

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

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**FORM 10-Q**

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

For the Quarterly Period Ended March 31, 2005

OR

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

Commission File Number 0-50626

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**XCYTE THERAPIES, INC.**

*(Exact name of registrant as specified in its charter)*

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**Delaware**  
*(State or other jurisdiction of  
incorporation or organization)*

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

**1124 Columbia Street, Suite 130  
Seattle, Washington 98104**  
*(Address of principal executive offices and zip code)*

**(206) 262-6200**  
*(Registrant's telephone number, including area code)*

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

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

On May 9, 2005, the registrant had an aggregate of 19,664,897 shares of common stock issued and outstanding.

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[Table of Contents](#)

**XCYTE THERAPIES, INC.**  
**QUARTERLY REPORT ON FORM 10-Q**  
**For the Quarter Ended March 31, 2005**  
**Table of Contents**

	<u>Page</u>
<b>PART I. FINANCIAL INFORMATION (UNAUDITED)</b>	
Item 1. Financial Statements	
<a href="#">Condensed Balance Sheets as of March 31, 2005 and December 31, 2004 (audited)</a>	3
<a href="#">Condensed Statements of Operations for the three-month periods ended March 31, 2005 and 2004 and from inception (January 5, 1996) to March 31, 2005</a>	4
<a href="#">Condensed Statements of Cash Flows for the three-month periods ended March 31, 2005 and 2004 and from inception (January 5, 1996) to March 31, 2005</a>	5
<a href="#">Notes to Condensed Financial Statements</a>	6
Item 2. <a href="#">Management's Discussion and Analysis of Financial Condition and Results of Operations</a>	10
Item 3. <a href="#">Quantitative and Qualitative Disclosures About Market Risk</a>	32
Item 4. <a href="#">Controls and Procedures</a>	33
<b>PART II. OTHER INFORMATION</b>	
Item 2. <a href="#">Unregistered Sales of Equity Securities and Use of Proceeds</a>	34
Item 6. <a href="#">Exhibits</a>	34
<a href="#">SIGNATURES</a>	35
<b>INDEX OF EXHIBITS</b>	

## PART I - FINANCIAL INFORMATION

## Item 1. Financial Statements

XCYTE THERAPIES, INC.  
(a development stage company)CONDENSED BALANCE SHEETS  
(in thousands, except share and per share data)

	March 31, 2005	December 31, 2004
	(Unaudited)	(Note 1)
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 4,362	\$ 13,897
Short-term investments	35,181	33,421
Prepaid expenses and other current assets	1,453	1,021
<b>Total current assets</b>	<b>40,996</b>	<b>48,339</b>
Property and equipment, net	6,496	6,208
Deposits and other assets	1,085	1,056
<b>Total assets</b>	<b>\$ 48,577</b>	<b>\$ 55,603</b>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 1,205	\$ 1,707
Accrued compensation and related benefits	898	665
Other accrued liabilities	1,121	417
Derivative liability	2,649	3,020
Current portion of deferred revenue	47	47
Current portion of equipment financings	1,587	1,556
<b>Total current liabilities</b>	<b>7,507</b>	<b>7,412</b>
Deferred revenue, less current portion	751	762
Equipment financings, less current portion	2,547	2,678
Other liabilities	625	631
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value per share		
Authorized—5,000,000 shares as of December 31, 2004 and March 31, 2005		
Designated 6% convertible exchangeable—2,990,000 shares as of December 31, 2004 and March 31, 2005		
Issued and outstanding—2,046,813 and 2,079,813 shares as of March 31, 2005 and December 31, 2004, respectively		
Aggregate preference in liquidation—\$20,673 at March 31, 2005	2	2
Common stock, par value \$0.001 per share		
Authorized—100,000,000 shares as of December 31, 2004 and March 31, 2005		
Issued and outstanding—19,664,897 and 19,498,256 as of March 31, 2005 and December 31, 2004, respectively	20	19
Additional paid-in capital	171,696	171,708
Deferred stock compensation	(1,057)	(1,417)
Accumulated other comprehensive loss	(39)	(9)
Deficit accumulated during the development stage	(133,475)	(126,183)
<b>Total stockholders' equity</b>	<b>\$ 37,147</b>	<b>\$ 44,120</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 48,577</b>	<b>\$ 55,603</b>

See accompanying notes.

**XCYTE THERAPIES, INC.**  
**(a development stage company)**  
**CONDENSED STATEMENTS OF OPERATIONS**  
**(Unaudited)**  
**(in thousands, except share and per share data)**

	Three months ended March 31,		Period from inception (January 5, 1996) to March 31, 2005
	2005	2004	
Revenue:			
License fee	\$ 12	\$ —	\$ 147
Collaborative agreement	4	12	201
Government grant	—	—	144
Total revenue	16	12	492
Operating expenses:			
Research and development	5,494	4,175	92,017
General and administrative	2,020	1,574	30,347
Total operating expenses	7,514	5,749	122,364
Loss from operations	(7,498)	(5,737)	(121,872)
Other income (expense):			
Interest income	258	42	4,151
Interest expense	(60)	(12,589)	(14,840)
Change in valuation of derivative	8	—	(719)
Loss on sale of equipment	—	—	(195)
Other income (expense), net	206	(12,547)	(11,603)
Net loss	(7,292)	(18,284)	(133,475)
Accretion of preferred stock	—	(8,973)	(25,385)
Net loss applicable to common stockholders	\$ (7,292)	\$ (27,257)	\$(158,860)
Basic and diluted net loss per common share	\$ (0.37)	\$ (7.98)	
Shares used in computation of basic and diluted net loss per common share	19,595,990	3,414,481	

See accompanying notes.

**XCYTE THERAPIES, INC.**  
**(a development stage company)**

**CONDENSED STATEMENTS OF CASH FLOWS**  
**(Unaudited)**  
**(in thousands)**

	Three months ended March 31,		Period from inception (January 5, 1996) to March 31, 2005
	2005	2004	
<b>Cash flows from operating activities</b>			
Net loss	\$ (7,292)	\$ (18,284)	\$ (133,475)
Adjustments to reconcile net loss to net cash used in operating activities:			
Non-cash research and development expense for technology licenses	—	—	1,716
Amortization of investment premiums, net	81	107	687
Non-cash stock compensation expense	285	608	10,278
Non-cash interest expense	12	12,524	13,074
Non-cash rent expense	9	9	145
Change in valuation of derivative	(8)	—	719
Depreciation and amortization	291	224	5,988
Loss on sale of property and equipment	—	—	195
Changes in assets and liabilities:			
Increase in prepaid expenses and other current assets	(433)	(1,436)	(1,640)
(Increase) decrease in deposits and other assets	(37)	806	(736)
Increase (decrease) in accounts payable	(502)	(266)	1,205
Increase in accrued liabilities	919	1,979	3,617
Net cash used in operating activities	(6,675)	(3,729)	(98,227)
<b>Cash flows from investing activities</b>			
Purchases of property and equipment	(578)	(374)	(11,942)
Proceeds from sale of property and equipment	—	—	64
Net cash acquired in acquisition	—	—	437
Purchases of investments available-for-sale	(36,634)	(503)	(179,950)
Purchases of investments held-to-maturity	—	—	(17,732)
Proceeds from maturities of investments available-for-sale	34,764	2,878	156,630
Proceeds from maturities of investments held-to-maturity	—	—	5,145
Net cash provided by (used in) investing activities	(2,448)	2,001	(47,348)
<b>Cash flows from financing activities</b>			
Net proceeds from issuances of preferred stock	—	—	103,042
Net proceeds from issuances of common stock	—	29,709	29,700
Net proceeds from issuances of convertible promissory notes	—	—	12,660
Common stock repurchased	—	—	(3)
Proceeds from stock options and warrants exercised	—	42	591
Proceeds from issuances of common stock in connection with employee stock purchase plan	—	—	10
Payment of preferred stock dividends	(300)	—	(300)
Proceeds from equipment financings	323	484	10,004
Principal payments on equipment financings	(435)	(250)	(5,767)
Net cash provided by (used in) financing activities	(412)	29,985	149,937
Net increase (decrease) in cash and cash equivalents	(9,535)	28,257	4,362
Cash and cash equivalents at beginning of period	13,897	2,241	—
Cash and cash equivalents at end of period	\$ 4,362	\$ 30,498	\$ 4,362
<b>Non-cash investing and financing activities</b>			
Common stock issued for acquisition	\$ —	\$ —	\$ 330
Preferred stock issued for acquisition	\$ —	\$ —	\$ 579
Preferred stock warrants issued for acquisition	\$ —	\$ —	\$ 330
Preferred stock warrants issued in connection with equipment financing	\$ —	\$ —	\$ 298
Preferred stock warrants issued in connection with lease	\$ —	\$ —	\$ 340
Preferred stock warrants issued in preferred stock financing	\$ —	\$ —	\$ 48
Issuance of common stock warrants and beneficial conversion in preferred stock	\$ —	\$ —	\$ 25,385
Accretion of preferred stock	\$ —	\$ (8,973)	\$ (25,385)
Conversion of redeemable convertible preferred stock and warrants into common stock and warrants	\$ —	\$ 76,043	\$ 76,043
Conversion of promissory notes and accrued interest into common stock	\$ —	\$ 13,065	\$ 13,065
Common stock issued in satisfaction of make-whole payments upon conversion of preferred	\$ 63	\$ —	\$ 1,785

stock

Property and equipment costs accrued	\$	247	\$	30	\$	247
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See accompanying notes.

**XCYTE THERAPIES, INC.**  
**(a development stage company)**

**Notes to the Condensed Financial Statements**  
**(Unaudited)**

**1. Organization and significant accounting policies**

***Organization***

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

***Basis of presentation***

The accompanying unaudited condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements. The unaudited condensed interim financial statements have been prepared on the same basis as the annual financial statements. In the opinion of management, the accompanying balance sheets and related interim statements of operations and cash flows reflect all adjustments, consisting of normal recurring adjustments, necessary for the fair presentation of the financial statements in conformity with accounting principles generally accepted in the United States of America. The results of operations of any interim period are not necessarily indicative of the results of operations for the full year or any other interim period. Further, the preparation of financial statements requires management to make estimates and assumptions that affect the recorded amounts reported therein. A change in facts or circumstances surrounding the estimate could result in a change to estimates and impact future operating results.

The financial statements and related disclosures have been prepared with the assumption that users of the interim financial statements have read or have access to the audited financial statements for the preceding fiscal year. Accordingly, these financial statements should be read in conjunction with the audited financial statements and notes thereto for the year ended December 31, 2004, contained in the annual report on Form 10-K filed by the Company with the Securities and Exchange Commission on March 31, 2005. The condensed balance sheet at December 31, 2004 has been derived from the audited financial statements at that date.

***Other comprehensive income (loss)***

Other comprehensive income (loss) includes certain changes in equity that are excluded from net income (loss). The Company's only other comprehensive income (loss) is unrealized gain (loss) on investments. Total comprehensive loss was \$7,322 and \$18,281 for the three months ended March 31, 2005 and 2004, respectively.

***Stock-based compensation***

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

As required under SFAS No. 123, the pro forma effects of stock-based compensation on net loss are estimated at the date of grant using the Black-Scholes option-pricing model. The Black-Scholes option-pricing model was developed for use in estimating the fair value of traded options that have no vesting restrictions and are fully transferable. Because the Company's employee stock options have characteristics significantly different from those of traded options, and because changes in the subjective input assumptions can materially affect the fair value estimate, the existing models do not, in management's opinion, necessarily provide a reliable single measure of the fair value of the Company's employee stock options.

## [Table of Contents](#)

The fair value of these options was estimated at the date of grant using the Black-Scholes option-pricing model with the following weighted average assumptions for the three months ended March 31, 2005 and 2004: risk-free interest rate of 3.5% and 5.0%; a dividend yield of 0%; expected volatility of 82% and 80%; and weighted average expected lives of the options of 4 years. The estimated weighted average fair value of stock options granted during the three months ended March 31, 2005 and 2004 was \$1.51 and \$12.46 per share of common stock, respectively.

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

	Three months ended March 31,	
	2005	2004
Net loss applicable to common stockholders, as reported	\$ (7,292)	\$ (27,257)
Add: Employee stock-based compensation, as reported	278	583
Deduct: Stock-based compensation determined under the fair value method	(552)	(701)
Pro forma net loss	\$ (7,566)	\$ (27,375)
Basic and diluted pro forma net loss per share	\$ (0.39)	\$ (8.02)

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

Deferred stock-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. Deferred stock-based compensation is amortized over the vesting period of the underlying option using the graded-vesting method.

### **Net loss per share**

Basic net loss per share is computed by dividing net loss applicable to common stockholders by the weighted average number of common shares outstanding for the period. Common stock equivalents, including convertible exchangeable preferred stock, redeemable convertible preferred stock, redeemable convertible preferred stock warrants, convertible promissory notes, common stock warrants and outstanding stock options are excluded from the calculation of diluted net loss per share because all securities are antidilutive for the periods presented. As of March 31, 2005 and 2004, the total number of shares excluded from the calculations of diluted net loss per common share was 10,714,078 and 823,765, respectively.

### **Recent accounting pronouncements**

In December 2004, the FASB issued SFAS 123R, *Share-Based Payment*. SFAS 123R establishes standards for the accounting for transactions in which an entity receives employee services in exchange for the entity's equity instruments or liabilities that are based on the fair value of the entity's equity instruments or that may be settled by the issuance of those equity instruments. SFAS 123R eliminates the ability to account for share-based compensation using APB 25 and generally requires that such transactions be accounted for using a fair value method. The provisions of this statement are effective in the first fiscal year beginning after June 15, 2005 and will become effective for the Company beginning with the first quarter of 2006. The impact that the adoption of this statement will have on the Company's financial position and results of operations is expected to be material. The impact will be determined by share-based payments granted in future periods, as well as the fair value model and assumptions the Company will choose, which have not been finalized yet.

## **2. Redeemable convertible preferred stock**

### **Accretion of preferred stock**

In connection with the conversion of the Company's Series E and Series F redeemable convertible preferred stock into common stock upon the closing of the initial public offering in March 2004, the Company recognized \$9.0 million of preferred stock accretion associated with the remaining discount on the preferred stock which had not previously been recognized.

## **3. Convertible exchangeable preferred stock**

In January 2005, the Company's Board of Directors declared a quarterly dividend in the amount of \$0.1467 per share of preferred stock, which was paid on February 1, 2005, to the holders of record as of the close of business on January 21, 2005. This quarterly dividend distribution totaled \$300,000. In April 2005, the Company's Board of Directors declared a quarterly dividend in the amount



## [Table of Contents](#)

of \$0.15 per share of preferred stock, which was paid on May 2, 2005, to the holders of record as of the close of business on April 22, 2005. This quarterly dividend distribution totaled \$307,000.

In the first quarter of 2005, holders voluntarily converted 33,000 shares of preferred stock into 140,425 shares of common stock. In connection with these conversions, the Company issued 26,216 shares of common stock to converting holders in satisfaction of the required dividend make-whole payments.

In accordance with Statement of Financial Accounting Standards No. 133, *Accounting for Derivative Instruments* (SFAS 133), the Company is required to separate and account for, as an embedded derivative, the dividend make-whole payment feature of the preferred stock offering. As an embedded derivative instrument, the dividend make-whole payment feature must be measured at fair value and reflected as a liability. Changes in the fair value of the derivative are recognized in earnings as a component of other income (expense). The Company determined the fair value of the dividend make-whole payment feature to be \$3.0 million at December 31, 2004. The carrying value of this derivative was reduced by \$363,000 during the first quarter of 2005, based on cash dividends paid and the fair value of common stock issued as dividend make-whole payments pursuant to voluntary holder conversions during this period. At March 31, 2005, the derivative liability was valued at \$2.6 million, resulting in the recognition of \$8,000 as other income for the three months ended March 31, 2005.

#### **4. Common stock**

##### ***Initial public offering***

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

#### **5. Stock Plans**

##### ***2003 Stock Plan***

In January 2005, the Board of Directors approved an amendment of the 2003 Plan, subject to stockholder approval, to increase the number of shares of common stock authorized for issuance under the 2003 Plan by 400,000 shares, to a total of 1,145,453 shares. In March 2005, the Board of Directors approved another amendment of the 2003 Plan, subject to stockholder approval, to increase the number of shares of common stock authorized for issuance under the 2003 Plan by an additional 200,000 shares, to a total of 1,345,453 shares. As of March 31, 2005, options covering an aggregate of 1,005,723 shares of common stock had been granted under the 2003 Plan, and 339,730 shares of common stock remained available for future grant under the 2003 Plan. As of March 31, 2005, 260,270 shares of common stock have been granted under the 2003 Plan subject to stockholder approval of the increase in shares of common stock authorized for issuance under the 2003 Plan and are not exercisable until such approval is obtained. Options granted that are subject to stockholder approval are deemed to be contingent grants and, therefore, no measurement date can occur until such approval is obtained. As a result, the stock price used in measuring compensation expense is the price on the date of stockholder approval. If the stock price on that date is greater than the exercise price, this will result in the recognition of deferred stock compensation, and because a grant is not deemed to have occurred until stockholder approval has occurred, no compensation expense will be recognized prior to the date of stockholder approval.

In the first quarter of 2005, the Board of Directors approved option grants totaling 262,500 shares of common stock to the Company's executive officers, which vest upon the meeting of certain Company milestones, or 100% of such options vest upon the four-year anniversary of the date of grant if such milestones are not met earlier. This milestones-based vesting provides that 50% of the shares vest based on certain clinical trial-related goals, 25% of the shares vest based on the consummation of certain corporate transactions, and 25% of the shares vest based on the achievement of FDA-related goals. For purposes of pro forma disclosure, the estimated fair value of the options will initially be amortized to expense over the four-year vesting period using the straight-line method. This amortization to expense will be accelerated, as necessary, based on the achievement of the milestones. As of March 31, 2005, none of the specified milestones had been achieved.

**6. Restructuring**

On March 22, 2005, the Company reduced its workforce by approximately 24%, to 81 employees, as a result of the Company's decision to limit clinical development to a planned Phase II/III clinical trial in chronic lymphocytic leukemia (CLL) and a planned Phase I/II trial in HIV. The Company recorded a charge in the first quarter of 2005 of \$303,000, consisting of severance, benefits and outplacement services. This amount is included in operating expenses for the three months ended March 31, 2005, with \$243,000 classified as research and development and \$60,000 classified as general and administrative. The total amount of the charge is accrued and included in current liabilities at March 31, 2005, and is expected to be fully paid in the second quarter of 2005.

On May 16, 2005, the Company announced its decision to focus its research and development efforts on HIV and to discontinue the planned Phase II/III clinical trial in CLL. The Company is currently evaluating whether further reductions in its workforce are appropriate given this more limited clinical development plan. At this time, the Company cannot estimate the impact that any such reductions would have on its results of operations or financial condition.

**Item 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

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

*In addition to historical information, this Quarterly Report on Form 10-Q contains forward-looking statements, including statements regarding product plans and investing activities, that involve risks and uncertainties that could cause actual results to differ materially. Factors that might cause or contribute to such differences include, but are not limited to, those discussed in the section entitled "Important Factors That May Affect Our Business, Results of Operations and Stock Price." You should carefully review the risks described herein and in other documents we file from time to time with the Securities and Exchange Commission, including the Annual Report on Form 10-K filed by us in March 2005. When used in this report, the words "expects," "could," "would," "may," "anticipates," "intends," "plans," "believes," "seeks," "targets," "estimates," "looks for," "looks to," and similar expressions, as well as statements regarding our focus for the future, are generally intended to identify forward-looking statements. You should not place undue reliance on these forward-looking statements, which speak only as of the date of this Quarterly Report on Form 10-Q. We undertake no obligation to publicly release any revisions to the forward-looking statements or reflect events or circumstances after the date of this document. We caution our investors that our business and financial performance are subject to substantial risks and uncertainties.*

**Overview**

We are a biotechnology company developing a new class of therapeutic products designed to enhance the body's natural immune responses to treat infectious diseases, in particular HIV, 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 March 31, 2005, our deficit accumulated during the development stage was \$133.5 million. Our operating expenses consist of research and development expenses and general and administrative expenses.

We have recognized revenues from inception through March 31, 2005 of approximately \$492,000 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 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.

## [Table of Contents](#)

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 March 31, 2005, we incurred research and development expenses of approximately \$92.0 million, substantially all of which relate to the research and development of this technology.

We recently announced that we are focusing our research and development efforts on the use of Xcellerated T Cells to treat HIV. On March 22, 2005, we reduced our workforce by approximately 24%, to 81 employees, as a result of our decision to limit clinical development to a planned Phase II/III clinical trial in CLL and a planned Phase I/II trial in HIV. On May 16, 2005, we announced our decision to focus our research and development efforts on HIV and to discontinue the planned Phase II/III clinical trial in CLL due primarily to delays and uncertainties regarding our ability to reach agreement with the FDA on a clinical trial protocol that would be feasible and affordable for us to pursue. We are currently evaluating whether further reductions in our workforce are appropriate given this more limited clinical development plan.

Although we have recently taken actions to reduce our research and development expenses in the short term, we expect our research and development expenses to increase again in the future if our planned Phase I trial in HIV is successful, as we continue to improve our proprietary Xcellerate Technology, and as we develop Xcellerated T Cells for additional clinical indications. Because of the risks and uncertainties inherent in the clinical trials and regulatory process, we are unable to estimate with any certainty the length of time or expenses to continue development of Xcellerated T Cells for commercialization. However, we expect our research and development expenses to increase as we continue to improve our proprietary Xcellerate Technology and develop Xcellerated T Cells for additional clinical indications.

### **General and Administrative Expenses**

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

### **Results of Operations**

#### **Three Months Ended March 31, 2005 and 2004**

##### *Revenue*

Revenue was approximately \$16,000 and \$12,000 for the three months ended March 31, 2005 and 2004, 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 73% of our operating expenses for each of the three-month periods ended March 31, 2005 and 2004. Research and development expenses increased 32%, from \$4.2 million for the three months ended March 31, 2004 to \$5.5 million for the three months ended March 31, 2005. The overall increase in research and development expenses is primarily the result of increases in salary and other personnel-related expenses, in addition to increases in scientific consulting and outside services fees, clinical trial costs, laboratory supplies and facility expenses. As of March 31, 2005 we had 65 employees in research and development and clinical development operations compared to 61 employees in research and development and clinical development operations as of March 31, 2004. However, these employee numbers were significantly higher for the first quarter of 2005 prior to our restructuring in late March 2005. As discussed above, we are currently focusing our efforts on advancing our product in a planned Phase I trial in HIV. As a result of our plan announced in March 2005 to limit clinical development to planned CLL and HIV trials, we reduced our workforce by approximately 24% on March 22, 2005, with the vast majority of this reduction affecting employees in research and development and clinical development operations. The overall increase in salary and other personnel-related expenses totaled approximately \$1.2 million, including approximately \$243,000 in termination benefits associated with the restructuring. Scientific consulting and outside services, clinical trial and laboratory supplies costs have increased as we continue to advance and expand our clinical development, with increases of approximately \$259,000, \$175,000 and \$90,000, respectively. In addition, facility expenses increased approximately \$125,000, as we continued to expand operations at our planned manufacturing plant in Bothell, Washington. These increases were partially offset by a reduction of amounts charged to expense for contractual obligations relating to developing our bead technology. Expenses associated with developing our bead technology totaled \$500,000 for the three months ended March 31, 2004, with no such costs incurred for the three months ended March 31, 2005. In addition, our non-cash stock compensation expense decreased from \$313,000 for the three months ended March 31, 2004 to \$109,000 for the three months ended March 31, 2005.

## [Table of Contents](#)

### *General and Administrative*

General and administrative expenses represented approximately 27% of our operating expenses for each of the three-month periods ended March 31, 2005 and 2004. General and administrative expenses increased 28%, from \$1.6 million for the three months ended March 31, 2004 to \$2.0 million for the three months ended March 31, 2005. The overall increase was due primarily to costs associated with being a public company, including increases in professional fees and insurance costs of approximately \$204,000 and \$124,000, respectively. Increases in general and administrative expenses were partially offset by a reduction in non-cash stock compensation expense. Non-cash stock compensation expense decreased from \$295,000 for the three months ended March 31, 2004 to \$177,000 for the three months ended March 31, 2005.

### *Other Income (Expense)*

Other income, comprised primarily of interest income and interest expense, totaled 206,000 for the three months ended March 31, 2005, compared to other expense of \$12.5 million for the three months ended March 31, 2004. Interest income increased 514%, from \$42,000 for the three months ended March 31, 2004 to \$258,000 for the three months ended March 31, 2005, due to increased cash and investment balances upon which interest is earned. Interest expense decreased from \$12.6 million for the three months ended March 31, 2004 to \$60,000 for the three months ended March 31, 2005. The large amount of interest expense in the first quarter of 2004 was associated with the convertible promissory notes issued in October 2003. Upon consummation of our initial public offering and conversion of the notes to common stock, we recognized \$11.3 million in interest expense, which represented the beneficial conversion feature of the notes. We also recognized an additional \$1.1 million in interest expense associated with the discount on the notes, representing the value of the proceeds allocated to the warrants received by the note holders.

Also included in other income in the first quarter of 2005 is the change in the derivative value associated with the make-whole payment on our outstanding convertible exchangeable preferred stock of \$8,000. The valuation of the derivative is dependent upon many factors, including estimated market volatility, and may fluctuate significantly, which may have a significant impact on our statement of operations.

### *Accretion of Preferred Stock*

For the three months ended March 31, 2004, we recognized \$9.0 million in accretion of preferred stock to arrive at our net loss applicable to common stockholders. No such accretion was recognized for the three months ended March 31, 2005. 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.

### **Liquidity and Capital Resources**

As of March 31, 2005, we had cash, cash equivalents and short-term investments of \$39.5 million, with cash equivalents being held in commercial paper and highly liquid money market accounts with financial institutions. Cash, cash equivalents and short-term investments were \$47.3 million as of December 31, 2004.

Net cash used in operating activities was \$6.7 million and \$3.7 million for the three months ended March 31, 2005 and 2004, respectively. Expenditures in these periods were generally the result of research and development expenses and general and administrative expenses in support of our operations.

Our investing activities, other than purchases and maturities of investments, have consisted primarily of purchases of property and equipment. Purchases of property and equipment totaled \$578,000 and \$374,000 for the three months ended March 31, 2005 and 2004, respectively. Property and equipment additions in the first quarter of 2005 are primarily associated with the renovation of our new manufacturing facility in Bothell, Washington.

Net cash used in financing activities totaled \$412,000 for the three months ended March 31, 2005, compared to net cash provided by financing activities of \$30.0 million for the three months ended March 31, 2004. 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.

Based on the current status of our product development and collaboration plans, we believe that our current cash, cash equivalents and investments will be adequate to satisfy our capital needs through at least the end of the second quarter of 2006. We are currently evaluating whether reductions in our workforce or other expenditures are appropriate based on our recently revised clinical development strategy. At this time, we cannot estimate the impact that any such reductions would have on our results of operations or financial condition.

## [Table of Contents](#)

We will likely seek additional financing prior to that time to, among other things, support our continuing product development, manufacturing and clinical trials in future periods. Furthermore, we expect to require additional funding before we are able to generate revenue, if at all, from our potential products. Additional financing may not be available on favorable terms, if at all. If we are unable to raise additional funds when we need them, we may have to delay, reduce or eliminate some or all of our development programs or our clinical trials. We also may have to license our technologies to others, including technologies that we would prefer to develop internally, to raise capital.

### **Recent Accounting Pronouncements**

In December 2004, the FASB issued SFAS 123R, *Share-Based Payment*. SFAS 123R establishes standards for the accounting for transactions in which an entity receives employee services in exchange for the entity's equity instruments or liabilities that are based on the fair value of the entity's equity instruments or that may be settled by the issuance of those equity instruments. SFAS 123R eliminates the ability to account for share-based compensation using APB 25 and generally requires that such transactions be accounted for using a fair value method. The provisions of this statement are effective in the first fiscal year beginning after June 15, 2005 and will become effective for us beginning with the first quarter of 2006. The impact that the adoption of this statement will have on our financial position and results of operations is expected to be material. The impact will be determined by share-based payments granted in future periods, as well as the fair value model and assumptions we will choose, which have not been finalized yet.

### **Critical Accounting Policies**

#### ***Stock-Based Compensation***

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

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

Prior to our initial public offering, we determined the fair value of our common stock for purposes of these calculations based on our review of the primary business factors underlying the value of our common stock on the date these option grants were made or revalued, viewed in light of our initial public offering and the initial public offering price per share. Subsequent to our initial public offering, the fair value is determined based on the price of the common stock as reported by the Nasdaq National Market in *The Wall Street Journal*.

#### ***Revenue Recognition***

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

#### ***Cash, Cash Equivalents and Investments***

We classify all investment securities as available-for-sale, carried at fair value. We report unrealized gains and losses as a separate component of stockholders' equity (deficit). We include amortization, accretion, interest and dividends, realized gains and losses and declines in value judged to be other-than-temporary on available-for-sale securities in interest income. Statement of Financial Accounting Standards No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, and Securities and Exchange Commission (SEC) Staff Accounting Bulletin (SAB) 59, *Accounting for Noncurrent Marketable Equity Securities*, provide guidance on determining when an investment is other-than-temporarily impaired. This evaluation depends on the specific facts and

## [Table of Contents](#)

circumstances. Factors that we consider in determining whether an other-than-temporary decline in value has occurred include: the market value of the security in relation to its cost basis; the financial condition of the investee; and the intent and ability to retain the investment for a sufficient period of time to allow for possible recovery in the market value of the investment.

### ***Clinical Trial Accruals***

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

### ***Derivative Instruments***

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

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

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

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

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

### ***We expect to continue to incur substantial losses, and we may never achieve profitability.***

We are a development stage company with limited operating history. We have incurred significant operating losses since we began operations in 1996, including net losses of approximately \$39.6 million for the year ended December 31, 2004 and \$7.3 million for the three months ended March 31, 2005, and we may never become profitable. As of March 31, 2005, we had a deficit accumulated during the development stage of approximately \$133.5 million. These losses have resulted principally from costs incurred in our research and development programs and from our general and administrative expenses. 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 may increase significantly in the future if we expand our research and development, conduct additional clinical trial activities, acquire or license technologies, scale up and improve our manufacturing operations, seek regulatory approvals and, if we receive FDA approval, commercialize our products. We also may be required to recognize additional losses based upon changes in the fair value of our derivative liability, which resulted from the dividend make-whole payment feature of our convertible preferred stock. These losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity and working capital. Because of the numerous risks and uncertainties

## [Table of Contents](#)

associated with our product development efforts, we are unable to predict when we may become profitable, if at all. If we are unable to achieve and then maintain profitability, the market value of our common stock and convertible preferred stock will likely decline.

### ***Our restructuring of our business to focus on HIV indications may prove unsuccessful.***

On May 16, 2005, we announced that we intend to refocus clinical development of our lead product, Xcellerated T Cells, on treating HIV and to discontinue further development of Xcellerated T Cells in CLL or other cancer indications at this time. Our decision to focus our resources on HIV may not result in any viable commercial products. We cannot be certain that we have chosen to focus on the best programs for near-term commercial success.

### ***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 infectious diseases, such as HIV, and other medical conditions require substantial amounts of capital. To date, we have raised capital through private equity financings, an initial public offering, a public offering of convertible preferred stock, the sale of convertible promissory notes and equipment leases. Currently, we anticipate that our cash, cash equivalents and investments will be adequate to satisfy our capital needs through at least the end of the second quarter of 2006, although we are evaluating whether reductions in our workforce or other expenditures are appropriate based on our recently revised clinical development strategy. If we are unable to obtain additional funding in a timely fashion, we may never conduct required clinical trials to demonstrate safety and clinical efficacy of Xcellerated T Cells, and we may never obtain FDA approval or commercialize any of our products. We will need to raise additional capital to, among other things:

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

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

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

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



## [Table of Contents](#)

***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 HIV. On March 22, 2005, we reduced our workforce by approximately 24%, to 81 employees, as a result of our decision to limit clinical development to a planned Phase II/III clinical trial in CLL and a planned Phase I/II trial in HIV. On May 16, 2005, we announced our decision to discontinue our planned Phase II/III clinical trial in CLL at this time due primarily to delays and uncertainties regarding our ability to reach agreement with the FDA on a clinical trial protocol that would be feasible and affordable for us to pursue. We are currently evaluating whether further reductions in our workforce are appropriate given this more limited clinical development plan. If we advance or expand our clinical trials in the future, we would need to expand our workforce and we cannot be sure that we will be able to hire employees with the skills and experience desirable or necessary to support such clinical development. Our management has broad discretion to suspend, scale down or discontinue any of these programs or to initiate new programs to treat other clinical indications. Xcellerated T Cells may never prove to be safe and clinically effective to treat any indication, and the market for any indication that we pursue may never prove to be profitable even if we obtain regulatory approval. Accordingly, we cannot assure you that any program we decide to pursue will lead to regulatory approval or will prove to be profitable.

***Evaluation of our potential product candidate for treatment of HIV is at an early stage and we may not be able to successfully develop or commercialize this product candidate.***

Our Xcellerated T Cells product is at an early stage of development for treatment of HIV. Significant further research and development, financial resources and personnel will be required to develop commercially viable products and obtain regulatory approvals. To date, we have only conducted preclinical development of Xcellerated T Cells to treat patients with HIV. One of our scientific founders and third party collaborators have conducted early independently-sponsored human clinical trials in HIV patients with low T cell counts using an earlier version of our proprietary technology. We did not control these clinical trials and some of these trials used a combination of CD4 and CD8 T cells and /or inserted a gene into the T cells, in contrast to our planned clinical trial(s), which will use only CD4 T cells and which will not insert any gene into the cells. These independently-sponsored clinical trials involved very limited number of patients and were not designed to produce statistically significant results as to efficacy or to ensure the results were due to the effects of activated T cells alone. In addition, 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. We cannot assure you that our preclinical experience or the data from these independently-sponsored trials are predictive of results which may be obtained in any clinical trial conducted by us. We expect that much of our efforts and expenditures over the next few years will be devoted to developing clinical trials in HIV. We have no products that have received regulatory approval for commercial sale.

Our ability to commercialize our product candidates depends on first receiving FDA approval. Thereafter, the commercial success of these product candidates will depend upon their acceptance by physicians, patients, third party payors and other key decision-makers as therapeutic and cost-effective alternatives to currently available products. If we fail to gain approval from the FDA or to produce a commercially successful product, we may not be able to earn sufficient revenues to continue as a going concern.

***Clinical development is uncertain.***

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. We have no experience in conducting clinical trials in patients with HIV. Patients with HIV typically have lower numbers and lower quality T cells than the cancer patients treated in our prior clinical trials. We may not be able to produce a sufficient quantity of Xcellerated T Cells that meet our minimum specifications to have a therapeutic effect in HIV patients. In addition, we only have limited experience in treating patients with multiple doses of Xcellerated T Cells, which may be required to achieve optimal therapeutic effects.

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 obtain in earlier clinical trials, or the FDA may disagree with how we interpret the data from these clinical trials. The FDA may not accept the endpoints we may choose in our clinical trials, such as the therapeutic effect of an increase in a patient's T cells or length of time during which a patient does not require anti-viral drugs, as valid endpoints for a pivotal trial that is

## [Table of Contents](#)

necessary for market approval. Moreover, clinical trials may require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit. Patients participating in the trials may die before completion of the trial or suffer adverse medical effects unrelated to treatment with Xcellerated T Cells. Many patients who enroll in clinical trials, particularly for treatment of HIV, have very weakened immune systems and compromised health generally, which may reduce the effectiveness of our therapy in these patients or increase the number of patients who cannot complete the clinical trial due to death or adverse medical effects unrelated to treatment with Xcellerated T Cells. These factors could lead to delays, termination or failure of our clinical trials. We and a number of other 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.

### ***The safety of our Xcellerate Technology in HIV is uncertain and we have no data demonstrating such safety.***

Our Xcellerate Technology is based on a novel approach to treat medical conditions that result in weakened immune systems. We will need to demonstrate that Xcellerated T Cells are safe in patients with HIV. Although we have data from several clinical trials we have conducted in patients with cancer in which we observed only a few serious side effects, we have no data on the safety and efficacy of Xcellerated T Cells to treat patients with HIV from any trial conducted by us. We do not have data on possible harmful long-term effects of Xcellerated T Cells and will not have any data on long-term effects in the near future. We may not be able to provide the FDA with satisfactory data that the Xcellerated T Cells we produce for HIV patients do not increase viral load or increase resistance to anti-viral drugs. 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. For these and other reasons, the safety, effectiveness and commercializability of our Xcellerate Technology is uncertain and may never be realized.

### ***Clinical development is highly dependent on the FDA.***

We cannot be sure that the FDA will let us proceed with the proposed design of our proposed clinical trial protocol(s) for Xcellerated T Cells in patients with HIV. We have previously had difficulty securing the agreement of the FDA on a significant clinical trial proposal. After several months of discussions with the FDA regarding our planned Phase II/III clinical trial in patients with CLL, we announced on May 16, 2005 that we were withdrawing this protocol as a result of delays and uncertainty regarding our ability to reach agreement with the FDA on a protocol that would be feasible and affordable for us to conduct.

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.

To date, the FDA has approved only a few cell-based therapies for commercialization. The processes and requirements associated with the regulation of biologic products 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;

## Table of Contents

- 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.

### ***Our restructuring may place additional strain on our resources and may harm the morale and performance of our personnel.***

Our restructuring in March 2005 resulted in an approximate 24% immediate reduction in our workforce to 81 employees at facilities in Seattle and Bothell, Washington. We are currently evaluating whether further reductions in our workforce are appropriate given our recently announced more limited clinical development plan. Our restructuring plan may yield unanticipated consequences such as attrition beyond our planned reduction in workforce. This workforce reduction could place significant strain on our administrative, operational and financial resources and result in increased responsibilities for certain personnel. As a result, our ability to respond to unexpected challenges may be impaired and we may be unable to take advantage of new opportunities. In addition, many of the terminated employees possess specific knowledge or expertise, and that knowledge or expertise may prove to have been important to our operations. In that case, their absence may create significant difficulties. In addition, this headcount reduction may subject us to the risk of litigation, which could result in substantial costs to us and could divert management's time and attention away from business operations.

### ***We may be unable to maintain our listing on Nasdaq, which could cause our stock price to fall and decrease the liquidity of our stock.***

Our common stock and preferred stock trades on the Nasdaq National Market, which has certain compliance requirements for continued listing, including a requirement that our common stock and preferred stock each have a minimum bid price of \$1.00 per share. If the minimum closing bid price per share is less than \$1.00 for a period of 30 consecutive business days, our shares may be delisted following a 180 day notice period during which the minimum closing bid price must be \$1.00 or above per share for a period of 10 consecutive business days, if we do not file an appeal. While the bid price per share of our preferred stock has never fallen below Nasdaq's minimum bid price of \$1.00 per share, the bid price per share of our common stock has recently fallen below Nasdaq's minimum bid price of \$1.00 per share. The closing bid price per share of our common stock was \$0.85 as of May 13, 2005, has been below \$1.00 for the last 16 consecutive business days, and may continue to decline.

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

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

If our shares were to be delisted from trading on the Nasdaq National Market and were neither relisted thereon nor listed for trading on the Nasdaq SmallCap Market, trading, if any, in our shares may continue to be conducted on the OTC Bulletin Board or in a non-Nasdaq over-the-counter market, such as the "pink sheets." Delisting of our shares would result in limited release of the market price of those shares and limited analyst coverage and could restrict investors' interest in our securities. Also, a delisting could materially adversely affect the trading market and prices for our shares and our ability to issue additional securities or to secure additional financing. In addition, if our shares were not listed and the trading price of our shares was less than \$5 per share, our shares could be subject to Rule 15c-9 under the Securities Exchange Act of 1934 which, among other things, requires that broker/dealers satisfy special sales practice requirements, including making individualized written suitability determinations and receiving a purchaser's written consent prior to any transaction. In such case, our securities could also be deemed to be a "penny stock" under the Securities Enforcement and Penny Stock Reform Act of 1990, which would require additional disclosure in connection with trades in those shares, including the delivery of a disclosure schedule explaining the nature and risks of the penny stock market. Such requirements could severely limit the liquidity of our securities.

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

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

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

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

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

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

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

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

***Our success may depend upon the acceptance of Xcellerated T Cells by the medical and HIV-activist communities.***

Our ability to market and commercialize Xcellerated T Cells in HIV would depend in part on the acceptance and utilization of our products by the medical and HIV-activist communities. In addition, there are a significant number of therapies to treat HIV on the market and in development with which Xcellerated T Cells would likely compete if commercialized. We will need to develop commercialization initiatives designed to increase awareness about us and Xcellerated T Cells among targeted audiences, including

## [Table of Contents](#)

public health and AIDS activists and community-based outreach groups in addition to the investment community. Currently, we have not developed any commercialization initiatives.

### ***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.***

Through March 2005, we manufactured Xcellerated T Cells for research and development and our clinical activities in one manufacturing facility in Seattle, Washington. We have not demonstrated the ability to manufacture Xcellerated T Cells beyond quantities sufficient for research and development and limited clinical activities. We have no experience manufacturing Xcellerated T Cells at the capacity that will be necessary to support large clinical trials or commercial sales. We recently relocated our manufacturing activities to our leased property in Bothell, Washington. We may encounter difficulties in obtaining the approvals for validating and operating this manufacturing facility. We may not be able to hire the qualified personnel that we may later require to accommodate the expansion of our operations and manufacturing capabilities.

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. We have very limited experience manufacturing Xcellerated T Cells in patients with HIV. HIV patients typically have a lower number and quality of T cells than patients with other medical conditions such as cancer, and we cannot assure you that we can manufacture Xcellerated T Cells for HIV patients in sufficient number or quality to have a therapeutic effect. 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. For these and other reasons, we may not be able to manufacture Xcellerated T Cells on a large scale or in a cost-effective manner.

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

### ***Our clinical trials may take longer to complete than we project or they may not be completed at all.***

The timing of the commencement, continuation and completion of clinical trials may be subject to significant delays relating to various causes, including scheduling conflicts with participating clinicians and clinical institutions, and difficulties in enrolling patients who meet trial eligibility criteria. Patient enrollment is a function of many factors, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the existence of competing clinical trials and the availability of alternative or new treatments. These factors could lead to delays, termination or failure of our clinical trials.

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

### ***Clinical trials are expensive, time consuming and their outcome is uncertain.***

Before we can obtain regulatory approval for the commercial sale of any product candidate that we wish to develop, we are required to complete preclinical development and extensive clinical trials in humans to demonstrate its safety and efficacy. Each of these trials

## [Table of Contents](#)

requires the investment of substantial expense and time. We expect to commence clinical trials in HIV in the future. There are numerous factors that could delay these clinical trials or prevent us from completing these trials successfully.

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

### ***The government and other third-party payors may control the pricing and profitability of our products.***

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

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

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

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

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

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

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

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

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

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

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

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

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

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



## [Table of Contents](#)

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

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

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

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

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

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

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

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

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

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



## [Table of Contents](#)

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

***We rely on a limited number of manufacturers and suppliers for some of the key components or our Xcellerate Technology. The loss of these suppliers, or their failure to provide us with adequate quantities of these key components when needed, could delay our clinical trials and prevent or delay commercialization of Xcellerated T Cells.***

We rely on third party suppliers for some of the key components used to manufacture Xcellerated T Cells. We rely on Lonza to develop and manufacture the antibodies that we use in our Xcellerate Technology. Either party may terminate our agreements with Lonza for breach or insolvency of the other party or if Lonza is unable to perform its obligations for scientific or technical reasons. Our current agreements with Lonza provide for manufacturing development and validation, and the creation and submission of materials required to obtain regulatory approval of the antibody manufacturing process. We are using the antibodies supplied by Lonza under the agreements to manufacture the Xcellerated T Cells used in our clinical trials. We are currently negotiating an agreement with Lonza to manufacture the antibodies for commercial use. If we are unable to negotiate this contract with Lonza or are unable to procure a suitable alternative manufacturer in a timely manner and on favorable terms, if at all, we may incur significant costs and be unable to continue developing our Xcellerate Technology. We are aware of few companies with the ability to manufacture commercial-grade antibodies.

Our Xcellerate Technology also depends in part on the successful attachment of the antibodies to magnetic beads. We currently use magnetic beads developed and manufactured by Dynal in Oslo, Norway. Under the terms of the agreement with Dynal, should we not buy a minimum of \$250,000 of beads in the first 12 months after the development phase ends and \$500,000 of beads annually thereafter over the remaining term of the agreement, Dynal shall have the right to terminate the agreement. The development phase, as defined in the Dynal agreement, has not yet been completed. Either party may terminate the agreement as of August 2009 for any reason, or earlier for the material breach or insolvency of the other party. If the agreement is not terminated by August 2009, either party can elect to extend the term of the agreement for an additional 5 years. Otherwise, it will automatically renew on a year to year basis. We are contractually obligated to obtain our beads from Dynal unless Dynal is unable to fill our orders or certain other circumstances arise. If Dynal terminates our contract or if Dynal discontinues manufacturing our beads for any reason, we may be unable to find a suitable alternative manufacturer in a timely manner, or at all, which would delay our clinical trials and delay or prevent commercialization of Xcellerated T Cells.

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

In addition, we currently use a custom bioreactor to manufacture Xcellerated T Cells that is available from only one manufacturer, Wave Biotech LLC. There are a limited number of manufacturers that are capable of manufacturing custom bioreactors. If Wave

## [Table of Contents](#)

Biotech is unwilling or unable to manufacture or supply us with custom bioreactors, we may be unable to find a suitable alternative in a timely manner, or at all, which would delay our clinical trials and delay or prevent commercialization of Xcellerated T Cells. We do not have agreements with Wave Biotech which obligate them to provide us with custom bioreactors.

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

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

***If we or any of our third-party manufacturers do not maintain high standards of manufacturing, our ability to develop and commercialize Xcellerated T Cells could be delayed or curtailed.***

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

***If our principal stockholders, executive officers and directors choose to act together, they may be able to control our management and operations, acting in their best interests and not necessarily those of other stockholders.***

Our executive officers, directors and principal stockholders, and entities affiliated with them, beneficially own in the aggregate approximately 54% of our common stock, and approximately 48% of our common and convertible preferred stock taken together on an as-converted to common stock basis. This significant concentration of share ownership may adversely affect the trading price of our common stock because investors often perceive disadvantages in owning stock in companies with controlling stockholders. These stockholders, acting together, have the ability to exert substantial influence over all matters requiring approval by our stockholders, including the election and removal of directors and any proposed merger, consolidation or sale of all or substantially all of our assets. In addition, they could dictate the management of our business and affairs. This concentration of ownership could have the effect of delaying, deferring or preventing a change in control of us or impeding a merger, consolidation, takeover or other business combination that could be favorable to you. Since the convertible preferred stock has very limited voting rights prior to conversion, owners of our convertible preferred stock will have little or no ability to control matters requiring approval of our stockholders.

***Our leased facilities are at risk of damage by earthquakes, and any damage to our facilities will harm our clinical trials and development programs.***

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

***If third party carriers fail to ship patient samples and our products in a proper and timely manner, the treatment of patients could be delayed or prevented, our reputation may suffer and we may incur liability.***

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

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

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

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

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

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

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

## [Table of Contents](#)

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, Favril, Inc., Genitope Corporation, IDM, S.A., Kirin Pharmaceutical and Therion Biologics Corporation. Many of our competitors have greater financial and other resources, larger research and development staffs and more experienced capabilities in researching, developing and testing products than we do. Many of these companies also have more experience in conducting clinical trials, obtaining FDA and other regulatory approvals and manufacturing, marketing and distributing therapeutic products. Smaller companies may successfully compete with us by establishing collaborative relationships with larger pharmaceutical companies or academic institutions. In addition, large pharmaceutical companies or other companies with greater resources or experience than us may choose to forgo ex vivo cell-based immunotherapy opportunities that would have otherwise been complementary to our product development and collaboration plans. Our competitors may succeed in developing, obtaining patent protection for or commercializing their products more rapidly than us. A competing company developing, or acquiring rights to, a more effective therapeutic product for the same diseases targeted by us, or one that offers significantly lower costs of treatment, could render our products noncompetitive or obsolete.

***In the future, we will need to grow significantly if we are going to expand our research and clinical activities, and we may be unable to manage that growth or hire qualified new personnel.***

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

***If we lose key management or scientific personnel, our business could suffer.***

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

## [Table of Contents](#)

life insurance on any of our other officers, employees or consultants. The loss of the services of one or more of our key employees could delay or curtail our research and development and product development efforts.

***We may undertake acquisitions in the future, and any difficulties from integrating these acquisitions could damage our ability to attain or maintain profitability.***

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

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

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

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

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

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

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

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

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

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

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

## [Table of Contents](#)

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

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

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

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

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

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

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

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

***We will soon be required to comply with Section 404 of the Sarbanes-Oxley Act of 2002 regarding internal control attestation and any inability to do so may negatively impact the report on our financial statements.***

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



## [Table of Contents](#)

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

### ***Legislative actions, potential new accounting pronouncements and higher insurance costs are likely to impact our future financial position and results of operations.***

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

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

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

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

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

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

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

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

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

***The future sale of our common and convertible preferred stock, and future issuances of our common stock upon payment of make-whole dividends, if any, could negatively affect our stock price.***

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

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

***Anti-takeover provisions could make it more difficult for a third party to acquire us.***

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

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

An exchange of convertible preferred stock for debentures, as well as any dividend make-whole or interest make-whole payments paid in our common stock, will be taxable events for U.S. federal income tax purposes, which may result in tax liability for the holder of convertible preferred stock without any corresponding receipt of cash by the holder. In addition, the debentures may be treated as having original issue discount, a portion of which would generally be required to be included in the holder’s gross income even though



## [Table of Contents](#)

the cash to which such income is attributable would not be received until maturity or redemption of the debenture. We will not distribute any cash to you to pay these potential tax liabilities.

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

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

***We do not intend to pay cash dividends on our common stock in the foreseeable future.***

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

### **Item 3. Quantitative and Qualitative Disclosures About Market Risk**

#### ***Interest Rate Risk***

Our short-term investments as of March 31, 2005 consisted of \$20.2 million in corporate bonds, \$13.5 million in federal agency obligations, and \$1.5 million in municipal bonds with contractual maturities of one year or less. Due to the short-term nature of our investments, we believe that our exposure to market interest rate fluctuations is minimal. The corporate bonds in which we invest are rated "A" or better by both Moody's and Standard and Poor's. Our cash and cash equivalents are held primarily in commercial paper and highly liquid money market accounts. A hypothetical 10% change in short-term interest rates from those in effect at March 31, 2005 would not have a significant impact on our financial position or our expected results of operations. We do not currently hold any derivative financial instruments.

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

#### ***Foreign Currency Risk***

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

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

#### ***Derivatives Valuation Risk***

The terms of our November 2004 convertible preferred stock offering include a dividend make-whole payment feature. This feature is considered to be an embedded derivative and was valued on the balance sheet at \$3.0 million at December 31, 2004. The carrying value of this derivative was reduced by \$363,000 during the first quarter of 2005, based on cash dividends paid and the fair value of common stock issued as dividend make-whole payments pursuant to voluntary holder conversions during this period. At March 31, 2005, the estimated fair value of the derivative liability was valued at \$2.6 million, resulting in the recognition of \$8,000 as other

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[Table of Contents](#)

income for the three months ended March 31, 2005. As the fair value of this derivative may fluctuate significantly from period to period, the resulting change in valuation may have a significant impact on our results of operations.

**Item 4. Controls and Procedures**

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

**Part II. Other Information**

**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds**

- (a) *Unregistered Sales of Equity Securities.* None.
- (b) *Use of Proceeds.* Our Registration Statement under the Securities Act of 1933 (File No. 333-109635) was declared effective by the SEC on March 16, 2004. All 4,200,000 shares of common stock offered in the final prospectus were sold at a price per share of \$8.00. The aggregate gross proceeds of the shares offered and sold were \$33.6 million, which resulted in net proceeds to us of approximately \$29.7 million after deducting underwriting discounts and commissions and other offering expenses of \$3.9 million. From the effective date of our initial public offering through March 31, 2005, we have used approximately \$27.0 million of these proceeds to fund clinical trial activities, manufacturing activities, preclinical research and development activities, and capital expenditures, and for other general corporate purposes. The remainder of the net proceeds from our initial public offering are invested in a variety of interest-bearing instruments, consisting of U.S. government and agency securities, high-grade U.S. corporate bonds, municipal bonds, commercial paper and money market accounts.
- (c) *Repurchases.* None.

**Item 6. Exhibits**

<u>Exhibit Number</u>	
3.1(1)	Amended and Restated Certificate of Incorporation of Xcyte Therapies, Inc.
3.2(1)	Amended and Restated Bylaws of Xcyte Therapies, Inc.
3.3(3)	Preferred Stock Certificate of Designations
4.1(1)	Form of Common Stock Certificate
4.2(3)	Preferred Stock Certificate of Designations
4.3(4)	Indenture
4.4(2)	Form of Preferred Stock Certificate
10.1†	Supply Agreement dated March 7, 2005 between Xcyte Therapies, Inc. and Cambrex Bio Science Walkersville, Inc.
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a).
31.2	Certification of Principal Financial and Accounting Officer pursuant to Rule 13a-14(a).
32.1	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350.
32.2	Certification of Principal Financial and Accounting Officer pursuant to 18 U.S.C. Section 1350.

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

**SIGNATURES**

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

XCYTE THERAPIES, INC.

By: /s/ Kathi L. Cordova

Kathi L. Cordova

*Duly Authorized Officer of Registrant and Principal  
Financial and Accounting Officer*

*Senior Vice President of Finance and Treasurer*

Date: May 16, 2005

Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as [\*]. A complete version of this exhibit has been filed separately with the Securities and Exchange Commission.

### SUPPLY AGREEMENT

This Supply Agreement (hereinafter referred to as the “Agreement”) is entered into this 7th day of March, 2005 (the “Effective Date”), by and between Cambrex Bio Science Walkersville, Inc. (“Seller”), with offices located at 8830 Biggs Ford Rd., Walkersville, MD 21793, USA and Xcyte Therapies, Inc. (“Buyer”), with offices located at 1124 Columbia Street, Suite 130, Seattle, WA 98104.

Now, therefore, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

#### 1. Product

Seller agrees to sell and Buyer agrees to purchase the materials specified in Exhibit A (the “Materials”) under the terms and conditions of this Agreement.

#### 2. Quality and Warranties

- a. Seller shall supply the Materials in accordance with the Quality Assurance Agreement (the “QA Agreement”) signed by the parties and in accordance with the specifications contained in Exhibit B, which shall include a functional test for the Materials to be performed by both parties that may be amended and/or updated from time to time upon mutual agreement of the parties (the “Functional Testing”), and any other specifications which the parties may mutually agree to in writing (the “Material Specifications”). Seller guarantees and warrants that at the time of delivery of the Materials to the Buyer designated delivery location, Materials shall comply with the applicable Material Specifications, and any laws, regulations, or statutes then applicable to the production of Materials, such as but not limited to cGMP (current good manufacturing practice) guidelines and ISO 9001 (2000).
- b. All Materials purchased by Buyer shall, prior to shipment, be inspected, tested and approved by Seller as satisfactory and meeting all applicable Material Specifications. Seller shall provide to Buyer a certification of analysis and/or conformance with each shipment that verifies that the Material(s) meets all applicable Material Specifications. Promptly after the Effective Date, Seller shall confirm in writing with Buyer the validated lot size of the Materials, and shall not change such lot size without the prior written consent of Buyer. Seller shall promptly notify Buyer of any discrepancies or nonconformance of raw materials known to Seller to be used in the production of the Materials (including but not limited to information relating to the operation of the aseptic filling suite).

- c. Upon request from Buyer, Seller shall fully cooperate in a site audit by any representatives of Buyer to assess and ensure adequate quality assurance systems in accordance with FDA's Quality System Regulations at 21 C.F.R. Part 820 and ISO 9001 (2000) in connection with the Materials. Buyer shall provide reasonable advance notice to Seller of such audit and conduct the audit during normal business hours at mutually agreed upon times. Buyer shall limit such audits to no more than once every 12 months unless Buyer reasonably determines there are quality issues or discrepancies that warrant additional audits. If Buyer observes a condition during an audit which reasonably causes it to believe that the Materials are not being manufactured in accordance with regulations as set forth in FDA's Quality System Regulations at 21 C.F.R. Part 820, ISO 9001 (2000) or the Materials Specifications, Seller shall address the concerns and provide necessary modifications required to bring the facilities and production procedures into such compliance.
- d. Should Buyer request Seller to provide proof of production, such as the certificate of analysis, of the Materials to a regulatory authority, Seller shall reasonably cooperate and supply available information in response to such request. Buyer shall reimburse any direct and reasonable costs incurred by Seller in complying with such request.
- e. Seller shall use commercially reasonable efforts to notify Buyer in advance of any supply shortage to allow Buyer enough time to identify an alternate supplier, and, in the event that Seller is unable to supply Materials to Buyer for more than a six month period, Seller shall cooperate in good faith with Buyer and any such alternate supplier to assist Buyer in securing an alternative means of supply, provided that any such alternative supplier enters into a confidentiality agreement with Seller upon terms and conditions reasonably satisfactory to Seller. In the event Seller's primary manufacturing location becomes incapable of producing the Materials, Seller will use commercially reasonable efforts to produce the Materials in an alternative cGMP facility, with Buyer's prior written consent.
- f. THE WARRANTIES IN THIS ARTICLE ARE EXCLUSIVE AND IN LIEU OF ALL OTHER WARRANTIES WHETHER STATUTORY, EXPRESS OR IMPLIED (INCLUDING ALL WARRANTIES OF MERCHANTABILITY AND FITNESS FOR PARTICULAR PURPOSE AND ALL WARRANTIES ARISING FROM COURSE OF DEALING OR USAGE OF TRADE).

### 3. **Orders, Forecasts and Price**

#### 3.1 Purchase Orders

Buyer must submit a written purchase order(s) (the "Purchase Order(s)") to Seller for Buyer's requirements of Materials. Buyer acknowledges that Seller's typical manufacturing cycle time from the date of receipt and acceptance of a Purchase Order is [\*], meaning that from the time the Purchase Order is received and

[\*] Certain information on this page has been omitted and filed separately with the Securities & Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

accepted by Seller, it will be a minimum of [\*] before the manufacture of the quantity of Materials covered by a Purchase Order is complete. Any Purchase Order that Buyer wishes to place with Seller shall be submitted by post/regular mail, facsimile or any other mutually agreed upon manner. Seller shall send its written confirmation of receipt of each Purchase Order from Buyer within seven (7) days from the date of receipt by Seller of the Purchase Order. If Buyer claims that no such confirmation was received, and Seller is able to demonstrate from its records that one was sent, then the Purchase Order(s) shall be considered accepted. Seller's failure to notify Buyer of Seller's rejection of a Purchase Order shall constitute Seller's acceptance of such Purchase Order. Each Purchase Order submitted by Buyer must contain a proposed delivery date. If Seller is unable to meet the proposed delivery date contained in the Purchase Order, Seller will duly note such in its confirmation of receipt of the Purchase Order, and Seller and Buyer will agree on a new delivery date in writing. Each Party shall have the right to require correction of obvious calculation and typing errors in the Purchase Order(s).

### 3.2 Price

The initial price of the Materials during the term of this Agreement shall be as listed on Exhibit A. An increase of [\*] shall be permitted on January 1 of every other year during the term of this Agreement, beginning January 1, 2006. If Seller's raw material costs associated with the supply of Materials increase or decrease by more than [\*] from the cost of such raw materials as of the Effective Date (as substantiated by Seller), and such change is due to reasons beyond the control of both parties, a reasonable adjustment to account for such change (downward or upward, as applicable) will be made to the Materials price so long as such price is agreed upon by both parties in writing as being reasonable based on the change in raw materials costs.

### 3.3 Forecasts

In addition to the submission of Purchase Orders, Buyer may, in its sole discretion and on a quarterly basis, provide Seller with a [\*] rolling forecast of Buyer's Materials requirements during the forthcoming [\*] period. Should Buyer wish to submit such forecasts, Seller shall confirm each such forecast in writing within ten (10) business days after receipt by Seller. If Seller is not able to confirm the total quantity requirement as detailed in the forecast, Seller shall, within the same ten (10) day time period, confirm the quantity that it is able to confirm at that time and give Buyer an early warning notice that it may be unable to meet the rest of the quantity requirements. Seller agrees that any forecast provided by Buyer is a non-binding estimate based on Buyer's assumptions at the time of submission of such forecast. However, if the quantity requirements of a forecast, or any portion of the quantity requirements, have been confirmed by Seller, the confirmed portion of such forecast shall become binding [\*] before the forecasted delivery date for such quantity of Materials. All forecasts, whether binding or non-binding, are subject to Buyer's submission of Purchase Orders.

[\*] Certain information on this page has been omitted and filed separately with the Securities & Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

### 3.4 Cancellation of Purchase Orders

Due to the manufacturing cycle time stated in Section 3.1, any cancellation of a Purchase Order by Buyer, which is not based upon a material breach of the Seller, must be made within 2 weeks of Seller's receipt of such Purchase Order. If a Purchase Order cancellation, which is not based upon a material breach of the Seller, is received by Seller outside of this timeframe, Buyer will be liable for the total quantity of Materials covered by such Purchase Order, in accordance with the pricing contained in Section 3.2.

### 3.5 Alternate Manufacturing Facility

An affiliate of Seller has an alternate manufacturing location for the Materials at laboratories and manufacturing plant located at Verviers, Belgium. In the event Seller's primary manufacturing location at Walkersville, MD becomes incapable of manufacturing the Materials, Seller will use commercially reasonable efforts to manufacture the Materials at such Belgium facility but only with Buyer's prior written consent. The Walkersville, MD plant will continue to take responsibility for regulatory and contractual compliance of product manufactured in Belgium, unless otherwise requested by Buyer. If Buyer elects to allow Seller to manufacture the Materials at such Belgium facility, Seller acknowledges and agrees that Seller shall be responsible for the shipping and importation costs to the extent such costs are in excess of the shipping costs if such Materials had been shipped from the Walkersville, MD facility to Buyer.

## 4. Shipment, Delivery and Delivery Dates

The price stated in Section 3.2 is for delivery of Materials by truck. Delivery by any other means will increase the price stated in Section 3.2. Shipment of the Materials shall be CPT SEATTLE, WASHINGTON, USA (INCOTERMS 2000) including packing. Delivery to any other destination designated by Buyer may increase the price. The delivery date shall be the date stated in the Purchase Order in accordance with Section 3.1, or such other date as the parties may mutually agree to in writing.

## 5. Inspection and Acceptance

Buyer shall have the right to request and pre-test any samples of the Materials available prior to lot shipment by Seller to Buyer. Within [\*] after receipt of any delivery of the Materials, Buyer shall inspect and conduct Functional Testing on such delivered Materials to determine whether the Materials meet the warranties contained in Section 2. If, based on such inspection and testing, Buyer finds more than [\*] of the Materials are defective (the "Acceptable Quality Limit") in any one particular lot shipment, Buyer shall have the right to reject the entire lot shipment. If the number of defective items of Materials falls below the Acceptable Quality Limit in a particular lot shipment, Buyer shall reject only the specific items found to be defective. Any rejection by Buyer due to failure to meet the

[\*] Certain information on this page has been omitted and filed separately with the Securities & Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.



warranties contained in Section 2, including functional product specifications, must be in writing, and if such written notice is not received within such [\*] period, then Buyer is deemed to have accepted that particular shipment of Materials. If Seller disputes a Buyer's rejection in good faith under this Section 5, the dispute shall be submitted to an arbitrator in accordance with Section 14.11. If Seller does not dispute Buyer's rejection, or if the arbitrator determines in accordance with Section 14.11 that such rejection is proper, Seller will replace such rejected shipment of Materials or refund to Buyer any sums paid therefor. In addition, Seller shall be responsible for the costs of all freight and shipping of the Materials back to Seller pursuant to a valid rejection by Buyer in accordance with this Section. Seller shall not be obligated to replace any Materials hereunder if the Materials' nonconformance was caused by Buyer's misuse, neglect, or improper storage. The remedies provided in this Agreement are Buyer's exclusive remedies for any failure of Seller to comply with the warranties contained in Section 2. Such remedies shall constitute complete fulfillment of all such liabilities of Seller whether the claims of Buyer are based in contract, in tort (including negligence or strict liability), or otherwise.

**6. Invoicing and Payment**

Seller shall invoice Buyer at the time of shipment of the Materials. Buyer must pay all invoices net [\*] from the date of the invoice. All payments must be in United States Dollars and must be by wire transfer or check.

**7. Title and Risk of Loss**

Title and risk of loss shall pass to Buyer when the Materials, together with all documents as required by this Agreement or the QA Agreement to be shipped with the Materials, have been delivered to Buyer at the destination specified in accordance with Section 4.

**8. Regulatory**

8.1 To the extent that Buyer determines that applications to and approval from the FDA or other governmental authority are necessary for a product manufactured by Buyer which incorporates or uses the Materials, Seller will cooperate fully with Buyer by providing available technical information about the Materials to Buyer for incorporation in Buyer's application (in a manner designed to protect the confidentiality of any proprietary information, data or materials therein) or by permitting Buyer to cross-reference Seller's device or drug master file to the extent it makes reference to the Materials. Seller may charge Buyer a reasonable fee for annual device or drug master file reference and updates and any other assistance provided by Seller under this Section 8.1, provided that Seller give Buyer prior written notice of such fee.

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## 8.2 Non-U.S. Requirements.

To the extent that any requirements of European or other non-US authorities are different than those of the U.S. government, the parties may amend the Material Specifications to bring them into compliance therewith, and agree to negotiate in good faith any modifications to the Material Specifications occasioned by virtue of Buyer's supply of the Materials to a European or other non-US country, and any change to the price of Materials necessitated by such modifications.

## 8.3 Export Control.

Each party shall not export or re-export, either directly or indirectly, any technical data relating to the Materials, incorporating Confidential Information or any direct product of the technical data (the Materials) in contravention of any laws or regulations of the United States, including but not limited to the United States Export Administration Act of 1979 as amended, the Trading With the Enemy Act, and the regulations of the U.S. Departments of Commerce, Defense, State, Energy and Treasury pursuant thereto.

## 8.4 Notice; Critical Changes.

Seller must provide Buyer with [\*] written notice prior to making any Critical Changes directly or indirectly related to the Materials. All other material changes affecting the Materials shall require 90 days' written notice to the Buyer. A "Critical Change" shall be defined as [\*].

## 9. Indemnification and Limitation of Liability

Each party agrees to defend, indemnify and hold the other party, its employees, agents, and representatives, harmless from any and all, losses, damages, claims, liabilities, judgments, costs (including but not limited to reasonable attorneys fees), and expenses arising out of or connected with the material breach of this Agreement by such party, except where caused by the sole negligence or wilful malfeasance of the indemnified party. Seller's total liability to Buyer for any and all claims under this Agreement shall be limited to the amount paid by Buyer to Seller during the twenty four (24) months preceding the event which gave rise to such liability. **IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER OR ANY OF ITS AFFILIATES FOR ANY CONSEQUENTIAL, INCIDENTAL, INDIRECT, SPECIAL, PUNITIVE OR EXEMPLARY DAMAGES (INCLUDING, WITHOUT LIMITATION, LOST PROFITS, BUSINESS OR GOODWILL) SUFFERED OR INCURRED BY SUCH OTHER PARTY OR ITS AFFILIATES IN CONNECTION WITH THIS AGREEMENT, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.**

[\*] Certain information on this page has been omitted and filed separately with the Securities & Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

## **10. Hardship and Force Majeure**

If, during the Term of this Agreement, there should be any case of hardship for one of the parties hereto, and, taking into account the interests of both of them, it would be considered unreasonable to request the affected party's continued performance, the parties shall use their best endeavours to reach an amicable solution. If an amicable solution for both parties cannot be reached, the dispute will be submitted to an arbitrator in accordance with Section 14.11. Any and all circumstances beyond the reasonable control of the parties including, but not limited to, acts of God, war, riots, labour disputes, lock-outs, unavoidable break-downs and acts of authorities, shall release the party hereto affected by such circumstances from its respective obligations under or pursuant to this Agreement for the duration of such contingencies and to the extent of the effects resulting therefrom. If any such case occurs, the party affected shall inform the other party immediately upon the affected party becoming aware of such circumstances and the affected party shall inform the other party of the presumable duration and extent of such contingency. Moreover, the party affected shall promptly take care to settle such contingencies so that the performance of the obligations under this Agreement can be resumed as soon as possible. The parties shall endeavour to make up for all deliveries of Materials not made because of such contingencies.

## **11. Confidential Information**

10.1 During the course of and in connection with this Agreement, one party (the "Disclosing Party") may provide certain Confidential Information, as hereinafter defined, to the other party (the "Receiving Party"). "Confidential Information" shall mean any and all information, data, know-how, whether written or otherwise, technical or non-technical, as well as tangible materials, including without limitation, reagents and materials, samples, models, drawings, assay protocols or diagrams disclosed by the Disclosing Party to the Receiving Party. Receiving Party acknowledges that all Confidential Information provided to the Receiving Party will be the sole property of the Disclosing Party and shall be treated as Confidential Information.

10.2 Receiving Party agrees: (i) to only use the Confidential Information for the purposes set forth herein; (ii) to treat the Confidential Information as it would its own confidential information (but in no event less than a reasonable degree of care); and (iii) not to disclose the Confidential Information to any third-party without the prior written consent of the Disclosing Party; except as required to be disclosed pursuant to the order or requirement of a court, administrative agency, or other governmental body; provided, however, that the Receiving Party shall provide prompt notice of such court order or requirement to the Disclosing Party to enable the Disclosing Party to seek a protective order or otherwise prevent or restrict such disclosure, if applicable.

10.3 The Receiving Party shall be relieved of all obligations under this Section 10 regarding Confidential Information, which the Receiving Party can demonstrate: (i) was known to the Receiving Party prior to receipt hereunder as set forth in the written records of the Receiving Party; or (ii) at the time of disclosure to the Receiving Party was generally available to the public, or which after disclosure hereunder, becomes generally available to the public, through no fault of the Receiving Party; or (iii) is hereafter made available to the

Receiving Party for use or disclosure by the Receiving Party from any third-party having a right to do so.

10.4 This Section 10 shall survive for a period of five (5) years from any termination or expiration of this Agreement.

**12. Intellectual Property**

Buyer acknowledges that all information surrounding the Materials, including but not limited to, formulations and the processing and manufacturing of Materials is the proprietary and confidential intellectual property of Seller; provided, however, that the design of the packaging used on the Materials supplied to Buyer hereunder shall be the proprietary and confidential intellectual property of Buyer.

**13. Term**

The term of this Agreement shall begin as of the Effective Date and shall terminate ten (10) years from such date (the "Term"). Thereafter, it shall continue for renewal terms of one (1) year each under the same terms and conditions, unless terminated in writing by giving at least twelve (12) months prior written notice if Seller is the terminating party and at least six (6) months prior written notice if Buyer is the terminating party.

**14. Misc.**

14.1 Assignment

This Agreement shall be binding on and inure to the benefit of the parties hereto and their successors and assigns. This Agreement and the rights and obligations hereunder may be assigned by Seller to an affiliate of Seller and/or in connection with an assignment of all or substantially all of the assets of Seller. Buyer shall be entitled to have its rights, benefits and obligations under this Agreement assigned to companies in which it holds a direct or indirect interest of at least 50%. Buyer shall inform Seller of such an assignment immediately.

14.2 Entire Agreement

The entire contract and understanding of the parties to this Agreement concerning the subject matter hereof is contained herein. This Agreement supersedes all prior agreements, representations or understandings of the parties with respect to the subject matter hereof

14.3 Amendments

Alterations to and amendments of this Agreement, including this clause and the Exhibits hereto, shall only be valid if made in writing and signed by both parties.

#### 14.4 Use of Name

Neither party shall make use of the establishment of this Agreement or the use of the other party's name(s) or trademarks or the name(s) of any member of the other party's staff for publicity or advertising purposes, except with the prior written consent of authorized representatives of the other party.

#### 14.5 Independent Contractors

For purposes of this Agreement, neither party shall not be deemed an agent or employee of the other party, and does not have authority to bind the other party. Rather, each party shall be deemed an independent contractor.

#### 14.6 Partial Invalidity

In the event that any of the provisions of this Agreement are invalid because they are inconsistent with the applicable law, this shall in no manner affect the validity of the other provisions of this Agreement. The parties hereto shall be obliged to replace such invalid provisions by new provisions having similar economic effects.

#### 14.7 General Conditions of Sale

Seller's general conditions of sale are not applicable to this Agreement. Should there be any conflict between terms contained on Buyer's Purchase Order and this Agreement, the terms of this Agreement shall govern.

#### 14.8 Applicable Law

This Agreement shall be construed in accordance with and be subject to the substantive laws of the State of New York.

#### 14.9 No Waiver

Any failure of a party to this Agreement to require the other party to comply with any provision of this Agreement shall not be deemed a waiver of such provision or any other provision of this Agreement.

#### 14.10 Notice

Any notice required or permitted to be given hereunder shall be mailed by registered or certified mail, with return receipt requested, delivered by hand to the party to whom such notice is required or permitted to be given hereunder, or sent by facsimile with documentation of successful transmittal. If mailed, any such notice shall be deemed to have been given three (3) days after deposit in the mail/post. If delivered by hand, any such notice shall be deemed to have been given when received by the party to whom notice is given. If sent via facsimile, any such notice shall be deemed given on the day it is sent.

If to Buyer: Attention: General Counsel  
Xcyte Therapies, Inc.  
1124 Columbia Street, Ste 130  
Seattle, WA 98104  
Facsimile: 206-262-0900

If to Seller: Attention: Roel Gordijn  
Cambrex Bio Science Walkersville, Inc.  
8830 Biggs Ford Road  
Walkersville, MD 21793  
Facsimile: 301-845-2924

With a copy to: Attention: General Counsel  
Cambrex Corporation  
One Meadowlands Plaza  
East Rutherford, NJ 07030  
Facsimile: 201-804-9852

Either Party may change the address to which notice to it is to be addressed by providing notice of such change in accordance with this provision.

#### 14.11 Arbitration

A three-member arbitral tribunal in accordance with the arbitration rules of the American Arbitration Association and administered by the American Arbitration Association shall exclusively and finally settle all disputes resulting from, concerning the validity of or arising in connection with this Agreement. The unsuccessful party shall bear all the costs of the proceedings. Where no party is completely successful, the costs of the proceedings and the costs and expenses incurred by the parties for the proper conduct of the matter shall be shared proportionately. Arbitration shall take place in Baltimore, Maryland, if Buyer is the party initiating arbitration, and in Seattle, Washington, if Seller is the party initiating arbitration, and the language of the proceedings shall be English.

IN WITNESS WHEREOF, the parties have executed this Agreement by and through their duly authorized representatives as of the date first written above.

Xcyte Therapies, Inc.

Cambrex Bio Science Walkersville, Inc.

By: /s/ Ronald J. Berenson

By: /s/ N. David Eansor

Name: Ronald J. Berenson

Name: N. David Eansor

Title: President and CEO

Title: Vice President

Exhibit A

Materials

<u>Materials</u>	<u>Part Code /Number</u>	<u>Price</u>
Xcyte stimulation medium in a 10L Platinum UltraPAK bag with 10L fill. Minumum batch size [*]	08-430B	\$ [*]

[\*] Certain information on this page has been omitted and filed separately with the Securities & Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.



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Exhibit B

Materials Specifications

**EXHIBIT 31.1**  
**CERTIFICATION**

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

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

Date: May 16, 2005

/s/ Dr. Ronald J. Berenson

Dr. Ronald J. Berenson

President, Chief Executive Officer and Director (Principal  
Executive Officer)

EXHIBIT 31.2  
CERTIFICATION

I, Kathi L. Cordova, certify that:

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

Date: May 16, 2005

/s/ Kathi L. Cordova

Kathi L. Cordova

Senior Vice President of Finance and Treasurer (Principal  
Financial and Accounting Officer)

**EXHIBIT 32.1**

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

In connection with the Quarterly Report of Xcyte Therapies, Inc. (the "Company") on Form 10-Q for the quarter ended March 31, 2005, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Dr. Ronald J. Berenson, Principal Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

Signature: /s/ Dr. Ronald J. Berenson  
Dr. Ronald J. Berenson  
President, Chief Executive Officer  
and Director (Principal Executive Officer)

Dated: May 16, 2005

**EXHIBIT 32.2**

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

In connection with the Quarterly Report of Xcyte Therapies, Inc. (the "Company") on Form 10-Q for the quarter ended March 31, 2005, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Kathi L. Cordova, Principal Financial and Accounting Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

Signature: /s/ Kathi L. Cordova

Kathi L. Cordova

Senior Vice President of Finance and Treasurer  
(Principal Financial and Accounting Officer)

Dated: May 16, 2005