

---

# SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

---

## FORM 10-Q

---

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

**For the Quarterly Period Ended March 31, 2004**

**OR**

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

**Commission File Number 0-50626**

---

# XCYTE THERAPIES, INC.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

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

On May 10, 2004, the registrant had an aggregate of 14,826,573 shares of common stock issued and outstanding.

---

[Table of Contents](#)

**XCYTE THERAPIES, INC.**  
**QUARTERLY REPORT ON FORM 10-Q**  
**For the Quarter Ended March 31, 2004**

**Table of Contents**

	<b>Page</b>
<b>PART I.</b>	
<b><a href="#">FINANCIAL INFORMATION</a></b>	
Item 1. <a href="#">Financial Statements</a>	
<a href="#">Condensed Balance Sheets as of March 31, 2004 and December 31, 2003</a>	3
<a href="#">Condensed Statements of Operations for the three-month periods ended March 31, 2004 and 2003 and from inception (January 5, 1996) to March 31, 2004</a>	4
<a href="#">Condensed Statements of Cash Flows for the three-month periods ended March 31, 2004 and 2003 and from inception (January 5, 1996) to March 31, 2004</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>	25
Item 4. <a href="#">Controls and Procedures</a>	26
<b>PART II.</b>	
<b><a href="#">OTHER INFORMATION</a></b>	
Item 1. <a href="#">Legal Proceedings</a>	27
Item 2. <a href="#">Changes in Securities, Use of Proceeds and Issuer Purchases of Securities</a>	27
Item 4. <a href="#">Submission of Matters to a Vote of Security Holders</a>	28
Item 6. <a href="#">Exhibits and Reports on Form 8-K</a>	29
<b><a href="#">SIGNATURES</a></b>	29

## 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)**

	<b>March 31, 2004</b>	<b>December 31, 2003</b>
	<b>(Unaudited)</b>	<b>(Note 1)</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 30,498	\$ 2,241
Short-term investments	8,821	11,299
Prepaid expenses and other current assets	1,921	519
	<hr/>	<hr/>
Total current assets	41,240	14,059
Property and equipment, net	2,916	2,767
Deposits and other assets	857	1,672
	<hr/>	<hr/>
Total assets	<b>\$ 45,013</b>	<b>\$ 18,498</b>
<b>Liabilities and stockholders' equity (deficit)</b>		
Current liabilities:		
Accounts payable	\$ 688	\$ 954
Accrued compensation and related benefits	525	405
Other accrued liabilities	1,681	856
Deferred revenue	845	—
Convertible promissory notes	—	11,652
Current portion of equipment financings	932	845
	<hr/>	<hr/>
Total current liabilities	4,671	14,712
Equipment financings, less current portion	1,152	993
Other liabilities	574	562
Commitments and contingencies		
Redeemable convertible preferred stock, Issued and outstanding— 6,781,814 shares as of December 31, 2003; none as of March 31, 2004	—	64,604
Redeemable convertible preferred stock warrants	—	2,467
Stockholders' equity (deficit):		
Preferred stock, \$0.001 par value per share		
Authorized—42,000,000 shares as of December 31, 2003; 5,000,000 shares as of March 31, 2004	—	—
Common stock, par value \$0.001 per share		
Authorized—70,000,000 shares as of December 31, 2003; 100,000,000 shares as of March 31, 2004		
Issued and outstanding—14,799,301 and 1,546,624 shares as of March 31, 2004 and December 31, 2003, respectively	15	2
Additional paid-in capital	146,484	24,532
Deferred stock compensation	(3,002)	(2,774)
Accumulated other comprehensive loss	(2)	(5)
Deficit accumulated during the development stage	(104,879)	(86,595)
	<hr/>	<hr/>
Total stockholders' equity (deficit)	\$ 38,616	\$ (64,840)
	<hr/>	<hr/>
Total liabilities and stockholders' equity (deficit)	<b>\$ 45,013</b>	<b>\$ 18,498</b>
	<hr/>	<hr/>

See accompanying notes.

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

**CONDENSED STATEMENTS OF OPERATIONS**  
**(in thousands, except share and per share data)**  
**(Unaudited)**

	Three months ended March 31,		Period from inception (January 5, 1996) to March 31, 2004
	2004	2003	
Revenue:			
License fee	\$ —	\$ —	\$ 100
Collaborative agreement	12	13	182
Government grant	—	—	144
Total revenue	12	13	426
Operating expenses:			
Research and development	4,175	2,699	71,000
General and administrative	1,574	1,154	23,025
Total operating expenses	5,749	3,853	94,025
Loss from operations	(5,737)	(3,840)	(93,599)
Other income (expense):			
Interest income	42	64	3,514
Interest expense	(12,589)	(66)	(14,599)
Loss on sale of equipment	—	(1)	(195)
Other income (expense), net	(12,547)	(3)	(11,280)
Net loss	(18,284)	(3,843)	(104,879)
Accretion of preferred stock	(8,973)	—	(25,385)
Net loss applicable to common stockholders	\$ (27,257)	\$ (3,843)	\$ (130,264)
Basic and diluted net loss per common share	\$ (7.98)	\$ (2.60)	
Shares used in computation of basic and diluted net loss per common share	3,414,481	1,477,836	

See accompanying notes.

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

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

	Three months ended March 31,		Period from inception (January 5, 1996) to March 31, 2004
	2004	2003	
<b>Cash flows from operating activities</b>			
Net loss	\$ (18,284)	\$ (3,843)	\$ (104,879)
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	107	66	413
Non-cash stock compensation expense	608	346	8,399
Non-cash interest expense	12,524	12	13,027
Non-cash rent expense from warrant issuances	9	9	111
Depreciation and amortization	224	216	4,915
Loss on sale of property and equipment	—	1	195
Changes in assets and liabilities:			
(Increase) decrease in prepaid expenses and other current assets	(1,436)	1	(2,107)
(Increase) decrease in deposits and other assets	806	16	(475)
Increase (decrease) in accounts payable	(266)	161	688
Increase (decrease) in accrued liabilities	1,979	(500)	3,802
Net cash used in operating activities	(3,729)	(3,515)	(74,195)
<b>Cash flows from investing activities</b>			
Purchases of property and equipment	(374)	(232)	(7,291)
Proceeds from sale of property and equipment	—	—	64
Net cash acquired in acquisition	—	—	437
Purchases of investments available-for-sale	(503)	(10,480)	(63,837)
Purchases of investments held-to-maturity	—	—	(17,732)
Proceeds from sales and maturities of investments available-for-sale	2,878	12,318	67,189
Proceeds from sales and maturities of investments held-to-maturity	—	—	5,145
Net cash provided by (used in) investing activities	2,001	1,606	(16,025)
<b>Cash flows from financing activities</b>			
Net proceeds from issuances of preferred stock	—	—	75,554
Net proceeds from issuances of common stock	29,709	—	29,709
Net proceeds from issuances of convertible promissory notes	—	—	12,660
Common stock repurchased	—	—	(3)
Proceeds from stock options and warrants exercised	42	—	564
Proceeds from equipment financings	484	136	6,536
Principal payments on equipment financings	(250)	(216)	(4,302)
Net cash provided by (used in) financing activities	29,985	(80)	120,718
Net increase (decrease) in cash and cash equivalents	28,257	(1,989)	30,498
Cash and cash equivalents at beginning of period	2,241	3,728	—
Cash and cash equivalents at end of period	\$ 30,498	\$ 1,739	\$ 30,498

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 cancer, infectious diseases and other medical conditions associated with compromised immune systems. As a development stage enterprise, substantially all efforts of the Company have been devoted to performing research and experimentation, conducting clinical trials, developing and acquiring intellectual properties, raising capital and recruiting and training personnel.

***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 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 contained in the Prospectus filed by the Company pursuant to Rule 424(b) under the Securities Act of 1933, as amended, relating to the Registration Statement on Form S-1, as amended (File No. 333-109653), with the Securities and Exchange Commission on March 17, 2004. The consolidated condensed balance sheet at December 31, 2003 has been derived from the audited financial statements at that date.

On March 4, 2004 the Company completed a 2 for 11 reverse stock split of the outstanding common and preferred stock and stock options and warrants, which was declared by the Company's Board of Directors on February 11, 2004. All share and per share amounts have been retroactively restated in the accompanying financial statements and notes for all periods presented to reflect the reverse stock split.

***Revenue recognition***

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

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

Other comprehensive income (loss) includes certain 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 totaled \$18,281 and \$3,847 for the three months ended March 31, 2004 and 2003, respectively.

## [Table of Contents](#)

### **Segments**

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

### **Stock-based compensation**

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

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

The fair value of these options was estimated at the date of grant using the Black-Scholes option-pricing model with the following weighted average assumptions for the three months ended March 31, 2004 and 2003: risk-free interest rate of 5.0%; a dividend yield of 0%; expected volatility of 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, 2004 and 2003 was \$12.46 and \$4.56 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,	
	2004	2003
Net loss applicable to common stockholders, as reported	\$(27,257)	\$(3,843)
Add: Employee stock-based compensation, as reported	583	313
Deduct: Stock-based compensation determined under the fair value method	(701)	(421)
Pro forma net loss	\$(27,375)	\$(3,951)
Basic and diluted pro forma net loss per share	\$ (8.02)	\$ (2.67)

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.

### **2. Initial Public Offering**

On March 19, 2004, the Company completed an initial public offering which, after deducting underwriting discounts and estimated 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 cash and cashless exercises, resulting in the issuance of 896,235 shares of common stock. In addition, the Company filed an Amended and Restated Certificate of Incorporation to amend the number of authorized shares of common stock to 100,000,000 and 5,000,000 shares of authorized preferred stock.

### **3. Significant agreements**

#### ***Manufacturing and supply contracts***

The Company entered into a development and supply agreement with Dynal S.A. during the year ended December 31, 1999. The Company has agreed to make nonrefundable payments totaling \$3.0 million for certain development activities conducted by Dynal S.A. As of March 31, 2004, the Company had made payments totaling \$2.5 million under the agreement, which were charged to research and development expense. The remaining payment of \$500,000 was accrued at March 31, 2004 and paid in April 2004. Under the terms of the supply agreement, should the Company not buy a minimum \$250,000 of beads in the first 12 months after the development phase ends and \$500,000 of beads annually thereafter over the remaining term of the agreement, Dynal shall have the right to terminate the agreement. Either party may terminate the agreement as of August 2009 for any reason, or earlier on account of the material breach or insolvency of the other party. If the agreement is not terminated by August 2009, either party can elect to extend the terms of the agreement for an additional five years. Otherwise, it will automatically renew on a year to year basis.

#### ***Corporate collaborations***

In November 2003, the Company licensed to Fresenius Biotechnology GmbH, a wholly-owned subsidiary of Fresenius AG, the Company's Xcellerate Technology on an exclusive basis in the field of HIV retroviral gene therapy, for development and commercialization in Europe with an option under certain circumstances to expand their rights to North America. The agreement with Fresenius requires the Company to transfer its Xcellerate Technology, including manufacturing capability, to Fresenius and supply all antibody-coated beads required by Fresenius to support its development and commercialization efforts. Fresenius had previously agreed to reimburse the Company for its expenses in transferring the technology and to pay the Company for the antibody-coated beads on a cost-plus basis. As of March 31, 2004, the Company had recognized \$182,000 as revenue related to the reimbursement of its actual costs. The terms of the agreement include potential royalties on net sales as well as up to 5.4 million Euros in potential milestone payments to the Company less applicable sublicense fees payable by Xcyte to third parties for each product developed. Fresenius' obligation to pay the Company royalties under this agreement terminates on a country by country basis upon the later of the last to expire of the licensed patents or fifteen years after the first commercial sale of a product in the country. The agreement is also subject to earlier termination by Fresenius at any time if Fresenius determines it cannot develop a commercially viable product or complete a required manufacturing audit; by Xcyte if Fresenius does not meet development milestones; and by either party for the material breach or insolvency of the other party.

### **4. Redeemable convertible preferred stock**

#### ***Accretion of preferred stock***

In connection with the conversion of the Company's Series E and Series F redeemable preferred stock into common stock upon the closing of the initial public offering, 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.

### **5. Convertible promissory notes**

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

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

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



## 6. Commitments and contingencies

### *Legal proceedings*

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

On May 7, 2001, the Company filed a motion seeking to dismiss the conspiracy claims, the only counts in the second amended complaint in which Xcyte Therapies was named as a defendant. On June 29, 2001, the court granted the motion to dismiss. On July 27, 2001, the plaintiff filed a fourth amended complaint, which again named the Company as a defendant and attempted to allege that Xcyte Therapies and our co-defendants unlawfully conspired against Mr. Lenahan. On August 31, 2001, the Company filed a motion to dismiss the conspiracy claims against Xcyte Therapies. On February 25, 2002, the court granted the motion to dismiss. However, the court granted the plaintiff one final chance to file an amended complaint. On March 26, 2002, the plaintiff filed a fifth amended complaint, which alleged similar claims as the fourth amended complaint. The Company filed a motion to dismiss the conspiracy claims, and, on July 22, 2002, the court granted the Company's motion to dismiss the plaintiff's fifth amended complaint with prejudice. On August 20, 2002, the plaintiff filed a notice of appeal in the Appellate Court of Illinois, First Judicial District, from the circuit court's order granting the Company's motion to dismiss. On April 7, 2003, the Company filed its response brief, and, on April 21, 2003, the plaintiff filed a reply brief. The Court heard oral arguments on March 16, 2004. On March 31, 2004, The Appellate Court affirmed the dismissal of the conspiracy claims against Xcyte Therapies. The Appellate Court also reinstated other claims against the other defendants. The plaintiff filed a petition for rehearing in the Appellate Court on April 21, 2004, and, to the Company's knowledge, the petition remains pending.

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

## **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 Form S-1 and the other Quarterly Reports on Form 10-Q to be filed by us in fiscal 2004. When used in this report, the words "expects," "could," "would," "may," "anticipates," "intends," "plans," "believes," "seeks," "targets," "estimates," "looks for," "looks to," and similar expressions, as well as statements regarding our focus for the future, are generally intended to identify forward-looking statements. You should not place undue reliance on these forward-looking statements, which speak only as of the date of this 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 cancer, infectious diseases and other medical conditions associated with weakened immune systems. We derive our therapeutic products from a patient's own T cells, which are cells of the immune system that orchestrate immune responses and can detect and eliminate cancer cells and infected cells in the body. We use our patented and proprietary Xcellerate Technology to generate activated T cells, which we call Xcellerated T Cells, from blood that is collected from the patient. Activated T cells are T cells that have been stimulated to carry out immune functions. Our Xcellerate Technology is designed to rapidly activate and expand the patient's T cells outside of the body in a process that employs magnetic beads densely covered with two monoclonal antibodies. 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, 2004, our deficit accumulated during the development stage was \$104.9 million. Our operating expenses consist of research and development expenses and general and administrative expenses.

We have recognized revenues from inception through March 31, 2004 of approximately \$426,000 from sublicense fees, payments under a collaborative agreement and income from a National Institutes of Health Phase I Small Business Innovation Research, or SBIR, grant in chronic lymphocytic leukemia. We currently do not market any products and will not for several years, if at all. Accordingly, we do not expect to have any product sales or royalty revenue for a number of years. Our net losses are primarily a result of research and development and general and administrative expenses incurred to support our operations. We anticipate incurring net losses over at least the next several years as we complete our clinical trials, apply for regulatory approvals, continue development of our technology and expand our operations.

### **Research and Development**

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

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

## [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, 2004, we incurred research and development expenses of approximately \$71.0 million, substantially all of which relate to the research and development of this technology. Currently, we are focusing our efforts on advancing our product through clinical trials. Because of the risks and uncertainties inherent in the clinical trials and regulatory process, we are unable to estimate with any certainty the length of time or expenses to continue development of Xcellerated T Cells for commercialization. However, we expect our research and development expenses to increase as we continue to improve our proprietary Xcellerate Technology and develop Xcellerated T Cells for additional clinical indications.

### ***General and Administrative Expenses***

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

### ***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 Small Business Innovation Research (SBIR) grant awarded to the Company by the National Institutes of Health. Revenue associated with up-front license fees and research and development funding payments are recognized ratably over the relevant periods specified in the agreement, generally the research and development period. Revenue under research and development cost-reimbursement agreements is recognized as the related costs are incurred. Revenue related to grant agreements is recognized as related research and development expenses are incurred.

### **Results of Operations**

#### ***Three Months Ended March 31, 2004 and 2003***

##### ***Revenue***

Revenue was approximately \$12,000 and \$13,000 for the three months ended March 31, 2004 and 2003, respectively. This revenue consisted of funds received as reimbursement of our actual costs under a collaboration agreement.

##### ***Research and Development***

Research and development expenses represented approximately 73% and 70% of our operating expenses for the three months ended March 31, 2004 and 2003, respectively. Research and development expenses increased 55%, from \$2.7 million for the three months ended March 31, 2003 to \$4.2 million for the three months ended March 31, 2004. The increase was primarily the result of contractual payments relating to developing our bead technology, in addition to increases in clinical trial costs, laboratory supplies, salary and other personnel-related expenses and non-cash stock compensation expense. Expenses associated with developing our bead technology totaled \$500,000 for the three months ended March 31, 2004, with no such costs incurred for the three months ended March 31, 2003. Clinical trial and laboratory supplies costs have increased as we continue to advance and expand our clinical testing. As of March 31, 2004 we had 61 employees in research and development and manufacturing operations compared to 46 employees in research and development and manufacturing operations as of March 31, 2003. In addition, our non-cash stock compensation expense increased from \$178,000 for the three months ended March 31, 2003 to \$313,000 for the three months ended March 31, 2004. We anticipate that research and development expenses will continue to grow in the foreseeable future as we expand our research, development and clinical trial activities.

##### ***General and Administrative***

General and administrative expenses represented approximately 27% and 30% of our operating expenses for the three months ended March 31, 2004 and 2003, respectively. General and administrative expenses increased 36%, from \$1.2 million for the three months ended March 31, 2003 to \$1.6 million for the three months ended March 31, 2004. The rise was due primarily to increases in professional fees, salary and other personnel-related expenses and non-cash stock compensation expense. Non-cash stock compensation expense increased from \$166,000 for the three months ended March 31, 2003 to \$295,000 for the three months ended March 31, 2004. We anticipate that general and administrative expenses will increase in the foreseeable future as we support our growth and incur the costs related to being a public company.

##### ***Other Income (Expense)***

Other expense, comprised primarily of interest expense and interest income, totaled \$3,000 for the three months ended March 31, 2003, compared to \$12.5 million for the three months ended March 31, 2004. Interest income decreased 34%, from \$64,000 for the three months ended March 31, 2003 to \$42,000 for the three months ended March 31, 2004, due to decreased average cash and investment balances upon which interest is earned and declining interest rates. Interest expense increased from \$66,000 for the three months

## [Table of Contents](#)

ended March 31, 2003 to \$12.6 million for the three months ended March 31, 2004, due to interest expense associated with the convertible promissory notes issued in October 2003. Upon consummation of our initial public offering and conversion of the notes to common stock, we recognized \$11.3 million in interest expense, which represented the beneficial conversion feature of the notes. We also recognized an additional \$1.1 million in interest expense associated with the discount on the notes, representing the value of the proceeds allocated to the warrants received by the note holders.

### *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, 2003. This accretion represented the remaining discount associated with our Series E and F preferred stock, which was recognized when the preferred stock was converted into common stock upon the closing of our initial public offering.

### **Liquidity and Capital Resources**

As of March 31, 2004, we had cash, cash equivalents and short-term investments of \$39.3 million, with cash equivalents being held primarily in highly liquid commercial paper and money market accounts. Cash, cash equivalents and short-term investments were \$13.5 million as of December 31, 2003.

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

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

Based on the current status of our product development and collaboration plans, we believe that the net proceeds of our initial public offering, together with our cash, cash equivalents and investments, will be adequate to satisfy our capital needs through at least the end of the second quarter of 2005. However, we may need additional financing prior to that time to, among other things, support our product development for Phase II or Phase III clinical trials. Furthermore, we expect to require additional funding before we are able to generate revenue, if at all, from our potential products. Additional financing may not be available on favorable terms, if at all. If we are unable to raise additional funds when we need them, we may have to delay, reduce or eliminate some or all of our development programs or our clinical trials. We also may have to license technologies to others that we would prefer to develop internally.

We have financed our operations since inception through private and public placements of equity securities, grant revenue, fees from a sublicense agreement, payments under a collaborative agreement, equipment financings and interest income earned on cash, cash equivalents and investments. From inception through March 31, 2004, we have raised net proceeds of \$75.6 million from private equity financings, \$29.7 million from our initial public offering and \$12.7 million from the sale of convertible promissory notes. Since our inception to March 31, 2004, we have received \$426,000 in revenue, \$6.5 million in equipment financings and \$3.5 million in interest income.

Since our inception, investing activities, other than purchases and maturities of investments, have consisted primarily of purchases of property and equipment. As of March 31, 2004, our investment in property and equipment was \$6.3 million. We anticipate our capital expenditures will increase in the future as we construct and renovate our planned manufacturing plant and expand our current facilities.

Net cash used in operating activities was \$3.7 million and \$3.5 million for the three months ended March 31, 2004 and 2003, respectively. Expenditures in these periods were generally a result of research and development expenses and general and administrative expenses in support of our 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."

## [Table of Contents](#)

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 \$18.5 million for the year ended December 31, 2003 and \$18.3 million for the three months ended March 31, 2004, and we may never become profitable. As of March 31, 2004, we had a deficit accumulated during the development stage of approximately \$104.9 million. These losses have resulted principally from costs incurred in our research and development programs and from our general and administrative expenses. We also expect to incur significant costs to renovate our leased facility for the manufacture of Xcellerated T Cells for our planned clinical trials and, if we receive FDA approval, for initial commercialization activities. To date, we have derived no revenues from product sales or royalties. We do not expect to have any significant product sales or royalty revenue for a number of years. Our operating losses have been increasing during the past several years and will continue to increase significantly in the next several years as we expand our research and development, participate in clinical trial activities, acquire or license technologies, scale up and improve our manufacturing operations, seek regulatory approvals and, if we receive FDA approval, commercialize our products. These losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity and working capital. Because of the numerous risks and uncertainties associated with our product development efforts, we are unable to predict when we may become profitable, if at all. If we are unable to achieve and then maintain profitability, the market value of our common stock will likely decline.

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

Developing products and conducting clinical trials for the treatment of cancer and infectious diseases require substantial amounts of capital. To date, we have raised capital through private equity financings, an initial public offering, sale of convertible promissory notes and equipment leases. Currently, we anticipate that our cash, cash equivalents and investments will be adequate to satisfy our capital needs through at least the end of the second quarter of 2005. If we are unable to timely obtain additional funding, we may never conduct required clinical trials to demonstrate safety and clinical efficacy of Xcellerated T Cells, and we may never obtain FDA approval or commercialize any of our products. We will need to raise additional capital to, among other things:

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

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

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

If we raise additional funds by issuing equity securities, further dilution to stockholders may result and new investors could have rights superior to 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.

***We may decide to pursue development programs for Xcellerated T Cells that may never receive regulatory approval or prove to be profitable.***

Because we have limited resources and access to capital to fund our operations, our management must make significant prioritization decisions on which programs to pursue and how much of our resources to allocate to each program. We are currently focusing our research and development efforts on the use of Xcellerated T Cells to treat CLL, multiple myeloma, non-Hodgkin's lymphoma, kidney cancer, prostate cancer and HIV. Our management has broad discretion to suspend, scale down or discontinue any of these programs or to initiate new programs to treat other clinical indications. Xcellerated T Cells may never prove to be safe and clinically effective to treat any of these indications, and the market for these indications may never prove to be profitable even if we obtain regulatory approval for these indications. Accordingly, we cannot assure you that the programs we decide to pursue will lead to regulatory approval or will prove to be profitable.

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

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

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

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

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

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

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

Our Xcellerate Technology is based on a novel approach to treat cancer and infectious diseases and is in an early stage of development. Our clinical trials and independent clinical trials using an earlier version of our technology, to date, have involved small numbers of patients, which, unless otherwise stated, were not designed to produce statistically significant results as to efficacy. In addition, these trials have not been randomized and double-blinded to ensure the results are due to the effect of Xcellerate Technology. Some of the data regarding our Xcellerate Technology were derived from independent clinical trials, including physician-sponsored trials, which we do not control. In addition, data from these independent clinical trials were derived using T cells activated with an earlier version of our proprietary technology. Success in early clinical trials does not ensure that large-scale trials will be successful nor does it predict final results. Acceptable results in early trials may not be repeated in later trials. In addition, we may not be able to

## [Table of Contents](#)

treat patients if we cannot collect a sufficient quantity of T cells that meet our minimum specifications to enable us to produce Xcellerated T Cells. Also, some patients may be unable to tolerate the required procedures for blood collection and administration of Xcellerated T Cells.

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

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

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

Conducting clinical trials is uncertain and expensive and often takes many years to complete. The results from preclinical testing and early clinical trials are often not predictive of results obtained in later clinical trials. In conducting clinical trials, we may fail to establish the effectiveness of Xcellerated T Cells for the targeted indication or we may discover unforeseen side effects. Moreover, clinical trials may require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit. Clinical trials are also often subject to unanticipated delays. In addition, we are currently developing a custom bioreactor system in our manufacturing process, and we will not be able to obtain FDA approval to commercialize Xcellerated T Cells without the FDA's acceptance of our manufacturing process using this bioreactor system. Also, patients participating in the trials may die before completion of the trial or suffer adverse medical effects unrelated to treatment with Xcellerated T Cells. This could delay or lead to termination of our clinical trials. A number of companies in the biotechnology industry have suffered significant setbacks in every stage of clinical trials, even in advanced clinical trials after positive results in earlier trials.

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

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

## [Table of Contents](#)

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

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

We currently manufacture Xcellerated T Cells for research and development and our clinical activities in one manufacturing facility in Seattle, Washington. We have not demonstrated the ability to manufacture Xcellerated T Cells beyond quantities sufficient for research and development and limited clinical activities. We have no experience manufacturing Xcellerated T Cells at the capacity that will be necessary to support large clinical trials or commercial sales. We plan to relocate our manufacturing activities to our leased property in Bothell, Washington, which we plan to renovate for the manufacture of Xcellerated T Cells for our planned clinical trials and, if we receive FDA approval, initial commercialization. However, we may encounter difficulties in obtaining the approvals for, and designing, constructing, validating and operating, any new manufacturing facility. We may also be unable to hire the qualified personnel that we will require to accommodate the expansion of our operations and manufacturing capabilities. If we relocate our manufacturing activities to a new facility during or after a pivotal clinical trial, we may be unable to obtain regulatory approval unless and until we demonstrate to the FDA similarity of the Xcellerated T Cells manufactured in the new facility to the Xcellerated T Cells manufactured in the prior facility. If we cannot adequately demonstrate similarity to the FDA, we could be required to repeat clinical trials which would be expensive and substantially delay regulatory approval.

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

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

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

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

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



## [Table of Contents](#)

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

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

## [Table of Contents](#)

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

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

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

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

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

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

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

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

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

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

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

## [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 media that we use to grow and freeze cells as part of our Xcellerate Technology. These media contain substances that have proved harmful if used in certain quantities. While we believe that we use sufficiently small quantities of these substances, harmful effects may still arise from our use of these media. As we continue to develop our Xcellerate Technology, we may encounter harmful side effects that we did not previously observe in our prior studies and clinical trials.

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

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

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

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

Our manufacturing process currently uses a commercially available tissue culture media that is available from only one manufacturer, Cambrex Bio Science Walkersville, Inc. If Cambrex is unwilling or unable to supply us with this media, we would need to use an alternative tissue culture media, which may delay our clinical trials and harm our business. We do not have agreements with Cambrex which obligate them to provide us with any products for future clinical trials or future commercial sales.

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

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

## [Table of Contents](#)

***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.

***Upon the expiration of a 180 day lock-up, a substantial number of our shares of common stock will become available for sale in the public market that may cause the market price of our stock to decline.***

On September 13, 2004, which is 180 days after the date of our initial public offering, approximately 9.2 million shares held by existing stockholders will become available for sale. If these stockholders sell substantial amounts of our common stock (including shares issued upon the exercise of outstanding options and warrants) in the public market at concentrated times, the market price of our common stock could fall. These sales also might make it more difficult for us to sell equity or equity-related securities in the future at a time and price acceptable to us.

***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.***

Based on the ownership of our common stock immediately prior to our initial public offering, our executive officers, directors and principal stockholders, and entities affiliated with them, beneficially owned in the aggregate approximately 42.6% of our common stock immediately following the offering. This significant concentration of share ownership may adversely affect the trading price of our common stock because investors often perceive disadvantages in owning stock in companies with controlling stockholders. These stockholders, acting together, 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 or impeding a merger or consolidation, takeover or other business combination that could be favorable to you.

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

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

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

We depend on third party carriers to deliver patient-specific blood cells to us and to deliver Xcellerated T Cells back to patients in a careful and timely manner. Our Xcellerate Technology currently requires that we process each patient's leukapheresis blood sample within 48 hours of collection. Xcellerated T Cells must currently be shipped in a frozen storage shipping container and received by the patient within six days from leaving our manufacturing facility. If the shipping containers fail to maintain the necessary temperature, Xcellerated T Cells could be damaged. If third party carriers fail to timely deliver the leukapheresis blood sample to us or fail to timely ship Xcellerated T Cells to the clinic, or if they damage or contaminate them during shipment, the treatment of patients could be delayed or discontinued, our reputation may suffer and we may incur liability.

## [Table of Contents](#)

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

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

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

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

Even if our Xcellerate Technology proves successful, we might not be able to remain competitive because of the rapid pace of technological development in the biotechnology field.

We are currently aware of several companies developing *ex vivo* cell-based immunotherapy products as a method of treating cancer and infectious diseases. These competitors include Antigenics, Inc., CancerVax Corporation, Cell Genesys, Inc., CellExSys, Inc., Dendreon Corporation, Favville, Inc., Genitope Corporation, IDM, S.A., Kirin Pharmaceutical and Valeocyte Therapies. Some of our competitors have greater financial and other resources, larger research and development staffs and more experienced capabilities in

## [Table of Contents](#)

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

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

We will need to add a significant number of new personnel and expand our capabilities in order to successfully pursue our research, development and commercialization efforts and secure collaborations to market and distribute our products. This growth may strain our existing managerial, operational, financial and other resources. We also intend to add personnel in our research and development and manufacturing departments as we expand our clinical trial and research capabilities. Our failure to manage our growth effectively could delay or curtail our product development and commercialization efforts and harm our business.

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

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

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

We may acquire additional businesses, products or product candidates that complement or augment our existing business. 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.***

Under our agreements with Lonza to purchase antibodies, we must make payments denominated in British pounds. As a result, from time to time, we are exposed to currency exchange risks. We do not engage in currency hedging. Accordingly, if the British pound strengthens against the US dollar, our payments to Lonza will increase in US dollar terms. We have paid a total of \$4.9 million to Lonza under our agreements with them as of March 31, 2004. At March 31, 2004, we had no outstanding obligations or future contractual commitments to Lonza. However, if our future purchases from Lonza require payments in British pounds, we will continue to be exposed to currency exchange risks.

The terms of our license agreement with Fresenius include potential royalties on net sales as well as up to 5.4 million Euros in potential milestone payments to us. As a result, we are exposed to currency exchange risks. We do not engage in currency hedging, and, if the Euro weakens against the US dollar, payments received from Fresenius will decrease in US 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 US Patent and Trademark Office to determine priority of invention. If third parties file oppositions in foreign countries, we may also have to participate in opposition proceedings in foreign tribunals to defend the patentability of the filed foreign patent applications. We may have to participate in interference proceedings involving our issued patents or our pending applications.

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

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

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

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

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

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

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

## [Table of Contents](#)

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

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

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

- results of our clinical trials;
- announcements of technological innovations or new products or services by us or our competitors;
- media reports and publications about immunotherapy;
- announcements concerning our competitors or the biotechnology industry in general;
- new regulatory pronouncements and changes in regulatory guidelines;
- general and industry-specific economic conditions;
- additions to or departures of our key personnel;
- changes in financial estimates or recommendations by securities analysts;
- variations in our quarterly results;
- the relatively small number of shares of our capital stock that are actively traded on the Nasdaq National Market;
- announcements about our collaborators or licensors; and
- changes in accounting principles.

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

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

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

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

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



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

If our common stockholders sell substantial amounts of common stock in the public market, or the market perceives that such sales may occur, the market price of our common stock could fall. After our offering, the holders of approximately 9.1 million shares of our common stock or warrants to purchase shares of our common stock had rights, subject to certain 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 5,000,000 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.

***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, 2004 consisted of \$7.5 million in corporate bonds and \$1.3 million in municipal bonds with contractual maturities of one year or less. Due to the short-term nature of our investments, we believe that our exposure to market interest rate fluctuations is minimal. The corporate bonds in which we invest are rated "A" or better by both Moody's and Standard and Poor's. Our cash and cash equivalents are held primarily in highly liquid commercial paper and money market accounts. A hypothetical 10% change in short-term interest rates from those in effect at March 31, 2004 would not have a significant impact on our financial position or on our expected results of operations. We do not currently hold any derivative financial instruments.

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

***Foreign Currency Risk***

For antibody development and supply services provided by Lonza, we must make payments denominated in British pounds. As a result, from time to time, we are exposed to currency exchange risks. We do not engage in currency hedging, and, if the British pound strengthens against the US dollar, our payments to Lonza will increase in US dollar terms. We have paid a total of \$4.9 million to Lonza under our agreements with them as of March 31, 2004. At March 31, 2004, we had no outstanding obligations or future contractual commitments to Lonza. However, we may elect to purchase additional antibodies from Lonza, in which case we would have to make payments in British pounds, exposing us to currency exchange risks in the future.

The terms of our license agreement with Fresenius include the receipt of potential royalties on net sales as well as up to 5.4 million Euros in potential milestone payments to us. As a result, we are exposed to currency exchange risks. We do not engage in currency

---

[Table of Contents](#)

hedging, and, if the Euro weakens against the US dollar, payments received from Fresenius will decrease in US dollar terms. A hypothetical 10% change in the Euro from the rate in effect at March 31, 2004 would not have a significant impact on our financial position or our expected results of operations.

**Item 4. Controls and Procedures**

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

## Part II. Other Information

### Item 1. Legal Proceedings

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

On May 7, 2001, we filed a motion seeking to dismiss the conspiracy claims, the only counts in the second amended complaint in which we were named as a defendant. On June 29, 2001, the court granted the motion to dismiss. On July 27, 2001, the plaintiff filed a fourth amended complaint, which again named us as a defendant and attempted to allege that we and our co-defendants unlawfully conspired against Mr. Lenahan. On August 31, 2001, we filed a motion to dismiss the conspiracy claims against us. On February 25, 2002, the court granted the motion to dismiss. However, the court granted the plaintiff one final chance to file an amended complaint. On March 26, 2002, the plaintiff filed a fifth amended complaint, which alleged similar claims as the fourth amended complaint. We filed a motion to dismiss the conspiracy claims, and, on July 22, 2002, the court granted our motion to dismiss the plaintiff's fifth amended complaint with prejudice. On August 20, 2002, the plaintiff filed a notice of appeal in the Appellate Court of Illinois, First Judicial District, from the circuit court's order granting our motion to dismiss. On April 7, 2003, we filed our response brief, and, on April 21, 2003, the plaintiff filed a reply brief. The Court heard oral arguments on March 16, 2004. On March 31, 2004, The Appellate Court affirmed the dismissal of the conspiracy claims against us. The Appellate Court also reinstated other claims against the other defendants. The plaintiff filed a petition for rehearing in the Appellate Court on April 21, 2004 and, to our knowledge, the petition remains pending.

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

### Item 2. Changes in Securities, Use of Proceeds and Issuer Purchases of Equity Securities

#### (c) Recent Sales of Unregistered Securities

In the quarter ended March 31, 2004, we issued 17,271 shares of unregistered common stock to consultants pursuant to the exercise of stock options under our 1996 Stock Option Plan. These options were exercised at a weighted average exercise price of \$1.77 per share. The issuance of these securities was deemed to be exempt from registration under the Securities Act in reliance on Rule 701 and Section 4(2) of the Securities Act.

#### (d) Use of Proceeds from Sale of Registered Securities

On March 19, 2004, we completed an initial public offering of our common stock pursuant to a registration statement on Form S-1 (File No. 333-109653) that was declared effective by the SEC on March 16, 2004. 4,200,000 shares of common stock offered in the final prospectus were sold at a price per share of \$8.00. The managing underwriters of our offering were Piper Jaffray & Co., RBC Capital Markets Corporation, Wells Fargo Securities, LLC and JMP Securities, LLC. The aggregate gross proceeds of the shares offered and sold were \$33.6 million. In connection with the offering, we paid an aggregate of \$2.35 million in underwriting discounts and commissions to the underwriters. In addition, the following table sets forth the other material expenses incurred in connection with the offering:

	<u>Amount</u>
Legal fees and expenses	677,933
Accounting fees and expenses	500,000
Printing and engraving expenses	211,079
Nasdaq National Market listing fee	100,000
Blue sky qualification fees and expenses	8,875
NASD filing fee	8,000
Transfer agent and registrar fees	3,500
Miscellaneous fees and expenses	30,219
	<hr/>
Total	\$1,539,606

## [Table of Contents](#)

After deducting the underwriting discounts and commissions and the offering expenses described above, we received net proceeds from our initial public offering of approximately \$29.7 million.

As of March 31, 2004, the proceeds were held in cash, cash equivalents and short-term marketable securities. We expect to use the net proceeds of our initial public offering for working capital and general corporate purposes, including:

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

Although we have identified some types of uses above, we have and reserve broad discretion to use the proceeds from our initial public offering differently. When and if the opportunity arises, we may use a portion of the proceeds to acquire or invest in complementary businesses, products or technologies. Pending any ultimate use of any portion of the proceeds from our initial public offering, we intend to invest the proceeds in short-term, investment-grade and interest-bearing instruments.

None of the net offering proceeds were paid, directly or indirectly, to: (i) directors or officers (other than as employee salary payments made in the ordinary course of business) of Xcyte Therapies, or their associates; (ii) persons owning ten percent or more of any class of equity securities of Xcyte Therapies; or (iii) affiliates of Xcyte Therapies.

Upon the closing of the initial public offering in March 2004, all outstanding shares of our preferred stock were automatically converted, on a one-for-one basis, into shares of common stock.

#### **Item 4. Submission of Matters to a Vote of Security Holders**

Effective March 1, 2004, the stockholders of Xcyte Therapies, Inc. approved the following items in an action by written consent:

- In connection with the closing of the Public Offering, an amendment and restatement of the Certificate of Incorporation to delete all references to the prior series of Preferred Stock, authorize undesignated Preferred Stock consisting of 5,000,000 shares, effect a reverse stock split, amend the automatic conversion provision, exclude Public Offering shares from anti-dilution protection and provide for certain other matters;
- Amendment and restatement of the Bylaws to, among other things, eliminate the ability of stockholders to take action by written consent;
- Amendment and restatement of the 1996 Stock Option Plan;
- Adoption of the 2003 Directors' Stock Option Plan;
- Adoption of the 2003 Stock Plan;
- Adoption of the 2003 Employee Stock Purchase Plan;
- Waiver of registration rights; and
- Amendment of certain warrants to allow for termination upon the Public Offering.

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

## Table of Contents

annual meeting of stockholders. Dr. Peter Langecker and Dr. Robert Williams will be in the class of directors whose initial term expires at the 2007 annual meeting of stockholders. Effective April 7, 2004, Dr. Robert Curry resigned from our board of directors. The nominating committee of our board of directors recently commenced a search to identify one or more nominees to serve on our board of directors.

### **Item 6. Exhibits and Reports on Form 8-K**

#### **(a) Exhibits:**

<u>Exhibit Number</u>	
3.1*	Amended and Restated Certificate of Incorporation of the Registrant
3.2*	Bylaws of the Registrant
4.1*	Form of Stock Certificate
10.1†	Amendment to the Development and Supply Agreement dated March 26, 2004 between Xcyte Therapies, Inc. and Dynal S.A.
10.2	Xcyte Therapies Inc. Code of Business Conduct and Ethics
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.

\* 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.

† Certain information in these exhibits has been omitted and filed separately with the Securities and Exchange Commission pursuant to a confidential treatment request under 17 C.F.R. Sections 200.80(b)(4), 200.83 and 230.406.

#### **(b) Reports on Form 8-K:**

The Company did not file any reports on Form 8-K during the three months ended March 31, 2004.

### **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 Officer  
Senior Vice President of Finance and Treasurer*

Date: May 17, 2004

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.

**AMENDMENT TO DEVELOPMENT AND SUPPLY AGREEMENT  
(RESEARCH BEADS)**

This agreement (this "Amendment Agreement") to amend that certain Development and Supply Agreement dated as of August 1, 1999, by and between Xcyte Therapies, Inc., a Delaware corporation ("Xcyte") and Dynal Biotech ASA, a Norwegian corporation ("Dynal"), as amended by that certain Letter Agreement dated April 22, 2002 (as amended, the "D&S Agreement"), is made by and between Xcyte and Dynal as of March 26, 2004 (the "Effective Date"). Xcyte and Dynal desire to amend certain aspects of the D&S Agreement to add the provisions set forth herein.

Now, therefore, in consideration of the mutual covenants and conditions contained herein and in the D&S Agreement as amended hereby, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

**1. Additional Definitions.**

(a) "Research Beads" shall mean super-paramagnetic micro beads, Dynabeads® CD3/CD28, the research grade of Xcyte™ Dynabeads® Product (i.e. [\*] conjugated with XR-CD3 and XR-CD28 (i.e., the Antibodies)) that are labeled and sold solely for use in research not involving the treatment, diagnosis, or dosing of human subjects or patients (whether directly with the beads or particles or indirectly through the introduction into humans of substances made or processed in whole or in part through use of the beads or particles) and also not involving the generation of T-cells for use in therapy.

(b) "Net Sales" shall mean the gross amount invoiced by Dynal for the sale or other disposition of Research Beads to Third Parties, less the sum of the following deductions for amounts actually incurred related to said sale or other disposition:

(i) normal, customary trade discounts (including volume discounts), credits and allowances and adjustments for rejections, recalls and returns;

(ii) cost of freight and insurance, sales, use, excise, value added and similar taxes, surcharges, duties and other governmental charges (other than income tax) imposed on the sale and included in the gross amount charged to customers; and

(iii) normal, customary wholesaler chargebacks and rebates (including rebates to government agencies and government mandates and managed healthcare negotiated rebates).

In addition, Dynal and its Affiliates shall be entitled to deduct from gross sales of Research Beads any receivables which are deemed to be uncollectable in accordance with GAAP (generally accepted accounting practices). For the avoidance of doubt, sales between Dynal and its Affiliates shall be excluded from the computation of Net Sales hereunder, but gross sales shall include the first sale to Third Parties by any such Affiliates.

---

\* Confidential treatment requested.

(c) For the avoidance of doubt, other terms used herein and defined in the D&S Agreement shall have herein the meanings so ascribed to them in the D&S Agreement.

## 2. Research Beads.

(a) Xcyte hereby represents and warrants to Dynal that (i) it has the full right, power and authority to enter into this Amendment Agreement and to grant the rights granted to Dynal and perform its obligations hereunder, (ii) it has obtained, and shall at all times during the term of the D&S Agreement hold and comply with, all Third Party consents and licenses required to enter into this Amendment Agreement and as may be necessary to grant the rights granted, and to supply the Antibodies, to Dynal hereunder, and, to Xcyte's knowledge, without infringing or otherwise conflicting with the rights of any Third Party.

(b) Xcyte hereby grants to Dynal the exclusive right, during the term of the D&S Agreement, to make, have made, sell, offer for sale, use, distribute and import Research Beads and to use the Xcyte™ mark as part of the Xcyte™ Dynabeads® mark in connection therewith. Without limiting Xcyte's obligations under the D&S Agreement, Dynal shall purchase from Xcyte, and Xcyte shall supply to Dynal, the Antibodies, used or expended in connection with the foregoing activities (as set forth in Section 2(c) below), and Dynal shall pay the royalties on the Research Beads (as set forth in Section 2(d) below).

(c) Dynal shall purchase the Antibodies from Xcyte at the following prices:

- Antibody XR CD3 and Antibody XR CD28: \$[\*] for [\*] of each Antibody]

Except for the initial shipment of Antibodies as set forth in Section 2(g), Dynal agrees that the prices set forth above are based on the purchase of Antibodies in [\*] volumes per Antibody. Xcyte may raise the price of the Antibodies set forth in this Section above no more often than once per year upon sixty (60) days advance written notice to Dynal, provided that no annual increase shall have the effect of raising the previous year's price by more than [\*] percent ([\*]%). In no event shall Dynal use the Antibodies for any purpose, including any internal Dynal research and development projects or external research and development collaborations, except as specifically allowed under the D&S Agreement, under this Amendment Agreement or with Xcyte's prior written consent. The Antibodies supplied to Dynal hereunder shall be shipped to Dynal CIP Oslo, Norway (Incoterms 2000).

(d) In further consideration for the rights granted hereunder, Dynal shall pay to Xcyte a royalty of [\*] percent ([\*] %) of Net Sales of Research Beads.

(e) Dynal hereby acknowledges and agrees that Xcyte shall have no obligation or responsibility to provide any assistance, consultation, advice, guidance, recommendation, or training ("Assistance") to any Third Party interested in purchasing or receiving, or any Third Party who has purchased or received any Research Beads from or on behalf of Dynal, and Dynal shall not recommend any Third Party to contact Xcyte for such Assistance without the prior written consent of Xcyte unless such Third Party expresses an interest in potential clinical applications using Xcyte™ Dynabeads®.

---

\* Confidential treatment requested.

(f) Dynal shall submit to Xcyte representative specimens of all promotional materials, labels and packaging (including inserts) used in connection with the promotion, marketing or sale of Research Beads, and a description of the manner in which such materials will be used, pursuant to this Section 2 and Xcyte shall provide Dynal with its written approval thereof (which approval shall not be unreasonably withheld), and thereafter, such representative specimens of such promotional materials, labels and packaging provided to Xcyte shall be deemed approved for use in connection with the promotion, marketing and sale of the Research Beads in the manner described by Dynal to Xcyte without any further approval by Xcyte. Any failure by Xcyte to respond to Dynal's request for approval within three (3) weeks after receipt of such materials as aforementioned shall be deemed approval by Xcyte, except that in no event shall approval be deemed to have been given on any portion of such promotional materials, labels and packaging that contains Xcyte's Confidential Information or other Xcyte proprietary information, unless Xcyte had previously approved the use thereof. Xcyte's review and/or approval of such materials, labels and packaging shall be solely for purposes of monitoring Dynal's compliance with its obligations hereunder and shall in no way constitute an endorsement thereof by Xcyte, nor limit in any way Dynal's obligations under Section 2(k) of this Amendment Agreement.

(g) Dynal agrees that, notwithstanding any specifications for the Antibodies under the D&S Agreement and without limiting any obligations of Xcyte with respect to the Antibodies under the D&S Agreement, Xcyte has not made and shall not make any commitment under or in connection with this Amendment Agreement that any Antibodies supplied specifically to be used on Research Beads will be manufactured or documented to conform to current Good Manufacturing Practices ("cGMP"). Other than as expressly set forth in the preceding sentence with respect to cGMP, Xcyte shall comply with all of its other obligations under the D&S Agreement relating to the Antibodies that are supplied for use on Research Beads hereunder, and warrants that the Antibodies shall conform to the specifications for the Antibodies set forth on Attachment A (as may be amended from time to time according to Attachment G of the D&S Agreement) of the D&S Agreement, as tested by Xcyte using its standard methods, at time of shipment by Xcyte to Dynal. For the first shipment following execution of this Amendment Agreement, Xcyte will supply Dynal with [\*] ([\*]) of each of the Antibodies for use on Research Beads, subject to Section 13.3 of the D&S Agreement. Upon request from Dynal, Xcyte will supply larger volumes of Antibodies, provided that Dynal agrees to purchase the Antibodies in [\*] volumes per Antibody. Dynal acknowledges and agrees that lead times for additional volumes of Antibodies requested by Dynal will be at least [\*] ([\*]) months for [\*] volume sizes. In no event shall Dynal use or divert any Antibodies supplied to it by Xcyte under the D&S Agreement for the Products which are necessary for the production of the Products to be supplied to Xcyte under the D&S Agreement away from such use, without prior written consent of Xcyte, whether for the production of Research Beads hereunder, or otherwise.

(h) Dynal shall, starting on the Effective Date of this Amendment Agreement, and thereafter twice a year (by June 30<sup>th</sup> and December 31<sup>st</sup> of each year), provide to Xcyte a good faith non-binding forecast of Dynal's requirements for the Antibodies pursuant to this Amendment Agreement for the ensuing twelve (12) month period.

---

\* Confidential treatment requested.



(i) Records, Reports and Audits.

(i) Dynal shall keep true and accurate records (A) of the types and structures of Antibodies used or expended (inclusive of quantities wasted in the course of manufacture or handling) in connection with the exercise by Dynal of its rights under Section 2 of this Amendment Agreement, and (B) of all Net Sales derived from the sale or transfer of Research Beads pursuant to this Section 2. All such records shall be retained for a period of at least three (3) years following the end of the calendar year in which such Net Sales arise and to which they relate.

(ii) Dynal shall submit to Xcyte written reports annually (on or before each anniversary date of this Amendment Agreement), in a form reasonably acceptable to Xcyte, stating in itemized detail (A) the type and volumes of Antibodies used or expended (inclusive of quantities wasted in the course of manufacture or handling) in connection with the exercise by Dynal of its rights under Section 2 of this Amendment Agreement during the preceding calendar quarter, and (B) Dynal's Net Sales derived from the sale or transfer of Research Beads made pursuant to Dynal's rights under this Section 2.

(iii) Within reasonable advance notice to Xcyte, but not more than once per calendar year, Dynal shall have the right to perform a planned audit (at any time during regular business hours). The objective with the audit is to verify that Xcyte follow up on its suppliers in line with the established quality system within Xcyte, and that the manufacturing and testing of the specified Antibodies are documented according to agreed specifications between Xcyte and the contract manufacturer. Any such audit shall be at Dynal's expense. Dynal shall permit the records referenced in clause (i) above to be inspected and audited at any time during regular business hours, at such place or places where such records are customarily kept, upon reasonable advance notice, but not more often than once per calendar year, by Xcyte through an independent certified accountant (which representatives and accountants shall be bound by obligations of confidentiality), solely to verify the accuracy of the reports and payments. Any such audit shall be at Xcyte's expense, unless the audit concludes that, with respect to the period under audit, Dynal's reports to Xcyte hereunder understated any amounts to such an extent that a payment by Dynal to Xcyte made or called for under this Amendment Agreement was more than five percent (5%) in error and in Dynal's favor, in which event Dynal shall pay or reimburse Xcyte for the reasonable expenses of such audit.

(iv) In addition to the foregoing, Dynal agrees to use good faith efforts to provide information to Xcyte which may come to the attention of Dynal pursuant to sales of the Research Beads relating to (A) potential clinical sites for the Research Beads or the Antibodies; and (B) Third Parties who intend to move Research Beads or Antibodies towards the clinic, including but not limited to any Third Party who purchases Research Beads in excess of three (3) vials per month over any consecutive six-month period or who express a clinical intent for the Research Beads; provided that, Dynal has the right to do so and subject to, any obligations of confidentiality that Dynal may have to any Third Parties. Information about a clinical site or Third Party shall include the name of the site or institution, the name of the investigator and any information relating to inventions or discoveries made with the Research Beads, to the extent such information is available to Dynal; provided that, Dynal has the right to do so and subject to, any obligations of confidentiality that Dynal may have to any Third Parties.

(v) Royalties payable to Xcyte shall be paid by Dynal quarterly within sixty (60) days from the end of the fiscal quarter, without invoicing by Xcyte. Each such payment shall be for unpaid royalties that accrued within or prior to Dynal's two most recently completed fiscal quarters. All other payments payable to Xcyte by Dynal hereunder shall be due and payable within thirty (30) days from the date of Xcyte's invoice; provided, however, that Xcyte may at its election, by notice to Dynal after Dynal's failure to pay any payments due to Xcyte within ninety (90) days from the date of Xcyte's invoice or in the case of royalties, within ninety (90) days from the end of the applicable fiscal quarter, set-off any such payments from any amounts then or thereafter to come due to Dynal from Xcyte under or in relation to the D&S Agreement. Dynal shall pay interest to Xcyte on any overdue payments under this Amendment Agreement at a rate of one and one-half percent (1 1/2%) per month from the date due until payment. All payments due to Xcyte shall be paid in U.S. Dollars. If any currency conversion shall be required hereunder, such conversion shall be made by using the exchange rate prevailing at the Bank of America, N.A., on the last business day of the calendar quarter reporting period to which such royalty payments relate. In addition to its other rights and remedies, Xcyte reserves the right upon notice to Dynal to suspend or terminate Dynal's rights under Section 2 of this Amendment Agreement if at any time Dynal fails to pay any amounts due (which are not in dispute) as required hereunder or otherwise materially breaches its obligations under this Section 2, provided that Dynal has failed to cure such material breach within thirty (30) days of having been requested by Xcyte in writing to do so.

(j) This Amendment Agreement has been entered by Xcyte to permit Dynal to engage in certain activities as stated herein that were not expressly permitted under the D&S Agreement or otherwise. Dynal acknowledges that Xcyte has not specified or guided the means or manner in which Dynal may engage in any such activities, and that Xcyte does not expect to earn any substantial financial returns from such activities by Dynal. Accordingly, but without limiting to Dynal's rights or Xcyte's obligations under the D&S Agreement:

(i) Dynal shall, at its risk, bear all expenses associated with the development, manufacture, certification, marketing approvals, documentation, promotion, sale, storage, shipment, import, export, and labeling of any and all Research Beads produced or to be produced by Dynal pursuant to or in relation to this Amendment Agreement, except with respect to the development, manufacture, certification, and storage of Antibodies during the period prior to shipment of such Antibodies by Xcyte to Dynal.

(ii) Dynal (and not Xcyte except in relation to Xcyte's obligations with respect to whether the Antibodies conformed to the specifications set forth on Attachment A (as may be amended from time to time according to Attachment G of the D&S Agreement) of the D&S Agreement at the time of shipment of such Antibodies from Xcyte to Dynal ) shall be responsible for compliance with all marketing approval, import, export, and other legal or regulatory requirements applicable to any and all of Dynal's activities hereunder.

(iii) EXCEPT AS SET FORTH IN THIS AMENDMENT AGREEMENT AND THE D&S AGREEMENT, XCYTE MAKES NO OTHER WARRANTY, EXPRESS OR IMPLIED, WITH RESPECT TO THE ANTIBODIES, AND XCYTE EXPRESSLY DISCLAIMS ANY IMPLIED WARRANTIES INCLUDING, BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF NON-INFRINGEMENT, MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

(iv) Dynal shall be liable for and shall defend, indemnify, and hold Xcyte harmless against any and all actions, claims, liabilities, losses, damages, and costs (including without limitation reasonable attorneys' fees) ("Losses"), of Xcyte or its owners, managers, agents, contractors or personnel in connection with any Third Party claims arising from any development, manufacture, certification, marketing approvals, documentation, promotion, sale, storage, shipment, import, export, or labeling of any Research Beads by or for Dynal, or for any breach of any of Dynal's representations, warranties or covenants under this Amendment Agreement; except that in no event shall Dynal be liable for any Losses arising from any breach of Xcyte of any of its representations, warranties or covenants under this Amendment Agreement (including, without limitation, any breach of its representations, set forth in Section 2(a) or any failure of the Antibodies to meet the specifications as set out in Section 2(g)) at the time of shipment by Xcyte to Dynal, in which event, Xcyte shall be liable for and shall defend, indemnify, and hold Dynal harmless against any and all actions, claims, liabilities, losses, damages, and costs (including without limitation reasonable attorney's fees), of Dynal or its owners, managers, agents, contractors or personnel in connection with any Third Party claims arising therefrom. The provisions of Section 10.4 of the D&S Agreement shall apply to this clause (iv).

(k) IN NO EVENT SHALL EITHER PARTY BE LIABLE FOR ANY SPECIAL, CONSEQUENTIAL OR INCIDENTAL DAMAGES BASED UPON BREACH OF WARRANTY, BREACH OF CONTRACT, NEGLIGENCE, STRICT TORT OR ANY OTHER LEGAL THEORY. DYNAL SHALL IN NO EVENT BE ENTITLED TO, AND XCYTE NOT BE SUBJECT TO, ANY ORDER FOR SPECIFIC PERFORMANCE FOR THE PROVISION OF RIGHTS OR ANTIBODIES UNDER OR IN RELATION TO THIS AMENDMENT AGREEMENT. **IN NO EVENT (OR EVENTS) WILL EITHER PARTY'S AGGREGATE LIABILITY NOR EITHER PARTY'S AGGREGATE DAMAGES FOR ANY ONE OR MORE BREACHES OR OTHER FAILURES OF THE OTHER PARTY UNDER OR IN RELATION TO THIS AMENDMENT AGREEMENT EXCEED THE SUM OF \$50,000.**

### 3. Trademarks.

The parties shall take such actions and institute such standard and practices as may be necessary to ensure that any use of the trademark Xcyte™ Dynabeads® in connection with the Research Beads under this Amendment Agreement, as well as in connection with the Products under the D&S Agreement, and in connection with any other use that may be authorized by the parties, does not dilute or in any way adversely effect Dynal's right in or to, or the good will associated with, the DYNABEADS mark (the "Dynal Mark"). Such actions shall include, but not be limited to, ensuring that each of the Dynal Mark and the XCYTE mark (the "Xcyte Mark") when used in combination (e.g., Xcyte™ Dynabeads®) are printed or displayed as separate and

distinctive marks, such as by way of using separate and distinctive colors, fonts and/or lettering size for each party's respective mark and always including the words "product(s)" or "bead(s)" after the Xcyte™ Dynabeads® mark. In addition, for the avoidance of doubt, Xcyte shall comply with its obligations under Section 7.1 of the D&S Agreement, including, but not limited to, by including a notice stating that "Dynabeads® is a registered trademark of Dynal Biotech ASA, Oslo, Norway, licensed to Xcyte" on all package insert, label, packing and promotion and marketing and all other printed materials or displays that bear or include the Xcyte™ Dynabeads® mark. Dynal shall also include a notice stating that "Xcyte is a trademark of Xcyte" on all printed materials or displays that bear or include the Xcyte™ Dynabeads® mark. Xcyte shall not have any rights to use the Dynal Mark other than in connection with the Products expressly permitted under this Amendment Agreement and the D&S Agreement, and Dynal shall not have any right to use the Xcyte Mark other than in connection with the Research Beads and the Products as expressly permitted under this Amendment Agreement and the D&S Agreement.

#### **4. Termination.**

Notwithstanding any termination provisions to the contrary in the D&S Agreement, Xcyte may terminate the rights granted to Dynal under this Amendment Agreement upon written notice to Dynal if any of the following occur:

(a) Dynal is more than sixty (60) days late in paying to Xcyte royalties, expenses, or any other monies due under this Amendment Agreement pursuant to Section 2(i)(v), and Dynal has failed to pay Xcyte in full within thirty (30) days of having been requested by Xcyte in writing to do so; or

(b) Dynal enters bankruptcy proceedings, voluntarily or involuntarily; or

(c) Dynal breaches any material terms of this Amendment Agreement and does not cure the breach within thirty (30) days after written notice of the breach.

Except as provided herein, upon any termination pursuant to this Section 4, the rights and obligations of the parties under this Amendment Agreement shall terminate, but such termination shall not affect any of the other terms or conditions of the D&S Agreement, which terms and conditions shall remain in full force and effect in accordance with the terms thereof. Notwithstanding the foregoing, (i) Sections 2(j)(iv) and 2(k) shall remain in effect during the term of the D&S Agreement and shall survive termination thereof, and (ii) Section 3 shall remain in effect during the term of the D&S Agreement.

#### **5. Continuing Effect.**

Except as modified herein, the terms and conditions of the D&S Agreement remain unchanged and in full force and effect and apply to this Amendment Agreement as if set out in full herein. In the event of any inconsistency between this Amendment Agreement and the D&S Agreement (prior to this Amendment Agreement), this Amendment Agreement shall prevail.

\* \* \* \* \*

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.

IN WITNESS WHEREOF, the parties have executed this Amendment Agreement by their duly authorized representatives.

XCYTE THERAPIES, INC.

DYNAL BIOTECH, ASA

By: /s/ Ronald J. Berenson

By: /s/ Jon Hindar

\_\_\_\_\_  
Ronald J. Berenson  
President and CEO  
Date Signed: April 4, 2004

\_\_\_\_\_  
Jon Hindar  
CEO  
Date Signed: 26 March 2004

LEGAL DEPT

/s/ JB

APPROVED

## XCYTE THERAPIES, INC.

## CODE OF BUSINESS CONDUCT AND ETHICS

*As Adopted by the Board of Directors on April 6, 2004***Introduction — General Statement of Company Policy.**

Xcyte Therapies, Inc. (the “Company”) requires lawful and ethical behavior at all times. The purpose of this Code of Business Conduct and Ethics (the “Code”) is to provide you with a statement of certain key policies and procedures of the Company for you to follow in conducting business in a legally and ethically appropriate manner. This Code is intended as one element in the Company’s efforts to ensure lawful and ethical conduct on the part of you and the Company. This Code is part of a larger process that includes compliance with the corporate policies themselves, an open relationship between you and your supervisors that is conducive to good business conduct and, above all, your integrity and good judgment.

In that regard, you must:

- comply with applicable laws, rules, and regulations;
- conduct all dealings with the Company’s customers, suppliers and competitors fairly, with honesty and integrity;
- ethically handle conflicts of interest, both real and perceived, in personal and professional relationships;
- produce, or cause to be produced, full, fair, accurate, timely and understandable disclosure in reports and documents that the Company files with or submits to the SEC and in other public communications;
- protect information, in any form, that belongs to the Company, its customers and suppliers;
- protect the Company’s assets and ensure their efficient use and report any suspected incident of fraud or theft immediately; and
- never use your position with the Company or Company assets or information for improper personal gain.

This includes some general principles. You will have to apply these principles to your own specific responsibilities. If you have any questions about the proper application of the principles or about what is required by the law in any given situation, you must consult with the Company’s General Counsel.

If you violate this Code, you will be subject to disciplinary action, up to and including immediate termination of your employment. You must report potential or actual violations of this Code to your immediate supervisor, or, alternatively, to the Company's General Counsel or the Chairman of the Audit Committee. If your situation requires that your identity be kept a secret, your anonymity will be protected.

Under no circumstances will you be subject to any disciplinary or retaliatory action for reporting a violation or potential violation, unless it is your own. However, making known false or malicious reports will not be tolerated, and you will be subject to appropriate disciplinary action if you file such reports.

No representation is expressed or implied that the policies stated in this Code are all of the Company's relevant policies, or that they are a comprehensive, full or complete explanation of the laws or standards of conduct that are applicable to you or the Company. You have a continuing obligation to familiarize yourself with applicable law and Company policy.

You must sign a certification in the attached form acknowledging receipt of this Code. This Code is available in the Company's Handbook, is posted on the Company's intranet and is included as an exhibit to the Company's annual report. This Code is also available to the public on the Company's website at [www.xcytetherapies.com](http://www.xcytetherapies.com).

\*\*\*\*\*

**Nothing contained in this Code of Business Conduct and Ethics is intended by the Company to be, nor shall it be construed as, an employment agreement.**

\*\*\*\*\*

## TABLE OF CONTENTS

<u>Section</u>	<u>Page</u>
Introduction — General Statement of Company Policy.	i
1. Lawful and Ethical Behavior.	1
2. Code of Ethics	1
3. Accurate Books and Records.	2
4. Confidential Information.	2
5. Securities Laws and Insider Trading.	3
6. Conflicts of Interest.	3
7. Gifts and Entertainment.	4
8. Corporate Opportunities.	4
9. Unauthorized Use of Company Property or Services.	5
10. Fair Competition.	5
11. Antitrust.	5
12. Government Business.	5
13. Political Activity.	6
14. Environment, Health and Safety; Substance Abuse.	6
15. Copyrights and Computer Software.	6
16. International Business.	7
17. Audits.	9



## **1. Lawful and Ethical Behavior.**

The foundation on which this Code of Business Conduct and Ethics is built is obeying the law and acting ethically. It is the Company's policy that you conduct business in accordance with applicable federal, state and local laws, rules and regulations and with the laws, rules and regulations of other countries in which the Company does business. In addition, the Company's policy demands that you adhere to the highest standard of business ethics and conduct.

You must be alert and sensitive to situations that could result in illegal, unethical, or improper action. When you are faced with a business decision that seems to have ethical overtones, here are some questions that should be helpful to determine if your actions are proper:

- Do I have all the necessary facts?
- Am I informed about all of the legal implications?
- Who has an important stake in the outcome (e.g., employees, customers, suppliers, etc.), and what is that stake?
- Does the issue raise ethical issues that go deeper than legal or institutional concerns?
- What are the options for acting, and which options will produce the most good and do the least harm? Which options respect the dignity of all stakeholders?
- Would I be proud to explain my actions to my family, fellow employees, customers - or on tonight's news broadcast?

If you remain uncertain about what to do, if you need advice, or if you have reason to believe that a domestic or foreign law could be violated in connection with Company business or that this Code has been violated in any way, notify your immediate supervisor, the Company's General Counsel or the Chairman of the Audit Committee at once.

## **2. Code of Ethics**

This Code of Ethics is promulgated by the Board of Directors under section 406 of the Sarbanes Oxley Act of 2002 and the related rules of the SEC and applies to all employees, officers and directors of the company. It contains standards reasonably necessary to promote: honest and ethical conduct, including the ethical handling of actual or apparent conflicts of interest between personal and professional relationships; full, fair, accurate, timely, and understandable disclosure in the periodic reports required to be filed by the issuer and in other public communications; and compliance with applicable governmental laws, rules and regulations.

You must:

1. Act with honesty and integrity, avoiding actual or apparent conflicts of interest in personal and professional relationships. You should recognize that even the appearance of a conflict of interest can damage the Company. A conflict of interest may exist because of a relationship of yours or of a family member that is inconsistent with the Company's best interests or could cause a conflict with your ability to perform your job responsibilities.

2. If you are an employee or officer, report to the Company's General Counsel any transaction that reasonably could be expected to give rise to a conflict of interest. If you are a director, report to the Board of Director's any transaction that reasonably could be expected to give rise to a conflict of interest pursuant to Section 144 of the Delaware General Corporation Law.

3. Produce, or cause to produced, full, fair, accurate, timely and understandable disclosure in reports and documents that the Company files with or submits to the Securities and Exchange Commission and in other public communications.

4. Comply with applicable governmental laws, rules and regulations.

5. Promptly report any violation of this Code of Ethics to the Company's General Counsel.

6. Proactively promote ethical behavior by other Company officers and employees involved in financial reporting.

You will be held accountable for your adherence to this Code of Ethics. Your failure to observe the terms of this Code of Ethics may result in disciplinary action, up to and including immediate termination of your employment.

If you are a senior executive officer (chief executive officer, chief financial officer, principal financial officer or controller), other executive officer or director, any request by you for a waiver of any provision of this Code of Ethics must be in writing and addressed to the Chairman of the Audit Committee. If you are not an executive officer or director, any request by you for a waiver of any provision of this Code of Ethics must be in writing and addressed to the Compliance Officer.

With regard to senior financial officers, other executive officers and directors, the Board will have the sole and absolute discretionary authority, acting upon such recommendation as may be made by the Audit Committee, to approve any waiver from this Code of Ethics. Any waiver for senior financial officers, other executive officers or directors from this Code of Ethics will be disclosed promptly on Form 8-K or any other means that complies with SEC rules or applicable listing standards.

### **3. Accurate Books and Records.**

The Company requires full, fair, accurate, timely and understandable recording and reporting of all Company information. You must act in a manner that ensures that all of the Company's books, records, accounts and financial statements are maintained in reasonable detail, appropriately reflect the Company's transactions and conform both to applicable legal requirements and to the Company's system of internal controls. To do so, you must execute and record transactions in accordance with all internal control procedures implemented by Company management. Furthermore, all of your expense reimbursements must accurately reflect the true nature and amount of the expenses. In addition, if you are in any way involved in preparing the Company's disclosure documents (such as SEC filings or press releases), you must produce full, fair, accurate, timely and understandable disclosure in such documents.

*It is very important that you do not create, or participate in the creation, or perpetuation of, any records that are intended to mislead anyone or conceal any improper act or conduct.*

### **4. Confidential Information.**

Confidential Company information is an important corporate asset that merits the same protection as the Company's' physical assets. It is very important for you to safeguard the Company's confidential

information and to refuse any improper access to such information entrusted to you or any employee for whatever purpose. You have entered into a non-disclosure or confidentiality agreement (as set forth in the Proprietary Information and Inventions Agreement) detailing your obligations regarding the Company's confidential information, and you must adhere to this agreement. You also have an obligation to protect the confidential information provided to the Company by its customers and suppliers and your fellow workers during the course of the Company's business. They expect your confidentiality — just as the Company expects theirs. Issues with respect to confidential information may also arise in securities transactions as further discussed in the "Securities Laws and Insider Trading" section below.

#### **5. Securities Laws and Insider Trading.**

The rules relating to trading in the Company's securities and those of other companies with which the Company does business are covered in detail in the Company's Insider Trading Policy, with which you must become familiar and with which you must comply at all times. If you are uncertain about the legal rules involving your purchase, sale or transfer of any securities of the Company or any securities in companies familiar to you by virtue of your work for the Company, you should consult with the Company's General Counsel before making any such purchase or sale.

#### **6. Conflicts of Interest.**

The Company knows that it can only be truly successful through the diligence and loyalty of its employees. Therefore, you must put the best interests of the Company at the forefront of any work-related activity or decision and scrupulously avoid conflicts of interest. You must use your best judgment in determining whether a conflict of interest exists and then avoid any conduct, activity, relationship or other situation that would create or cause an actual or potential conflict of interest.

While it is not possible to identify every particular activity that might give rise to a conflict of interest, a conflict of interest may exist because of a relationship of yours or of a family member that is inconsistent with the Company's best interests or could cause a conflict with your ability to perform your job responsibilities. If you or your family members are engaged in any of the activities listed below, then there may be a conflict of interest. If you are an employee or officer, you must disclose the facts concerning this activity to your immediate supervisor or the General Counsel in order to have the Company address the situation. If you are a director, you must disclose the facts concerning this activity to the Board.

(a) any ownership interest in any supplier, customer or competitor (other than nominal amounts of stock in publicly traded companies);

(b) any consulting or employment relationship with any customer, supplier or competitor;

(c) any outside activity that harms a relationship between the Company and any customer or potential customer, or that interferes with a current or potential contract relationship;

(d) any outside business activity that is competitive with any of the Company's businesses;

(e) any outside activity of any type that is so substantial as to call into question your ability to devote appropriate time and attention to your duties and responsibilities to the Company;

(f) any service on any board of directors or advisory board of any customer, supplier or competitor unless such board service has been disclosed to the Company;

(g) any direct supervisory, review or other influential position on the job evaluation, pay or benefits of any close relative who is employed by the Company;

(h) any sales or purchases of anything to or from the Company (unless it is pursuant to a routine program of disposal of surplus property that is offered to all employees in general); and

(i) any situation in which, without proper authorization, you are required or tempted to disclose, or do disclose, any trade secret, confidential or proprietary information or intellectual property of the Company.

If you have any questions regarding activity which may create a conflict of interest, please discuss the situation immediately with your immediate supervisor or the General Counsel, if you are an employee or officer. If you are a director, you should consult your own independent counsel if you have any questions regarding activity that may create a conflict of interest. If you know of a conflict of interest that exists elsewhere in the Company, you must disclose such conflict to the General Counsel.

The Company reserves the right to determine when actual or potential conflicts of interest exist, and then to take any action, which in the sole judgment of the Company, is needed to prevent the conflict from continuing, or in the case of a director, disclose such actual or potential conflict of interest and take such actions as are appropriate in accordance with Section 144 of the Delaware General Corporation Law. Such action may include, but is not limited to, having you divest the conflicting interest or return the benefit or gain received, realigning your duties and responsibilities, or disciplinary action, up to and including immediate termination of your employment or removal from the Board.

#### **7. Gifts and Entertainment.**

Generally, you and members of your immediate family may not accept gifts, services, discounts or favors from those with whom the Company does business or considers doing business. Gifts, entertainment, favors or gratuities are subject to the following guidelines:

(a) You may accept gifts of nominal value ordinarily used for sales promotion (for example, calendars, appointment books, pens, etc.).

(b) Ordinary “business lunches” or reasonable entertainment consistent with local social and business customs may also be permissible if these actions can be reciprocated by you and are reasonable in cost and frequency.

If you receive a gift that does not fall within these guidelines, you must report it to your supervisor and return the gift. If return of the gift is not practical, you should give it to the Company for charitable disposition or such other disposition as the Company deems appropriate.

#### **8. Corporate Opportunities.**

You may not use corporate property, information, or position for improper personal gain. You owe a duty to the Company to advance its legitimate interests when the opportunity to do so arises. You are prohibited from competing with the Company or taking advantage for personal gain of any opportunity that is discovered through the use of Company property, information or position. You should report any corporate opportunity to your supervisor or other appropriate individual within the Company to determine whether the Company desires to take advantage of the opportunity.

If you are an officer, you have an additional obligation not to take advantage for personal gain of any opportunity that the Company may have an interest in pursuing, notwithstanding that your knowledge of such opportunity is obtained independently of your relationship with the Company.

#### **9. Unauthorized Use of Company Property or Services.**

You may only use Company property (including the e-mail system) for legitimate business purposes. You may not use or remove from Company premises any Company property or services for any personal benefit or the personal benefit of anyone else. The Company realizes that sometimes the line between personal and Company benefits is difficult to draw, and sometimes there are both personal and Company benefits in certain activities. Examples include articles of a technical or professional nature that may enhance the stature or reputation of the author and also may have some benefit to the Company, and employee participation in continuing education programs. You must obtain approval from your supervisor in advance of any use of Company property or services that is not solely for the benefit of the Company.

#### **10. Fair Competition.**

The Company intends to succeed in the marketplace through superior performance, not by unethical or manipulative practices. You must treat customers and suppliers honestly and fairly. Do not make false or misleading remarks to customers or suppliers about other customers/suppliers or about competitors of the Company, their products or their services. You must avoid deprecation and criticism of competitors, their products or services, but you may state truthful descriptions of specifications and shortcomings of such products or services.

#### **11. Antitrust.**

The economies of the United States and of most countries in which the Company does business are based on the principle that competition and profit will produce high-quality goods at fair prices. Most countries, including the United States, have laws prohibiting certain business practices that could inhibit effective competition. Whether termed antitrust, competition, or free trade laws, the rules are designed to keep the marketplace thriving and competitive. These antitrust laws are broad and far-reaching, and touch upon and affect virtually all aspects of the Company's operations.

The antitrust laws generally prohibit agreements that restrict competition and include agreements between competitors as to pricing, bidding, production, supply and customer practices. These laws also apply to various forms of unfair conduct that may tend to create a monopoly.

The Company supports these laws not only because they are the law, but also because it believes in the free market and the idea that healthy competition is essential to its long-term success. As such, you should avoid conduct that violates or appears to violate these laws. In all cases where there is question or doubt about a particular activity or practice, you should contact the Company's General Counsel before taking any action that may fall within the scope of these laws.

#### **12. Government Business.**

Special requirements often apply when contracting with any government body (including national, state, provincial, municipal, or other similar government divisions in local jurisdictions).

Because government officials are obligated to follow specific codes of conduct and laws, you must take special care in government procurement. Some key requirements for you to follow in doing business with a government are:

- Accurately representing which Company products are covered by government contracts;
- Not offering or accepting kickbacks, bribes, gifts, gratuities or anything else of value with the intent of obtaining favorable treatment from the recipient (a gift that is customary in the business sector may be perceived as a bribe by a government official);
- Not improperly soliciting or obtaining confidential information, such as sealed competitors' bids, from government officials prior to the award of a contract;
- Hiring present and former government personnel may only occur in compliance with applicable laws and regulations (as well as consulting the General Counsel).

### **13. Political Activity.**

You may not use corporate funds or other assets — including your work time, Company premises, or Company equipment — to make political contributions of any kind to any candidate, political party or in support of any referendum or initiative. This prohibition covers not only direct contributions but also indirect assistance or support of candidates or political parties through the purchase of tickets to special dinners or other fund-raising events, and the furnishing of any other goods, services or equipment to political parties or committees. Political contributions or activities by you on your own behalf and with your own money and on your own time are, of course, permissible. The Company will not reimburse you directly or indirectly for any political contribution or for the cost of attending any political event.

### **14. Environment, Health and Safety; Substance Abuse.**

The Company is committed to providing a work environment that strives to protect employee health and safety, as health and safety are important aspects of job performance. It is also the Company's policy to manage its business in a manner that is sensitive to the environment and conserves natural resources. You must learn and follow the safety procedures applicable to your job, and you must comply with all environmental, health and safety laws.

Furthermore, substance abuse poses serious health and safety risks not only to the few abusers, but also to all employees who work with them. Therefore, in furtherance of the above general policy, you may not possess any illegal drug, any legal prescription drug that is a controlled substance (unless the prescription has been issued to you and is being used in a manner consistent with the prescribed directions for use), or any alcohol on Company property, except in the case of Company-sanctioned events. You are also prohibited from being on Company property under the influence of alcohol or any controlled or illegal substance.

### **15. Copyrights and Computer Software.**

You may sometimes need to use third-party copyrighted material to perform your job. It is the Company's policy to respect copyright laws. Therefore, before you may use such third-party material, appropriate authorization from the copyright holder must be obtained. The need for such permission may exist whether or not the end product containing third-party material is for personal use, for Company use internally or other use.

You must observe the terms and conditions of any license agreements to which the Company is a party. In most cases, you do not have the right to make copies of software, except for backup purposes. This includes not only the substantial software programs the Company may license, but also the smaller so-called “shrink-wrap” programs typically used for word processing, spreadsheets and data management.

You may not copy copyrighted intellectual property licensed to the Company or otherwise make use of property, other than on your Company computer in furtherance of Company business, and such use must be as permitted under the copyright laws. It is against Company policy and it may be unlawful for you to copy, reproduce, scan, digitize, broadcast, or modify third-party copyrighted material when preparing Company products or promotional materials, unless written permission from the copyright holder has been obtained prior to the proposed use. Improper use could subject both the Company and you to possible civil and criminal actions for copyright infringement. It is also against Company policy for you to use the Company’s facilities for the purpose of making or distributing unauthorized copies of third-party copyrighted materials for personal use or for use by others.

#### **16. International Business.**

The Company observes the highest ethical standards in all of its business transactions — including those involving foreign countries. You may not take any action in connection with any international transaction or any action in any foreign country that would be illegal or improper in the US. Furthermore, you are required to observe all applicable foreign laws to which you or the Company may be subject, including foreign tax laws, customs duties and regulations, drug testing, licensing, manufacturing and marketing laws, rules and regulations and currency restrictions. You should not take any actions that are intended to improperly circumvent the application of such laws. Some of the concerns raised by international business are as follows:

##### *(a) Foreign Corrupt Practices Act.*

With limited exceptions, the Foreign Corrupt Practices Act prohibits the Company and you from, among other things, making an offer, payment, promise to pay or authorization of the payment of any money, or offer, gift, promise to give, or authorization of the giving of anything of value to any foreign official, any foreign political party or official thereof or any candidate for foreign political office, or any other person, such as a foreign agent or consultant, knowing that all or a portion of such money or thing of value will be offered, given or promised, directly or indirectly, to any foreign official, any foreign political party or official thereof, or any candidate for foreign political office, for the purpose of (i) influencing any act or decision of such foreign official in his or her official capacity, (ii) inducing such foreign official to do or omit to do any act in violation of the lawful duty of such official, or (iii) securing any improper advantage, or inducing such foreign official to use his or her influence with a foreign government or instrumentality thereof to affect or influence any act or decision of such government or instrumentality, in order to assist the Company in obtaining or retaining business for or with, or directing business to, any person.

If you are asked to make any such payment, you should consult with your supervisor and the General Counsel before taking any action.

*(b) Antiboycott Laws.*

U.S. antiboycott laws prohibit or severely restrict the Company from participating in boycotts against countries friendly to the US, and require the Company to report both legal and illegal boycott requests to the U.S. government. If you are involved in selling the Company's products internationally, you must become familiar with the antiboycott laws and observe all of their requirements. Further information and guidance can be obtained from the General Counsel.

*(c) New Foreign Countries.*

The decision to expand the Company's distribution or to establish an operation in any other country, besides those in which it is already qualified to do business, may carry many important legal and tax implications. You must not undertake to expand the Company's operations into any country outside the US without prior consultation with the General Counsel.

*(d) Export Controls.*

In general, any goods that the Company sells to a customer in a foreign country must be covered by an export license. The definition of "export" is quite broad and can include conversations of a technical nature with a citizen of another country even though that conversation takes place entirely within the US. Another example of a possible export would include tours of the Company's facilities where foreign visitors could obtain technical information.

There are certain statutory licenses which allow exporting of certain products — generally nonmilitary or non-high-technology goods — to the United States' allies without any further license. Export control regulations are, however, quite complex, and if you are involved in any export transaction you must observe at least the following two rules:

- (i) You must satisfy yourself that there is some regulation or specific export license that covers the export you want to make. This includes exports of technology, as well as exports of goods or services.
- (ii) You must furnish only truthful and accurate information to other Company employees, to the government or to companies that the Company may have hired to facilitate the Company's export transactions. This includes both information as to the technology in question and information as to the economic value of the exports.

If you are involved in the Company's export business, you must be reasonably alert to situations in which inaccurate information may have been furnished, either to the Company or to any of the Company's agents, involving the ultimate destination or use of the goods. This is particularly important for goods of the type that are not permitted to be shipped to certain countries.

*If you have any doubt as whether a situation involves an "export" within the meaning of the applicable export control laws, or as to the truth or accuracy of the information being furnished to the Company regarding the ultimate destination or use of products the Company exports, you must contact your supervisor or the General Counsel.*



*(e) Imports.*

All goods imported into the US must pass through customs and, except in some limited cases where there are exemptions, a duty must be paid. The amount of that duty is based upon the classification of the goods and the value of the merchandise. You must furnish truthful and accurate information to any customs official or to any agent that the Company hires to facilitate its imports.

*(f) Bioterrorism.*

You must report any requests to manufacture or sell any drug or other product that could be used in an act of terrorism to the General Counsel.

**17. Audits.**

In some cases, the Company will monitor compliance with its policies by audits. These may be done by the Company's legal counsel or at the direction of the General Counsel/internal auditor. You are required to cooperate fully with any such audits and to provide truthful and accurate responses to any request.

\*\*\*\*\*

## CERTIFICATION PURSUANT TO SECTION 302

## 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) 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
  - (c) 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 17, 2004

/s/ Dr. Ronald J. Berenson

---

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

## CERTIFICATION PURSUANT TO SECTION 302

## CERTIFICATION

I, Kathi L. Cordova, certify that:

1. I have reviewed this 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) 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
  - (c) 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 17, 2004

/s/ Kathi L. Cordova

---

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

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

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

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

Signature: /s/ Dr. Ronald J. Berenson

---

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

Dated: May 17, 2004

**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, 2004, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Kathi L. Cordova, Principal Financial and Accounting Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

Signature: /s/ Kathi L. Cordova

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

Dated: May 17, 2004