011 Plan, all awards will be assumed or continued or substituted by the successor entity. If a successor entity does not assume, continue or substitute awards, then all such awards will accelerate and become fully vested and exercisable and will terminate prior to the effective time of the change in control and will terminate at the time of the change in control. In the event of such termination, such holders of options and stock appreciation rights will be given notice and an opportunity to exercise such awards. Alternatively, we may make or provide for a cash payment to participants holding options and

stock appreciation rights equal to the difference between the per share cash consideration payable to stockholders in the sale event and the per share exercise price of the options or stock appreciation rights.

Our board of directors may amend or discontinue the 2011 Plan and the Committee may amend or cancel outstanding awards for purposes of satisfying changes in law or any other lawful purpose, but no such action may adversely affect rights under an award without the holder's consent. Certain amendments to the 2011 Plan require the approval of our stockholders.

No awards may be granted under the 2011 Plan after the date that is 10 years from the effectiveness of the plan.

Limitation on Liability and Indemnification Matters

Our amended and restated certificate of incorporation and bylaws contain provisions that limit the personal liability of our directors for monetary damages to the fullest extent permitted by Delaware law. Consequently, our directors will not be personally liable to us or our stockholders for monetary damages for any breach of fiduciary duties as directors, except liability for:

•any breach of the director’s duty of loyalty to us or our stockholders;

•any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;

•unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the Delaware General Corporation Law; or

•any transaction from which the director derived an improper personal benefit.

Our amended and restated certificate of incorporation provides that we indemnify our directors to the fullest extent permitted by Delaware law. In addition, our amended and restated bylaws provide that we indemnify our directors and officers to the fullest extent permitted by Delaware law. Our amended and restated bylaws also provide that we shall advance expenses incurred by a director or officer in advance of the final disposition of any action or proceeding, and permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in that capacity, regardless of whether we would otherwise be permitted to indemnify him or her under the provisions of Delaware law. We have entered and expect to continue to enter into agreements to indemnify our directors, executive officers and other employees as determined by the board of directors. With certain exceptions, these agreements provide for indemnification for related expenses including, among others, attorneys’ fees, judgments, fines and settlement amounts incurred

by any of these individuals in any action or proceeding. We believe that these bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers. We also maintain directors' and officers' liability insurance.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and bylaws may discourage stockholders from bringing a lawsuit against our directors for breach of their fiduciary duty of care. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and other stockholders. Further, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damage awards against directors and officers. At present, there is no pending litigation or proceeding involving any of our directors, officers or employees for which indemnification is sought, and we are not aware of any threatened litigation that may result in claims for indemnification.

Equity Compensation Plan Information

The following table summarizes information about common stock that may be issued upon the exercise of options, warrants and rights under all of our equity compensation plans as of July 31, 2013.

	Number of Securities to be Issued upon Exercise of Outstanding Options[3], Warrants and Rights	Weighted Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in First Column)	
Equity compensation plans approved by stockholders [1]	3,763,228	$ 6.74	9,194,058	(2)

(1) The number of shares available under our 2011 Stock Plan increases on January 1 of each year by up to 5% of the outstanding shares of common stock on the immediately preceding December 31.

(2) Includes 1,037,153 shares that were issued pursuant to RSU awards that were canceled as net settlement for the tax liability related to RSU vesting. Under the terms of our 2011 Stock Plan these shares are available for issuance in future equity awards.

(3) Excludes 4,027,601 shares subject to restricted stock units and performance stock units outstanding as of July 31, 2013 that were issued under the 2011 plan.

OWNERSHIP OF GUIDEWIRE SOFTWARE, INC. COMMON STOCK

The following table sets forth, as of the record date, the shares of our common stock beneficially owned by:

- Each person known by us to own beneficially more than 5% of our common stock;
- Each individual who served as a director or named executive officer during fiscal year 2013; and
- All directors and executive officers as a group.

Beneficial ownership is determined in accordance with SEC rules, which generally attribute beneficial ownership of securities to each person who possesses, either solely or shared with others, the power to vote or dispose of those securities. Shares of common stock subject to stock options that are currently exercisable or unexercisable, and RSUs that vest, within sixty days of the record date, are deemed outstanding for purposes of computing the percentage ownership of the person holding such options and/or RSUs, but are not deemed outstanding for computing the percentage of any other person. The percentage of beneficial ownership for the following table is based on 58,651,158 shares of common stock outstanding as of the record date. To our knowledge, except as indicated in the footnotes to this table and subject to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all shares of common stock.

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Name and Address [1]	Shares Beneficially Owned Number of Shares of Common Stock	Percent of Class (%)
5% Stockholders:		
FMR LLC [2]	5,465,189	9.3
T. Rowe Price Associates, Inc. [3]	4,000,496	6.8
Directors and Executive Officers:		
Marcus S. Ryu [4]	1,318,632	2.2
Karen Blasing [5]	22,456	*
Priscilla Hung [6]	95,654	*
Jeremy Henrickson [7]	85,952	*
Alexander C. Naddaff [8]	36,021	*
Kenneth W. Branson [9]	1,206,532	2.0
John Cavoores [10]	11,420	*
Craig Conway [11]	80,923	*
Neal Dempsey [12]	89,470	*
Guy Dubois[10]	8,520	*
Steven M. Krausz [13]	21,636	*
Craig Ramsey [13]	345,472	*
Clifton Thomas Weatherford [14]	43,423	*
All directors and executive officers as a group (13 persons) [15]	3,366,111	5.6

* Less than 1%.

(1) Unless noted otherwise in the footnotes, all addresses are c/o Guidewire Software, Inc., 1001 E. Hillsdale Blvd., Suite 800, Foster City, CA 94404.

(2) Based solely on information reported on a Schedule 13GA filed with the SEC on February 14, 2013, by FMR LLC and Edward C. Johnson 3d, consists of 5,465,189 shares beneficially held by FMR LLC and Mr. Johnson, 5,465,189 shares for which FMR LLC and Mr. Johnson possess sole dispositive power. Fidelity Management and Research Company, a wholly-owned subsidiary of FMR LLC, is the beneficial owner of 5,465,189 shares as a result of acting as investment adviser to various investment companies. The principal address for FMR LLC is 82 Devonshire Street, Boston, MA 02109.

(3) Based solely on information reported on a Schedule 13G filed with the SEC on February 13, 2013, by T. Rowe Price Associates, Inc., consists of 4,000,496 shares beneficially held by T. Rowe Price Associates Inc., 1,001,696 shares for which T. Rowe Price Associates, Inc. possess sole dispositive power. T. Rowe Price Associates, Inc. is the beneficial owner of 4,000,496 shares as a result of acting as investment adviser to various investment companies. The principal address for T. Rowe Price Associates, Inc. is 100 E. Pratt Street, Baltimore, MD 21202.

(4) Includes 748,434 shares that may be acquired within 60 days of the record date through the exercise of stock options and 74,375 RSU shares that will be vested and released within 60 days of the record date.

(5) Includes 17,959 shares that may be acquired within 60 days of the record date through the exercise of stock options and 3,062 RSU shares that will be vested and released within 60 days of the record date.

(6) Includes 47,605 shares that may be acquired within 60 days of the record date through the exercise of stock options and 9,062 RSU shares that will be vested and released within 60 days of the record date.

(7) Includes 69,181 shares that may be acquired within 60 days of the record date through the exercise of stock options and 7,250 RSU shares that will be vested and released within 60 days of the record date.

(8) Includes 24,355 shares that may be acquired within 60 days of the record date through the exercise of stock options and 10,125 RSU shares that will be vested and released within 60 days of the record date.

(9) Includes 520,000 shares that may be acquired within 60 days of the record date through the exercise of stock options. 90,000 shares are held by the Branson Family Foundation (the "Foundation"). Mr. Branson, in his

capacity as a member of the board of directors and the Foundation's CFO and Secretary, shares voting and dispositive powers.

(10) Includes 5,936 shares that may be acquired within 60 days of the record date through the exercise of stock options and 2,584 RSU shares that will be vested and released within 60 days of the record date.

(11) Includes 8,839 shares that may be acquired within 60 days of the record date through the exercise of stock options and 28,209 RSU shares that will be vested and released within 60 days of the record date.

(12) Includes 8,839 shares that may be acquired within 60 days of the record date through the exercise of stock options and 2,584 RSU shares that will be vested and released within 60 days of the record date. 78,047 shares are held by Dempsey 1996 Revocable Trust. Mr. Dempsey, in his capacity as co-trustee, shares voting and dispositive powers.

(13) Includes 8,839 shares that may be acquired within 60 days of the record date through the exercise of stock options and 2,584 RSU shares that will be vested and released within 60 days of the record date.

(14) Includes 8,839 shares that may be acquired within 60 days of the record date through the exercise of stock options and 7,584 RSU shares that will be vested and released within 60 days of the record date.

(15) Includes 1,483,601 shares that may be acquired within 60 days of the record date through the exercise of stock options by the current directors and Named Executive Officers and 152,587 RSU shares that will be vested and released to the current directors and Named Executive Officers within 60 days of the record date.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

Transactions with Our Executive Officers and Directors

Stock Option Awards

The grants of certain stock options and RSUs to our directors and executive officers and related equity compensation policies are described above in “Information Regarding Compensation of Directors and Executive Officers” and “Compensation Discussion and Analysis.”

Employment Agreements

We have entered into agreements containing compensation, termination and change of control provisions, among others, with certain of our executive officers as described in “Compensation Discussion and Analysis-Executive Agreements and Termination of Employment Arrangements.”

Indemnification of Officers and Directors

We have also entered into indemnification agreements with each of our directors and executive officers. The indemnification agreements and our certificate of incorporation and bylaws require us to indemnify our directors and executive officers to the fullest extent permitted by Delaware law.

Our amended and restated certificate of incorporation and bylaws contain provisions that limit the personal liability of our directors for monetary damages to the fullest extent permitted by Delaware law. Consequently, our directors will not be personally liable to us or our stockholders for monetary damages for any breach of fiduciary duties as directors, except liability for:

•Any breach of the director's duty of loyalty to us or our stockholders;
•Any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
•Unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the Delaware General Corporation Law; or
•Any transaction from which the director derived an improper personal benefit.

Our amended and restated certificate of incorporation provides that we indemnify our directors to the fullest extent permitted by Delaware law. In addition, our amended and restated bylaws provide that we indemnify our directors and officers to the fullest extent permitted by Delaware law. Our amended and restated bylaws also provide that we shall advance expenses incurred by a director or officer in advance of the final disposition of any action or proceeding, and permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in that capacity, regardless of whether we would otherwise be permitted to indemnify him or her under the provisions of Delaware law. We have entered and expect to continue to enter into agreements to indemnify our directors, executive officers and other employees as determined by the board of directors. With certain exceptions, these agreements provide for indemnification for related expenses including, among others, attorneys' fees, judgments, fines and settlement amounts incurred by any of these individuals in any action or proceeding. We believe that these bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers. We also maintain directors' and officers' liability insurance.

Policies and Procedures for Related Party Transactions

We have adopted a formal written policy that our executive officers, directors and principal stockholders, including their immediate family members and affiliates, are not permitted to enter into a related party transaction with us without the prior consent of our audit committee or other independent members of our board of directors in the case it is inappropriate for our audit committee to review such transaction due to a conflict of interest. Any request for us to enter into a transaction with an executive officer, director, principal stockholder or any of such persons' immediate family members or affiliates, in which the amount involved exceeds $120,000, must first be presented to our audit committee for review, consideration and approval. All of our directors, executive officers and employees are required to report to our audit committee any such related party transaction. In approving or rejecting the proposed agreement, our audit committee shall consider the relevant facts and circumstances available to and deemed relevant by the audit committee, including, but not limited to the risks, costs and benefits to us, the terms of the transaction, the availability of other sources for comparable services or products and, if applicable, the impact on a director's independence. Our audit committee shall approve only those agreements that, in light of known circumstances, are in, or are not inconsistent with, our best interests, as our audit committee determines in the good faith exercise of its discretion.

SECTION 16(A) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE

Section 16(a) of the Exchange Act requires our executive officers and directors and persons who own more than 10% of a registered class of our equity securities to file reports of ownership on Form 3 and changes in ownership on Forms 4 or 5 with the SEC. Such officers, directors and 10% stockholders are also required by SEC rules to furnish us with copies of all Section 16(a) reports they file. Based solely upon our review of the copies of such forms provided to us and written representations from our executive officers and directors with respect to our 2013 fiscal year, we believe that all Section 16(a) filing requirements during fiscal 2013 were complied with, with the following exception:

- A Form 4 filing to be made on behalf of Marcus S. Ryu with respect to two additional transactions was made late on a Form 4 filed on January 29, 2013.

ADDITIONAL INFORMATION

Other Matters

We know of no other matters to be submitted at the 2013 annual meeting of stockholders. If any other matters properly come before the annual meeting of stockholders, it is the intention of the proxy holders to vote the shares they represent as the board of directors may recommend.

THE BOARD OF DIRECTORS
/s/ Marcus S. Ryu

MARCUS S. RYU
President and Chief Executive Officer
Dated: October 30, 2013

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