XCYTE THERAPIES INC
Form S-1
October 07, 2004
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As filed with the Securities and Exchange Commission on October 7, 2004

Registration No. 333-

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-1

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

XCYTE THERAPIES, INC.

(Exact name of registrant as specified in its charter)

Delaware	**2834**	**91-1707622**
(State or other jurisdiction of incorporation or organization)	**(Primary Standard Industrial Classification Code Number)**	**(I.R.S. Employer Identification Number)**

1124 Columbia Street, Suite 130

Seattle, Washington 98104

(206) 262-6200

(Address, including zip code, and telephone number, including area code, of registrant s principal executive offices)

Ronald J. Berenson, M.D.

President and Chief Executive Officer

Xcyte Therapies, Inc.

1124 Columbia Street, Suite 130

Seattle, Washington 98104

(206) 262-6200

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

Copies to:

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

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

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

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

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

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

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

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	**Amount to be Registered(1)**	**Proposed Maximum Offering Price Per Share**	**Proposed Maximum Aggregate**	**Amount of Registration Fee**

			Offering Price(1)	
Convertible Exchangeable Preferred Stock, par value $0.001	1,725,000	$ 10.00	$ 17,250,000	$ 2,185.58
Convertible Subordinated Debentures	$ 17,250,000(2)	(3)	(3)	(3)
Common Stock, par value $0.001	(4)	(3)	(3)	(3)
Common Stock, par value $0.001	1,000,000(5)	$ 3.33(6)	$ 3,333,333.33	$ 421.92

(1) Estimated solely for the purpose of computing the amount of the registration fee pursuant to Rule 457(o) under the Securities Act of 1933.

(2) This number represents a total of $17,250,000 aggregate principal amount of Convertible Subordinated Debentures issuable if we elect to exchange all of the Convertible Exchangeable Preferred Stock for Convertible Subordinated Debentures. For purposes of estimating the number of debentures to be included upon exchange of the preferred stock, we calculated the amount of debentures issuable upon exchange based on an exchange price of $10 per share of preferred stock.

(3) No additional consideration will be received for the common stock or the convertible subordinated debentures and, therefore, no registration fee is required pursuant to Rule 457(i).

(4) This number represents shares of common stock issuable upon conversion of the Convertible Exchangeable Preferred Stock or the Convertible Subordinated Debentures. In addition, the shares set forth in the table, pursuant to Rule 416 under the Securities Act of 1933, include an indeterminate number of shares of common stock issuable upon conversion of the preferred stock or the debentures, as these amounts may be adjusted as a result of stock splits, stock dividends and antidilution provisions, or in payment of such make-whole obligations.

(5) This number represents the estimated maximum number of shares of our common stock issuable to satisfy the dividend make-whole payment and interest make-whole payment pursuant to the terms of the Convertible Exchangeable Preferred Stock or the Convertible Subordinated Debentures. In addition, the shares set forth in the table, pursuant to Rule 416 under the Securities Act of 1933, include an indeterminate number of shares of common stock issuable as a result of stock splits and stock dividends.

(6) Estimated solely for the purpose of calculating the registration fee, pursuant to Rule 457(c), based on the average of the high and low sales price of our common stock on the Nasdaq Stock Market on October 6, 2004.

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

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

SUBJECT TO COMPLETION, DATED OCTOBER 7, 2004

1,500,000 Shares

XCYTE THERAPIES, INC.

% Convertible Exchangeable Preferred Stock

(Cumulative Dividend, Liquidation Preference $10 Per Share)

- Xcyte Therapies, Inc. is offering 1,500,000 shares of % convertible exchangeable preferred stock, which is referred to in this prospectus as convertible preferred stock.

- Dividends will be cumulative from the date of original issue at the annual rate of % of the liquidation preference of the convertible preferred stock, payable quarterly on the day of , , , and , commencing , 2005. Any dividends must be declared by our board of directors and must come from funds that are legally available for dividend payments.

- You may convert each share of the convertible preferred stock into shares of our common stock based on the initial conversion price of $, subject to certain adjustments.

- We may elect to automatically convert the convertible preferred stock into our common stock if the closing price of our common stock has exceeded $, which is 150% of the conversion price of the convertible preferred stock, for at least 20 trading days during any 30-day trading period, ending within five trading days prior to notice of automatic conversion.

- If we elect to automatically convert, or you elect to voluntarily convert, some or all of the convertible preferred stock into our common stock prior to

- We may elect to redeem the convertible preferred stock after , 2007 on the terms described in this prospectus.

- At our option, we may exchange the convertible preferred stock in whole, but not in part, on any dividend payment date beginning on , 2005 for our % convertible subordinated debentures. If we elect to exchange the convertible preferred stock for debentures, the exchange rate will be $10 principal amount of debentures for each share of the convertible preferred stock. The debentures, if issued upon exchange of the convertible preferred stock, will mature 25 years after the exchange date and will have terms substantially similar to those of the preferred stock.

- The convertible preferred stock has no maturity date and no voting rights prior to conversion into common stock, except under limited circumstances.

- Shares of our common stock are listed on the Nasdaq National Market under the symbol XCYT. The last reported sale price of our common shares on October 6, 2004 was $3.40 per share. We will make an application to list the convertible preferred stock on the Nasdaq National Market under the symbol XCYTP.

, 2007, we will make an additional payment on the convertible preferred stock equal to the aggregate amount of dividends that would have been payable on the convertible preferred stock through and including , 2007, less any dividends already paid on the convertible preferred stock.

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

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

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

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

Piper Jaffray **JMP Securities**

The date of this prospectus is , 2004.

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

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PROSPECTUS SUMMARY

This summary highlights selected information appearing elsewhere in this prospectus. While this summary highlights what we consider to be the most important information about us, you should carefully read this prospectus and the registration statement of which this prospectus is a part in their entirety before making an investment decision, especially the risks of investing in the convertible preferred stock, which we discuss under Risk Factors beginning on page 9, and our financial statements and related notes beginning on page F-1.

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

Our Business

We are a biotechnology company developing a new class of therapeutic products designed to enhance the body s natural immune responses to treat cancer, infectious diseases and other medical conditions associated with weakened immune systems. We derive our therapeutic products from a patient s own T cells, which are cells of the immune system that orchestrate immune responses and can detect and eliminate cancer cells and infected cells in the body. We use our patented and proprietary Xcellerate Technology to generate activated T cells, which we call Xcellerated T Cells, from blood that is collected from the patient. Activated T cells are T cells that have been stimulated to carry out immune functions. Our Xcellerate Technology is designed to rapidly activate and expand the patient s T cells outside of the body. These Xcellerated T Cells are then administered to the patient.

We believe, based on clinical trials to date, that our Xcellerate Technology can produce Xcellerated T Cells in sufficient numbers to generate rapid and potent immune responses to treat a variety of medical conditions. In our ongoing clinical studies using our Xcellerate Technology, we have observed an increase in the quantity and a restoration of the diversity of T cells in patients with weakened immune systems. We have submitted the findings on the increase in quantity of T cells to the FDA and plan to submit additional data in our next annual report. We believe we can efficiently manufacture Xcellerated T Cells for therapeutic applications. We expect Xcellerated T Cells may be used alone or in combination with other complementary treatments.

Our clinical trials and independent clinical trials using an earlier version of our technology, to date, have involved small numbers of patients and we have not designed nor been required to design such trials to produce statistically significant results as to efficacy. These trials have neither been randomized nor blinded to ensure that the results are due to the effects of Xcellerated T Cells. Success in early clinical trials neither ensures that large-scale trials will be successful nor predicts final results. We and other clinical investigators have completed or are conducting clinical trials in the following indications:

- ***Chronic lymphocytic leukemia, or CLL.*** In our ongoing Phase I/II clinical trial in CLL, treatment with Xcellerated T Cells resulted in a 50% to 100% reduction in the size of enlarged lymph nodes in 12 of 17 (71%) patients for whom data was available as of September 27, 2004. In addition, there was a 50% or greater reduction in spleen size as measured below the rib cage by physical examination in 10 of the 13 patients (77%) with enlarged spleens. These findings were submitted to the FDA in the Information Packet for a Type B End of Phase II meeting held on September 23, 2004. At this meeting we discussed with the FDA our plans for a Phase II/III clinical trial of Xcellerated T Cells in patients with CLL who have been previously treated with chemotherapy and have failed treatment with Campath, an FDA-approved drug used to treat CLL. Based on feedback from the FDA during

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

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

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

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

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

Our Strategy

Our goal is to be a leader in the field of T cell therapy and to leverage our expertise in T cell activation to develop and commercialize products to treat patients with cancer, infectious diseases and other medical conditions associated with weakened immune systems. We plan to initially develop Xcellerated T Cells to treat life-threatening diseases, such as cancer and HIV, which currently have inadequate treatments. Key elements of our strategy include the following:

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

Risks Associated With Our Business

We are a development stage company. We are subject to numerous risks and obstacles, and we have highlighted the most important of them in Risk Factors beginning on page 9. In particular, we have a limited operating history and have incurred losses in each fiscal year since our inception. We incurred net losses of approximately $18.5 million for the year ended December 31, 2003 and $24.4 million for the six months ended June 30, 2004, and our deficit accumulated during the development stage was approximately $111.0 million as of June 30, 2004. We have no commercial products for sale, and we anticipate that we will incur substantial and increasing losses over the next several years as we expand our research, development and clinical trial activities, acquire or license technologies, scale up and improve our manufacturing operations, seek regulatory approval and, if we receive FDA approval, commercialize our products. Because of the numerous risks and uncertainties associated with our product development efforts, we are unable to predict whether or when we will achieve profitability. Our clinical trials and independent clinical trials using an earlier version of our technology, to date, have involved small numbers of patients, and we have not designed nor been required to design such trials to produce statistically significant results as to efficacy. These trials have neither been randomized nor blinded to ensure that the results are due to the effects of the Xcellerated T Cells. The results reported are preliminary and success in early clinical trials

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

Our Corporate Information

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

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THE OFFERING

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

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

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

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

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SUMMARY FINANCIAL DATA

The following summary financial data for the years ended December 31, 1999 through 2003 have been derived from our audited financial statements. The following summary financial data for the six-month periods ended June 30, 2003 and 2004, and the summary balance sheet data as of June 30, 2004 have been derived from our unaudited condensed financial statements. The unaudited condensed financial statements have been prepared on a basis consistent with our audited financial statements and include all adjustments we consider necessary for the fair presentation of the information. Operating results for the six months ended June 30, 2004 are not necessarily indicative of the results that may be expected for the entire year ending December 31, 2004. This information is only a summary and should be read together with the financial statements and the notes to those statements appearing elsewhere in this prospectus and the information under Selected Financial Data and Management s Discussion and Analysis of Financial Condition and Results of Operations.

	Years ended December 31,					Six months ended June 30,	
	1999	2000	2001	2002	2003	2003	2004
	(in thousands, except per share data)					(unaudited)	
Statement of Operations Data							
Total revenue	$ 16	$ 98	$ 30	$	$ 170	$ 72	$ 36
Operating expenses:							
Research and development	5,471	11,257	14,701	14,663	13,685	7,029	8,601
General and administrative	1,654	2,403	5,204	4,979	4,322	2,194	3,297
Total operating expenses	7,125	13,660	19,905	19,642	18,007	9,223	11,898
Loss from operations	(7,109)	(13,562)	(19,875)	(19,642)	(17,837)	(9,151)	(11,862)
Other income (expense), net	162						