TERCICA INC
Form 10-Q
August 16, 2004
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SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

x Quarterly report pursuant to Section 13 or 15(d) of the Securities and Exchange Act of 1934

For the Quarterly Period Ended June 30, 2004

OR

¨ Transition report pursuant to Section 13 or 15(d) of the Securities and Exchange Act of 1934

Commission File Number 000-50461

TERCICA, INC.

(Exact name of Registrant as specified in its charter)

Delaware	**26-0042539**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**

651 Gateway Boulevard

Suite 950

South San Francisco, CA 94080

(650) 624-4900

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

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 x No ¨

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

As of July 23, 2004, there were 24,550,442 shares of the Registrant s Common Stock outstanding.

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TERCICA, INC.

(A DEVELOPMENT STAGE COMPANY)

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

TERCICA, INC.

(A DEVELOPMENT STAGE COMPANY)

CONDENSED BALANCE SHEETS

(In thousands)

(Unaudited)

	June 30, 2004	December 31, 2003
Assets		
Current assets:		
Cash and cash equivalents	$ 12,300	$ 1,949
Short-term investments	56,705	35,364
Prepaid expenses and other current assets	1,715	2,772
Total current assets	70,720	40,085
Property and equipment, net	2,351	2,314
Other assets	50	85
Total assets	$ 73,121	$ 42,484
Liabilities and stockholders equity (deficit)		
Current liabilities:		
Accounts payable	$ 3,698	$ 5,351
Accrued expenses	1,158	1,214
Liability for early exercise of stock options	218	174
Total current liabilities	5,074	6,739
Liability for early exercise of stock options noncurrent portion	260	306
Commitments and contingencies		
Series A convertible preferred stock		24,853
Series B convertible preferred stock		43,784
Stockholders equity (deficit):		
Common stock	24	2
Additional paid-in capital	174,091	51,308

Deferred stock compensation	(8,535)	(5,984)
Accumulated other comprehensive loss	(150)	(18)
Deficit accumulated during the development stage	(97,643)	(78,506)
Total stockholders equity (deficit)	67,787	(33,198)
Total liabilities and stockholders equity (deficit)	$ 73,121	$ 42,484

See accompanying notes.

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TERCICA, INC.

(A DEVELOPMENT STAGE COMPANY)

CONDENSED STATEMENTS OF OPERATIONS

(In thousands, except share and per share data)

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,		Period from October 1, 2000 (inception) through June 30,
	2004	2003	2004	2003	2004
Costs and expenses:					
Research and development*	$ 7,157	$ 3,898	$ 12,830	$ 6,153	$ 34,537
Selling, general and administrative*	3,373	966	5,254	1,665	12,692
Acquired in-process research and development	1,167		1,417		8,157
Total costs and expenses	(11,697)	(4,864)	(19,501)	(7,818)	(55,386)
Interest expense					(106)
Interest and other income, net	250	32	364	76	878
Net loss	(11,447)	(4,832)	(19,137)	(7,742)	(54,614)
Deemed dividend related to beneficial conversion feature of convertible preferred stock					(44,153)
Net loss allocable to common stockholders	$ (11,447)	$ (4,832)	$ (19,137)	$ (7,742)	$ (98,767)
Basic and diluted net loss per share allocable to common stockholders	$ (0.48)	$ (2.77)	$ (1.32)	$ (4.56)	
Shares used to compute basic and diluted net loss per share allocable to common stockholders	23,851,898	1,747,200	14,543,829	1,695,976	
*Includes non-cash stock-based compensation expense as follows:					
Research and development	$ 361	$ 165	$ 751	$ 199	$ 1,546
Selling, general and administrative	346	2	738	2	996

Total	$ 707	$ 167	$ 1,489	$ 201	$ 2,542

See accompanying notes.

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TERCICA, INC.

(A DEVELOPMENT STAGE COMPANY)

CONDENSED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Six Months Ended June 30,		Period from October 1, 2000 (inception) through June 30,
	2004	2003	2004
Cash flows from operating activities:			
Net loss	$ (19,137)	$ (7,742)	$ (54,614)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	197	19	308
Property and equipment written-off			8
Amortization of deferred stock compensation	1,434	148	2,338
Amortization of premiums relating to available-for-sale securities	535		1,006
Stock compensation in exchange for consulting services	55	53	204
Issuance of warrants in connection with convertible note			105
Issuance of stock in exchange for intellectual property			130
Acquired in-process research and development			4,071
Changes in operating assets and liabilities:			
Prepaid expenses and other assets	1,092	(60)	(1,765)
Accounts payable	(1,653)	2,433	3,698
Accrued expenses	(57)	521	1,158
Net cash used in operating activities	(17,534)	(4,628)	(43,353)
Cash flows from investing activities:			
Purchases of property and equipment	(234)	(1,104)	(2,667)
Purchases of available-for-sale securities	(105,312)		(168,964)
Proceeds from sales and maturities of available-for-sale securities	83,305		111,104
Net cash used in investing activities	(22,241)	(1,104)	(60,527)
Cash flows from financing activities:			
Net proceeds from issuance of Class A and B shares			1,004
Liquidating distribution to Tercica Limited shareholders			(9)
Net proceeds from issuance of preferred stock			63,800
Proceeds from issuance of convertible note			500
Proceeds from issuance of Series A convertible preferred stock for exercise of warrants			160
Proceeds from issuance of common stock, excluding early exercised options	65		153

Proceeds from early exercised options	40	231	551
Net proceeds from initial public offering of common stock	50,021		50,021
Net cash provided by financing activities	50,126	231	116,180
Net increase (decrease) in cash and cash equivalents	10,351	(5,501)	12,300
Cash and cash equivalents, beginning of period	1,949	15,871	
Cash and cash equivalents, end of period	$ 12,300	$ 10,370	$ 12,300
Supplemental schedule of noncash activities:			
Issuance of stock in exchange for intellectual property	$	$	$ 130
Issuance of Series A convertible preferred stock to a collaboration partner in exchange for acquired in-process research and development	$	$	$ 4,071
Issuance of warrants in connection with convertible note	$	$	$ 105
Issuance of warrants as commissions in connection with Series A preferred stock financing	$	$	$ 41
Conversion of convertible note into Series A convertible preferred stock	$	$	$ 500
Issuance of common stock from vesting of early exercises of stock options	$ 42	$ 56	$ 145
Deferred stock compensation	$ 3,986	$ 3,206	$ 10,873
Deemed dividend related to beneficial conversion feature of convertible preferred stock	$	$	$ 44,153
Conversion of Series A and B convertible preferred stock into common stock	$ 68,636	$	$ 68,636

See accompanying notes.

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TERCICA, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO THE FINANCIAL STATEMENTS

(Unaudited)

1. Company and Summary of Significant Accounting Policies

Organization and Business

Tercica Limited, a New Zealand Company, was formed in October 2000. Tercica Medica, Inc. was incorporated in Delaware in December 2001, adopted the calendar year as its fiscal year and subsequently changed its name in September 2003 to Tercica, Inc. (the Company). In early 2002, the Company acquired (at amounts approximating Tercica Limited s historical net book value) an immaterial amount of assets, including intellectual property rights, from Tercica Limited as its operations were moved from New Zealand to California. In March 2002, Tercica Limited made a final, immaterial distribution to its stockholders in connection with its legal liquidation.

These development stage financial statements and accompanying notes include the results of operations from the inception of Tercica Limited in October 2000 as both entities were under common control as evidenced by the following factors: (i) all of the investors of Tercica Limited were founding stockholders of Tercica, Inc., (ii) substantially all of the employees of Tercica Limited became employees of Tercica, Inc., (iii) the nearly identical business plans adopted by both entities and (iv) the commencement of negotiations to obtain the Genentech license by Tercica Limited and the completion of those negotiations by Tercica, Inc. (the Company).

The Company is a biopharmaceutical company focused on the development of recombinant human insulin-like growth factor-1 (rhIGF-1) for the treatment of short stature, diabetes and other endocrine system disorders. The Company licensed from Genentech, Inc. its rights to rhIGF-1 for a broad range of indications, including for short stature worldwide and diabetes in the United States. The Company has Phase III clinical data for the use of rhIGF-1 in Severe Primary IGF-1 deficiency (IGFD). The Company intends to complete the validation of its rhIGF-1 manufacturing process and submit a New Drug Application with the United States Food and Drug Administration by early 2005 for this indication. The Company plans to initiate late-stage clinical trials for the use of rhIGF-1 in multiple other indications.

The Company is considered to be in the development stage as its primary activities since incorporation have been establishing its facilities, recruiting personnel, conducting research and development, business development, business and financial planning, and raising capital.

Basis of Presentation

The accompanying unaudited condensed financial statements have been prepared in accordance with the requirements of the Securities and Exchange Commission (SEC) for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by accounting principles generally accepted in the Unites States of America (GAAP) can be condensed or omitted. In the opinion of management, the financial statements include all normal and recurring adjustments that are considered necessary for the fair presentation of the Company s financial position and operating results.

The results of the Company s operations can vary during each quarter of the year. Therefore, the results and trends in these interim financial statements may not be the same as those for the full year. The information included in this quarterly report on Form 10-Q should be read in conjunction with the financial statements for the year ended December 31, 2003 and accompanying notes included in the Company s Registration Statement on Form S-1, as amended, declared effective by the SEC on March 16, 2004.

The condensed balance sheet at December 31, 2003 has been derived from the audited financial statements at that date but does not include all of the information and footnotes required by GAAP in the United States for complete financial statements.

Use of Estimates

The preparation of financial statements in conformity with GAAP in the United States requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

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TERCICA, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO THE FINANCIAL STATEMENTS (continued)

(Unaudited)

Research and Development Costs

In accordance with Statement of Financial Accounting Standards (SFAS) No. 2, *Accounting for Research and Development Costs*, research and development costs are expensed as incurred. Research and development expenses include payroll and personnel expenses, consulting expenses, laboratory supplies, and certain allocated expenses.

Acquired In-Process Research and Development

Acquired in-process research and development relates to in-licensed technology, intellectual property and know-how. The nature of the remaining efforts for completion of research and development activities surrounding rhIGF-1 generally include completion of clinical trials, completion of manufacturing validation, interpretation of clinical and preclinical data and obtaining marketing approval from the FDA and other foreign regulatory bodies, the cost, length and success of which are extremely difficult to determine. Numerous risks and uncertainties exist with timely completion of development projects, including clinical trial results, manufacturing process development results, and ongoing feedback from regulatory authorities, including obtaining marketing approval. In addition, products under development may never be successfully commercialized due to the uncertainties associated with the pricing of new pharmaceuticals, the cost of sales to produce these products in a commercial setting, changes in the reimbursement environment, or the introduction of new competitive products. As a result of the uncertainties noted above, the Company charges in-licensed intellectual property and licenses for unapproved products to acquired in-process research and development.

Stock Compensation

The Company accounts for employee stock options using the intrinsic-value method in accordance with Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees*, Financial Accounting Standards Board Interpretation (FIN) No. 44, *Accounting for Certain Transactions involving Stock Compensation*, *an interpretation of APB No. 25*, and related interpretations and has adopted the disclosure-only provisions of SFAS No. 123, *Accounting for Stock-Based Compensation,* as amended.

The Company has elected to continue to follow the intrinsic value method of accounting as prescribed by APB Opinion No. 25. The information regarding net loss as required by SFAS No. 123 has been determined as if the Company had accounted for its employee stock options under the fair value method of that Statement. The resulting effect on net loss pursuant to SFAS No. 123 is not likely to be representative of the effects on net loss pursuant to SFAS No. 123 in future years, since future years are likely to include additional grants and the irregular impact of future years vesting.

The fair value of each option grant is estimated at the date of grant using the Black-Scholes method with the following weighted-average assumptions:

	Three Months Ended June 30,		Six Months Ended June 30	
	2004	2003	2004	2003
Risk-free interest rate	3.1%	2.0%	2.7%	2.1%
Dividend yield				
Volatility factors	0.8	0.8	0.8	0.8
Weighted-average expected life of options (years)	4.0	3.9	3.8	3.9

During the six months ended June 30, 2004 and 2003, certain stock options were granted with exercise prices that were below the reassessed fair value of the common stock at the date of grant. Deferred compensation of $0 and $2.9 million for the three months ended June 30, 2004 and 2003, respectively, and $4.0 million and $3.2 million for the six months ended June 30, 2004 and 2003, respectively, was recorded in accordance with APB Opinion No. 25, and is being amortized over the related vesting period of the options. The Company recorded employee stock compensation expense of $0.7 million and $0.1 million for the three months ended June 30, 2004 and 2003, respectively, and $1.4 million and $0.1 million for the six months ended June 30, 2004 and 2003, respectively.

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TERCICA, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO THE FINANCIAL STATEMENTS (continued)

(Unaudited)

The following table illustrates the effect on net loss allocable to common stockholders had the Company applied the fair value provisions of SFAS No. 123 to employee stock compensation:

	Three Months Ended June 30,		Six Months Ended June 30		Period from October 1, 2000 (inception) through June 30,
(In thousands, except per share data)	**2004**	**2003**	**2004**	**2003**	**2004**
Net loss allocable to common stockholders, as reported	$ (11,447)	$ (4,832)	$ (19,137)	$ (7,742)	$ (98,767)
Plus: Employee stock compensation expense based on intrinsic value method	680	138	1,434	148	2,338
Less: Employee stock compensation expense determined under the fair value method for all awards	(772)	(64)	(1,458)	(81)	(2,455)
Pro forma net loss allocable to common stockholders	$ (11,539)	$ (4,758)	$ (19,161)	$ (7,675)	$ (98,884)
Net loss per share allocable to common stockholders:					
Basic and diluted, as reported	$ (0.48)	$ (2.77)	$ (1.32)	$ (4.56)	
Basic and diluted, pro forma	$ (0.48)	$ (2.72)	$ (1.32)	$ (4.53)	

Stock compensation arrangements to non-employees are accounted for in accordance with SFAS No. 123 and Emerging Issues Task Force (EITF) No. 96-18, *Accounting for Equity Instruments that Are Issued to Other than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*, using a fair value approach. The compensation costs of these arrangements are subject to remeasurement over the vesting terms as earned.

Recent Accounting Developments

In March 2004, the Financial Accounting Standards Board (FASB) issued a Proposed SFAS, *Share-Based Payment, an amendment of FASB Statements Nos. 123 and 95* (Exposure Draft). The Exposure Draft would eliminate the ability to account for share-based compensation transactions using APB Opinion No. 25, and generally would require such transactions be accounted for using a fair-value-based method and the resulting cost recognized in the financial statements. The Company is closely monitoring developments related to the Exposure Draft and will adopt the final standards, if any, upon issuance.

In March 2004, the FASB s Emerging Issues Task Force (EITF) reached a consensus on EITF 03-01, *The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments.* EITF 03-01 provides guidance regarding disclosures about unrealized losses on available-for-sale debt and equity securities accounted for under Statement of Financial Accounting Standard No. 115, *Accounting for Certain Investments in Debt and Equity Securities.* The guidance for evaluating whether an investment is other-than-temporarily impaired should be applied in other-than-temporary impairment evaluations made in reporting periods beginning after June 15, 2004. The Company s adoption of this EITF did not have a material effect on our financial position or results of operations.

Comprehensive Loss

Comprehensive loss is comprised of net loss and unrealized gains/losses on available-for-sale securities in accordance with SFAS No. 130, *Reporting Comprehensive Income*. The following table presents the calculation of comprehensive loss (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
Net loss, as reported	$ (11,447)	$ (4,832)	$ (19,137)	$ (7,742)
Change in unrealized gains (losses) on marketable securities	(152)		(132)	
Comprehensive Loss	$ (11,599)	$ (4,832)	$ (19,269)	$ (7,742)

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TERCICA, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO THE FINANCIAL STATEMENTS (continued)

(Unaudited)

Reclassifications

At December 31, 2003, the Company included approximately $10.1 million of floating rate debt in cash and cash equivalents as all the debt had interest rate reset features of not more than every 40 days. As such, while the debt had actual maturity dates extending well beyond 90 days, the interest rate reset feature of the debt was considered to create an effective maturity for the debt of less than 90 days and was therefore such amounts were included in cash equivalents. Upon further review, these instruments are more appropriately classified in short-term investments. Although certain of these investments may have a contractual maturity greater than one year, the Company has classified all investments as short-term given the fact they are all available for sale and available for use in the Company s current operations. Accordingly, the accompanying unaudited condensed balance sheet and statement of cash flows reflect the reclassification of these amounts from cash equivalents to short-term investments at December 31, 2003.

2. Initial Public Offering

On March 22, 2004, the Company completed its initial public offering of 5,500,000 shares of its common stock, at $9.00 per share. Net cash proceeds of the initial public offering were approximately $43.1 million, after deducting underwriter discounts, commissions and other offering expenses. In conjunction with the closing of the initial public offering, all of the Company s outstanding shares of Series A and Series B convertible preferred stock outstanding at the time of the offering were automatically converted into 15,297,308 shares of common stock.

On March 30, 2004, the underwriters of the Company s initial public offering exercised in full their over-allotment option for 825,000 shares of its common stock. On April 2, 2004, the Company received the net cash proceeds of approximately $6.9 million, after deducting underwriter discounts, commissions and other offering expenses.

In connection with the Company s initial public offering, all outstanding warrants to purchase 146,250 shares of common stock were net exercised resulting in 139,750 shares of common stock issued with the warrant for the remaining 6,500 shares relinquished as non-cash payment.

3. Net Loss Per Share

Basic net loss per share allocable to common stockholders is calculated by dividing the net loss allocable to common stockholders by the weighted-average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted net loss

per share allocable to common stockholders is computed by dividing the net loss allocable to common stockholders by the weighted-average number of common share equivalents outstanding for the period determined using the treasury-stock method. For purposes of this calculation, common stock subject to repurchase by the Company, preferred stock, options, and warrants are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive.

	Three Months Ended June 30,		Six Months Ended June 30,	
(In thousands, except share and per share data)	**2004**	**2003**	**2004**	**2003**
Historical				
Numerator:				
Net loss allocable to common stockholders	$ (11,447)	$ (4,832)	$ (19,137)	$ (7,742)
Denominator:				
Weighted-average common shares outstanding	23,933,118	1,879,036	14,630,889	1,846,567
Less: Weighted-average unvested common shares subject to repurchase	(81,220)	(131,836)	(87,060)	(150,591)
Denominator for basic and diluted net loss per share allocable to common stockholders	23,851,898	1,747,200	14,543,829	1,695,976
Basic and diluted net loss per share allocable to common stockholders	$ (0.48)	$ (2.77)	$ (1.32)	$ (4.56)

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TERCICA, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO THE FINANCIAL STATEMENTS (continued)

(Unaudited)

	Six Months Ended June 30,	
	2004	**2003**
Historical outstanding dilutive securities not included in diluted net loss per share allocable to common stockholders calculation		
Preferred stock		6,426,662
Warrants		146,250
Options to purchase common stock	1,999,736	1,009,098
	1,999,736	7,582,010

4. Cash, Cash Equivalents and Short-Term Investments

The following is a summary of available-for-sale securities (in thousands):

	June 30, 2004			
	Amortized Cost	**Gross Unrealized Gains**	**Gross Unrealized Losses**	**Fair Value**
Available-for-sale debt securities maturing within 1 year:				
Commercial paper	$ 12,955	$	$ (9)	$ 12,946
Corporate bonds	7,982		(20)	7,962
Federal agency bonds	30,953		(29)	30,924
Municipal bonds	16,570		(91)	16,479
Total available-for-sale debt securities	$ 68,460	$	$ (149)	$ 68,311

December 31, 2003

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Available-for-sale debt securities maturing within 1 year:				
Corporate bonds	$ 14,758	$	$ (13)	$ 14,745
Federal agency bonds	4,353		(3)	4,350
Floating rate bonds	10,100			10,100
Municipal bonds	6,171	4	(6)	6,169
Total available-for-sale debt securities	$ 35,382	$ 4	$ (22)	$ 35,364

The Company s financial instruments are classified as follows (in thousands):

	June 30, 2004	December 31, 2003
Cash	$ 694	$ 1,949
Cash equivalents	11,606	
Cash and cash equivalents	12,300	1,949
Short-term investments	56,705	35,364
Total	$ 69,005	$ 37,313

There were no realized gains or losses on the sale of available-for-sale securities for both periods presented.

5. Amended and Restated Certificate of Incorporation

On March 22, 2004, the Company amended and restated its certificate of incorporation to increase the authorized common stock from 20,500,000 to 100,000,000. The Company is also authorized to issue 5,000,000 shares of preferred stock.

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TERCICA, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO THE FINANCIAL STATEMENTS (continued)

(Unaudited)

6. Amended Lease Agreement

On June 28, 2004, the Company entered into an amended lease agreement to extend the lease term on its present facility. The lease term has been extended to June 2005. This amended agreement resulted in future minimum lease commitments of approximately $19,000 and $206,000 for the remainder of 2004 and fiscal year 2005, respectively.

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MANAGEMENT S DISCUSSION AND

ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This report includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities and Exchange Act of 1934, as amended. All statements other than statements of historical facts are forward-looking statements for purposes of these provisions, including any projections of earnings, revenues or other financial items, any statement of the plans and objectives of management for future operations, any statements concerning proposed new products or licensing or collaborative arrangements, any statements regarding future economic conditions or performance, and any statement of assumptions underlying any of the foregoing. In some cases, forward-looking statements can be identified by the use of terminology such as may, will, expects, plans, anticipates, estimates potential, or continue or the negative thereof or other comparable terminology. Although we believe that the expectations reflected in the forward-looking statements contained herein are reasonable, there can be no assurance that such expectations or any of the forward-looking statements will prove to be correct, and actual results could differ materially from those projected or assumed in the forward-looking statements. Our future financial condition and results of operations, as well as any forward-looking statements, are subject to inherent risks and uncertainties, including but not limited to the risk factors set forth below, and for the reasons described elsewhere in this report. All forward-looking statements and reasons why results may differ included in this report are made as of the date hereof, and we assume no obligation to update these forward-looking statements or reasons why actual results might differ.

Overview

We are a biopharmaceutical company focused on the development of recombinant human insulin-like growth factor-1 (rhIGF-1) for the treatment of short stature, diabetes and other endocrine system disorders. We licensed rights of Genentech, Inc. to rhIGF-1 for a broad range of indications, including for short stature worldwide and diabetes in the United States. We have Phase III clinical data for the use of rhIGF-1 in children with Severe Primary IGF-1 deficiency (IGFD). We intend to complete the validation of our rhIGF-1 manufacturing process and submit a New Drug Application (NDA) with the United States Food and Drug Administration (FDA) by early 2005 for this indication. We plan to initiate late-stage clinical trials for the use of rhIGF-1 in other indications, including Primary IGFD, which includes children with a less severe form of IGFD. In order to align our terminology with the academic literature and our regulatory filings, we have replaced the term Pediatric with Primary in characterizing the type of IGF-1 deficiency being addressed by rhIGF-1 therapy, and thus now use the terms Primary IGFD and Severe Primary IGFD. We believe there are approximately 30,000 children in the United States with Primary IGFD who are referred to pediatric endocrinologists for evaluation of their short stature, including 6,000 with Severe Primary IGFD.

Tercica, Inc. was formed in December 2001 as a Delaware corporation. In March 2002, Tercica, Inc. acquired an immaterial amount of assets, including intellectual property rights, from Tercica Limited, a New Zealand company that had been formed in October 2000. Tercica Limited then made a liquidating distribution to its stockholders in March 2002. Tercica Limited and Tercica, Inc. shared a common business strategy and overlapping stockholders. As such, our financial statements include the activities of Tercica Limited, as the predecessor to Tercica, Inc., from October 1, 2000.

In April 2002, we licensed from Genentech intellectual property to develop and commercialize rhIGF-1 for a broad range of indications, including short stature and diabetes in the United States. In December 2002, we entered into a development and commercial supply contract for the manufacture of bulk rhIGF-1 drug substance with Cambrex Baltimore. In July 2003, we signed an international license and collaboration agreement with Genentech obtaining its rights to develop and commercialize rhIGF-1 products outside of the United States for all indications other than diabetes and diseases and conditions of the central nervous system.

As of June 30, 2004, we had approximately $69.0 million in cash, cash equivalents and short-term investments. We have funded our operations since inception through the private placement of equity securities and an initial public offering of common stock. In 2002, we raised $20.0 million through the sale of shares of our Series A preferred stock. In 2003, we raised $43.8 million through the sale of shares of our Series B preferred stock. On March 17, 2004 we completed our initial public offering of common stock in which we raised net cash proceeds of approximately $43.1 million and received an additional $6.9 million of net cash proceeds on April 2, 2004 in connection with the underwriters exercise of the over-allotment option.

Revenues

We have not generated any operating revenues since our inception and do not expect to generate any revenue from the sale of our lead product candidate, rhIGF-1, until at least 2005, at the earliest.

Research and Development Expenses

Research and development expenses consist primarily of contract manufacturing expenses, payroll and related costs, consulting costs for the analysis of clinical trial results, costs associated with seeking regulatory approval for the marketing of our products, costs

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for planning our clinical trials and non-cash stock compensation. Our research and development activities are primarily focused on transferring and validating Genentech s commercial scale manufacturing process at our contract manufacturer and using that process to make drug product suitable for clinical use and sale, and development activities related to Primary IGFD. Because we licensed non-clinical, clinical and chemistry, manufacturing and controls data and know-how from Genentech in 2002, we did not incur significant development expenses prior to 2002. However, we expect to fund our own development activities and will continue to incur significant costs in the future. During 2003, our research and development activities were primarily focused on two projects: the transfer of our rhIGF-1 manufacturing process and the development project for Primary IGFD. At the end of 2003, we began to manage the development project for Severe Primary IGFD as a separate project from the development project for Primary IGFD and completed the transfer of Genentech s commercial scale manufacturing process at our contract manufacturer. Our primary focus in research and development in the first half of 2004 was associated with the establishment and validation of our rhIGF-1 manufacturing process at our contract manufacturer and preparations for the anticipated NDA filing in Severe Primary IGFD. We expect the remainder of 2004 to be focused on the establishment and validation of our rhIGF-1 manufacturing process at our contract manufacturers and completion of our development project for Severe Primary IGFD. Our projects or intended projects may be subject to change from time to time as we evaluate our research and development priorities and available resources.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of salaries and other related costs for personnel in corporate administration and marketing and non-cash stock compensation. Other costs include facility costs, insurance, information technology and professional fees for legal, marketing and accounting services. In the first six months of 2004, we continued to expand our staffing and infrastructure and initiated planning for sales and marketing activities.

Critical Accounting Policies and the Use of Estimates

The preparation of our financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in our financial statements and accompanying notes. Actual results could differ materially from those estimates. The items in our financial statements requiring significant estimates and judgments are as follows:

Stock Compensation

We account for employee stock options using the intrinsic-value method in accordance with Accounting Principles Board, or APB, Opinion No. 25, *Accounting for Stock Issued to Employees*, Financial Accounting Standards Board, or FASB, Interpretation No. 44, *Accounting for Certain Transactions involving Stock Compensation*, *an interpretation of APB No. 25*, and related interpretations and have adopted the disclosure-only provisions of Statement of Financial Accounting Standards, or SFAS, No. 123, *Accounting for Stock-Based Compensation*, or SFAS No. 123.

In December 2002, the FASB issued SFAS No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure*. SFAS No. 148 amends SFAS No. 123 to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. We have elected to continue to follow the intrinsic value method of accounting as prescribed by APB No. 25. The information regarding net loss as required by SFAS No. 123 has been determined as if we had accounted for our employee stock options under the fair value method of that statement. The resulting effect on net loss pursuant to SFAS No. 123 is not likely to be representative of the effects on net loss pursuant to SFAS No. 123 in future years, since future years are likely to include additional grants and the irregular impact of future years vesting.

Stock compensation expense, which is a non-cash charge, results from stock option grants at exercise prices below the deemed fair value of the underlying common stock resulting in our recording stock compensation associated with these grants. Stock compensation expense is amortized over the vesting period of the underlying option, generally four years. From inception through January 31, 2004, we recorded deferred stock compensation of $10.9 million. We did not record any deferred stock compensation subsequent to January 31, 2004. At June 30, 2004, we had a total of $8.5 million of deferred stock compensation remaining to be amortized over the vesting period of the stock options.

The total unamortized deferred stock compensation recorded for all option grants through January 31, 2004 will be amortized as follows: $2.8 million for the year ending December 31, 2004; $2.8 million for the year ending December 31, 2005; $2.7 million for the year ending December 31, 2006 and $1.7 million for the year ending December 31, 2007.

Acquired In-Process Research and Development

Acquired in-process research and development relates to in-licensed technology, intellectual property and know-how. The nature of the efforts for completion of research and development activities generally include completion of clinical trials, completion

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of manufacturing validation, interpretation of clinical and preclinical data and obtaining marketing approval from the FDA and other foreign regulatory bodies, the cost, length and success of which are extremely difficult to determine. Numerous risks and uncertainties exist with timely completion of development projects, including clinical trial results, manufacturing process development results, and ongoing feedback from regulatory authorities, including obtaining marketing approval. In addition, products under development may never be successfully commercialized due to the uncertainties associated with the pricing of new pharmaceuticals, the cost of sales to produce these products in a commercial setting, changes in the reimbursement environment, or the introduction of new competitive products. As a result of the uncertainties noted above, we charge in-licensed intellectual property and licenses for unapproved products to acquired in-process research and development.

Recent Accounting Developments

In March 2004, the FASB issued a proposed SFAS, *Share-Based Payment, an amendment of FASB Statements Nos. 123 and 95* (Exposure Draft). The Exposure Draft would eliminate the ability to account for share-based compensation transactions using APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and generally would require such transactions be accounted for using a fair-value-based method with the resulting cost recognized in the financial statements. We are closely monitoring developments related to the Exposure Draft and will adopt the final standard, if any, upon issuance.

In March 2004, the FASB s Emerging Issues Task Force (EITF) reached a consensus on EITF 03-01, *The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments.* EITF 03-01 provides guidance regarding disclosures about unrealized losses on available-for-sale debt and equity securities accounted for under Statement of Financial Accounting Standard No. 115, *Accounting for Certain Investments in Debt and Equity Securities.* The guidance for evaluating whether an investment is other-than-temporarily impaired should be applied in other-than-temporary impairment evaluations made in reporting periods beginning after June 15, 2004. Our adoption of this EITF did not have a material effect on our financial position or results of operations.

Results of Operations

Three Months Ended June 30, 2004 and 2003

Research and Development Expenses. Research and development expenses increased to $7.2 million for the three months ended June 30, 2004, from $3.9 million for the comparable period in 2003. The $7.2 million in expenses were comprised of project costs associated with the establishment of our rhIGF-1 manufacturing process at Cambrex Baltimore totaling $4.4 million, internal personnel and other costs totaling $2.1 million, and our development projects for Severe Primary IGFD and Primary IGFD totaling $0.7 million.

The $3.3 million increase over the comparable quarter in 2003 was due primarily to increased project costs for the establishment of our rhIGF-1 manufacturing process, which increased $1.6 million from the second quarter of 2003, increased personnel costs of $1.1 million and costs related to our development projects for Severe Primary IGFD and Primary IGFD, which increased $0.6 million. The Severe Primary IGFD and Primary IGFD project costs related primarily to several small studies and the review and analyses of the Phase III clinical trial data in preparation for the NDA filing.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased to $3.4 million for the three months ended June 30, 2004, from $1.0 million for the three months ended June 30, 2003. The increase of $2.4 million was primarily attributable to increased

headcount and non-cash stock compensation expenses of approximately $1.3 million; legal, marketing consultants and professional fees of approximately $0.6 million; and expenses of $0.5 million, primarily related to our public company status. We expect selling, general and administrative expenses to continue to increase substantially as we continue to expand staffing and infrastructure, and initiate our preparations for marketing and selling activities.

Acquired In-Process Research and Development. Acquired in-process research and development expense was approximately $1.2 million for the three months ended June 30, 2004. The costs resulted from a $1.2 million payment to Genentech related to the exclusive license to Genentech s worldwide rights to Insulin-like Growth Factor-1(IGF-1) combined with Insulin-like Growth Factor Binding Protein-3 (IGFBP-3) for all indications, other than diseases and conditions of the central nervous system and, outside of the United States, diabetes.

Interest and Other Income, net. Interest and other income, net, increased to $250,000 for the three months ended June 30, 2004, from $32,000 for the comparable period in 2003. The increase was due to interest on higher average cash, cash equivalents and short-term investment balances as a result of the cash proceeds received from the issuance of Series B preferred stock in July 2003 and from our initial public offering in March 2004.

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Six Months Ended June 30, 2004 and 2003

Research and Development Expenses. Research and development expenses increased to $12.8 million for the six months ended June 30, 2004, from $6.2 million for the comparable period in 2003. The $12.8 million in expenses were comprised of project costs associated with the establishment of our rhIGF-1 manufacturing process at Cambrex Baltimore totaling $7.2 million, internal personnel and other costs totaling $4.0 million, and our development projects for Severe Primary IGFD and Primary IGFD totaling $1.6 million.

In the six months ended June 30, 2004, project costs for the establishment of our rhIGF-1 manufacturing process increased $2.8 million from the comparable period in 2003, and were driven primarily by production activities at Cambrex Baltimore, including manufacturing batches of rhIGF-1 at large scale on a repeated basis, and evaluating the consistency, stability and quality of those batches. The remaining costs of establishing our rhIGF-1 manufacturing process will depend on the number of batches needed to show consistency, stability and quality of large scale rhIGF-1 production, including those costs associated with ensuring that production of drug substance and drug product is performed in a manner consistent with current good manufacturing practices (cGMP). The costs associated with our development projects for Severe Primary IGFD and Primary IGFD for the six months ended June 30, 2004 increased by approximately $1.3 million from the comparable period in 2003. The Severe Primary IGFD and Primary IGFD project costs related primarily to the review and analyses of the Phase III clinical trial data in preparation for an NDA filing. Other costs for the six months ended June 30, 2004 increased $2.6 million from the comparable period in 2003, which was substantially related to increased personnel costs.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased to $5.3 million for the six months ended June 30, 2004, from $1.7 million for comparable period in 2003. This increase of $3.6 million was primarily attributable to increased headcount and non-cash stock compensation expenses of approximately $2.3 million; legal, marketing consultants and professional fees of approximately $0.8 million; and expenses of $0.5 million, primarily related to our public company status. We expect selling, general and administrative expenses to continue to increase substantially as we continue to expand staffing and infrastructure, and initiate our preparations for marketing and selling activities.

Acquired In-Process Research and Development. Acquired in-process research and development expense was approximately $1.4 million for the six months ended June 30, 2004. The costs resulted from a $1.2 million payment to Genentech related to the exclusive license to Genentech s worldwide rights to IGF-1 combined with IGFBP-3 for all indications, other than diseases and conditions of the central nervous system and, outside of the United States, diabetes, and $250,000 of costs resulting from the execution of a patent license.

Interest and Other Income, net. Interest and other income, net, increased to $364,000 for the six months ended June 30, 2004, from $76,000 for the comparable period in 2003. The increase was due to interest on higher average cash, cash equivalents and short-term investment balances as a result of the cash proceeds received from the issuance of Series B preferred stock in July 2003 and from our initial public offering in March 2004.

Liquidity and Capital Resources

As of June 30, 2004, we had an accumulated deficit of $97.6 million, which is comprised of $53.4 million of accumulated net losses and $44.2 million of a non-cash deemed dividend related to the beneficial conversion feature of convertible preferred stock. We have funded our operations and growth from inception with net cash proceeds of $66.1 million in private equity financings and $50.0 million from our initial public offering of common stock.

Cash, cash equivalents and short term investments increased to $69.0 million at June 30, 2004 from $37.3 million at December 31, 2003 primarily due to net proceeds of $50.0 from the issuance our common stock in our initial public offering, partially offset by cash used in operating activities of $17.5 million. The increase in net cash used in operating activities was due to increased personnel and related costs associated with our growth, project costs related to establishment of our rhIGF-1 manufacturing process at Cambrex Baltimore, and our development projects for Severe Primary IGFD and Primary IGFD.

Net cash used in investing activities increased to $22.2 million in the six months ended June 30, 2004 as a result of net purchases of short-term investments. Net cash provided by financing activities for the six months ended June 30, 2004 increased to $50.1 million primarily as a result of net proceeds received from our initial public offering of common stock.

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Contractual Obligations and Commercial Commitments

Our contractual obligations as of June 30, 2004 were as follows (in thousands):

	Payments due by period				
		Less than			More than
	Total	1 year	1-3 years	3-5 years	5 years
Operating lease commitments	$ 567	$ 487	$ 51	$ 29	$

Our commitments for operating leases relate to leases for real estate covering our present facility. The leases will expire in June 2005.

We also have contractual payment obligations, the timing of which is contingent on future events. Under our license agreements with Genentech, payments of up to $1.5 million in total would be due if milestones relating to the initial product approvals of rhIGF-1 for Severe Primary IGFD in the United States and Europe are achieved. Additional milestone payments would be due for subsequent indication approvals, in both the United States and Europe. In May 2004, we paid $1.2 million to Genentech for license rights for rhIGF-1in combination with IGFBP-3.

Under our agreement with Cambrex Baltimore, we are obligated to reimburse Cambrex Baltimore on a time and materials and per batch basis in connection with the establishment of our rhIGF-1 manufacturing process. We estimate that our total purchase commitment to Cambrex Baltimore is approximately $8.5 million through December 31, 2005.

Operating Capital and Capital Expenditure Requirements

We believe that our cash, cash equivalents and short-term investments as of June 30, 2004 of $69.0 million will be sufficient to meet our projected operating requirements at least through 2005. Currently, we plan to make significant expenditures to establish and operate our rhIGF-1 drug substance manufacturing process at Cambrex Baltimore in a manner consistent with cGMPs, as well as to support our regulatory and clinical trial activities. We estimate the remaining costs to complete the establishment of our rhIGF-1 manufacturing process will be approximately $7.0 to $8.5 million through the end of 2004. We estimate that the remaining 2004 costs to prepare and submit an NDA filing for Severe Primary IGFD will be approximately $1.1 to $1.7 million. In late 2004 we intend to initiate a Phase III clinical trial for Primary IGFD, which we estimate will cost approximately $7.0 to $9.0 million and take approximately two years to complete. Our projects may be subject to change from time to time as we evaluate our research and development priorities and available resources.

Our future capital needs and the adequacy of our available funds will depend on many factors, including:

- the validation of our rhIGF-1 manufacturing process at Cambrex Baltimore, including the success of our cGMP production activities;

the success of drug product manufacturing and results of stability and product comparability studies performed at third-party contractors;

the rate of progress and cost of our future clinical trials and other research and development activities;

the costs and timing of domestic and international regulatory approvals for rhIGF-1;

the pace of expansion of administrative expenses;

the status of competing products; and

our ability to market and sell rhIGF-1.

Due to the significant risks and uncertainties inherent in the manufacturing, clinical development and regulatory approval processes, the costs to complete our projects through to product commercialization are not accurately predictable. Results from manufacturing development and clinical trials may not be favorable. Further, data from clinical trials is subject to varying interpretation, and may be deemed insufficient by the regulatory bodies reviewing applications for marketing approvals. As such, our development projects are subject to risks, uncertainties and changes that may significantly impact cost projections and timelines.

Our capital requirements may increase in future periods. As a result, we may require and attempt to raise additional funds through equity or debt financings, collaborative arrangements with corporate partners or from other sources. We have no commitments for any additional financings and additional funding may not be available to finance our operations when needed or on acceptable terms. Additional funding may also result in dilution to our stockholders. See also the disclosure under Part II, Item 2, Use of Proceeds.

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RISK FACTORS

FACTORS THAT MAY AFFECT FUTURE RESULTS

In addition to the other information contained in this Form 10-Q, we have identified the following additional risks and uncertainties that may have a material adverse effect on our business, financial condition or results of operations. Investors should carefully consider the risks described below before making an investment decision. The risks described below are not the only ones we face. Additional risks not presently known to us or that we currently believe are immaterial may also impair our business operations. Our business could be harmed by any of these risks. The trading price of our common stock could decline due to any of these risks and investors may lose all or part of their investment. This section should be read in conjunction with the Condensed Financial Statements and Notes thereto, and Management s Discussion and Analysis of Financial Condition and Results of Operations contained in this Form 10-Q.

Risks Related to Our Business

We are a development stage company with a limited operating history and may not be able to generate revenue or attain profitability.

We are a development stage company focused on the development and commercialization of recombinant human insulin-like growth factor-1 (rhIGF-1) for the treatment of short stature, diabetes, and other endocrine disorders. Since our inception in October 2000, we have accumulated a deficit of $97.6 million as of June 30, 2004 and have not generated any revenue from operations. We incurred a net loss of $19.1 million during the six months ended June 30, 2004. We expect to incur substantial net losses for the foreseeable future to further develop and commercialize rhIGF-1. We are unable to predict the extent of these future net losses, or when we may attain profitability, if at all. If we are unable to generate significant revenue from rhIGF-1 or attain profitability, we will not be able to sustain our operations.

If we lose our licenses from Genentech, we may be unable to continue our business.

We have licensed intellectual property rights and technology from Genentech, under our U.S. and International License and Collaboration agreements with Genentech. Under each agreement, Genentech has the right to terminate our license if we are in material breach of our obligations under that agreement and fail to cure that breach. Under the terms of the agreements, we are obligated, among other things, to use reasonable business efforts to meet specified milestones, including filing for regulatory approval in the United States for an IGFD indication by December 31, 2005 and for either a diabetes indication or a substitute indication by December 31, 2006. If we fail to use reasonable business efforts to meet our development milestones for either agreement, Genentech may terminate that agreement. If either agreement were terminated, then we would have no further rights to utilize the technology and intellectual property covered by that agreement to develop, manufacture and commercialize rhIGF-1 for any indication. This may prevent us from continuing our business.

We are subject to Genentech s option rights with respect to the development and commercialization of rhIGF-1 for all diabetes and non-orphan indications in the United States.

Under our U.S. License and Collaboration Agreement with Genentech, Genentech has the option to elect to jointly develop and commercialize rhIGF-1 for all diabetes and non-orphan indications in the United States. Orphan indications are designated by the United States Food and Drug Administration (FDA) under the Orphan Drug Act, and are generally rare diseases or conditions that affect fewer than 200,000 individuals in the United States. With respect to those rhIGF-1 indications in the United States, once Genentech has exercised its option to jointly develop and commercialize, Genentech has the final decision on disputes relating to development and commercialization of such indications. With respect to those rhIGF-1 indications in the United States for which Genentech either elects not to exercise its option, or has no right to exercise its option, our ability to sublicense the development and commercialization of such indications requires the consent of Genentech.

If we do not receive a regulatory marketing approval of rhIGF-1 for Severe Primary IGFD, our business will be harmed.

We need FDA approval to market rhIGF-1 for therapeutic uses in the United States. We are currently developing rhIGF-1 for the treatment of Severe Primary IGF-1 deficiency (IGFD), Primary IGFD, which includes children with a less severe form of IGFD, and diabetes. We are planning on filing in early 2005 a New Drug Application (NDA) in the United States for marketing rhIGF-1 for the treatment of Severe Primary IGFD. The FDA has substantial discretion in the approval process and may refuse to accept our NDA; may decide after review of our NDA that our data is insufficient to allow approval of rhIGF-1 for Severe Primary IGFD; and/or may limit our approval and/or restrict our marketing labeling to a small subset of patients with Severe Primary IGFD. We cannot predict the size of the subset of patients with Severe Primary IGFD to which the FDA may limit any marketing approval and rhIGF-1 labeling. If we fail to obtain the FDA s approval for the marketing of rhIGF-1 for this indication, our business will be harmed.

In the protocol for the Phase III clinical trial that we are using to support our NDA filing for Severe Primary IGFD, the disease being treated was identified as growth hormone insensitivity syndrome, or GHIS. Everywhere in this document where we discuss existing Phase III clinical trial results for rhIGF-1, such results were from children identified at the time as having GHIS. However, there are varying academic and clinical terminologies that describe children with growth hormone resistance and IGF-1 deficiency. We believe that the disease described by the term Severe Primary IGFD is substantially equivalent to the disease described by the term GHIS, relates to approximately the same number of pediatric patients, and more accurately describes the pediatric patient population for which we will be filing our NDA and seeking regulatory marketing approval.

If the FDA disagrees with us and determines that Severe Primary IGFD is not substantially equivalent to GHIS and/or that the number of children with GHIS are less than those with Severe Primary IGFD, the FDA may determine that our data do not support an NDA filing for Severe Primary IGFD; may not accept or approve our NDA for the treatment of Severe Primary IGFD; and/or may limit our approval and/or restrict our marketing labeling to a small subset of patients with Severe Primary IGFD. Even if the FDA agrees with us that Severe Primary IGFD is substantially equivalent to GHIS, the FDA may still determine that our data do not support an NDA filing for Severe Primary IGFD or GHIS; may not accept or approve our NDA for the treatment of Severe Primary IGFD or GHIS; and/or may limit our approval and/or restrict our marketing labeling to a small subset of patients with Severe Primary IGFD. Since our NDA filing and marketing approval for Severe Primary IGFD are key to our business plan and development of rhIGF-1, any of the FDA s determinations, requirements or labeling restrictions discussed above would substantially harm our business.

The means by which the FDA could restrict our marketing labeling could include, for example, requiring us to include in our rhIGF-1 labeling additional specific diagnostic tests to establish the diagnosis of Severe Primary IGFD and/or by requiring that children must fail to respond to treatment with growth hormone prior to being treated with rhIGF-1. Such requirements would add additional cost and complexity in making the diagnosis of Severe Primary IGFD and substantially limit the number of patients for whom our product is prescribed, which would substantially harm our business.

The regulatory review and marketing approval process in the United States, which includes evaluation of preclinical studies and clinical trials of our rhIGF-1 for Severe Primary IGFD, as well as the evaluation of our manufacturing process and our contract manufacturers facilities, is lengthy, expensive and uncertain. Securing FDA approval for rhIGF-1 for Severe Primary IGFD will require the submission of extensive preclinical and clinical data and supporting information to the FDA to establish rhIGF-1 s safety and effectiveness for this indication, as well as for any additional indications for which we seek marketing approval. We have limited experience in filing and pursuing applications necessary

to gain FDA approvals.

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We are currently validating our manufacturing process for rhIGF-1 at our contract manufacturers. If the FDA is not satisfied with our validation data, we may need to expend additional resources to conduct further studies to obtain data that the FDA believes is sufficient. Depending on the extent of these additional studies, approval of our NDA or other applications may be delayed by several years, or may require us to expend more resources than we have planned or are available. It is also possible that additional studies may not suffice to make our NDA or other applications approvable. If any of these outcomes occur, we may be forced to abandon our NDA or other applications for approval, which might cause us to cease operations.

We will need to file similar applications with regulatory authorities in foreign countries to market rhIGF-1 for any indications in those countries. We have not yet initiated the regulatory process in Europe. If we fail to obtain European approval or if such approval is delayed, the geographic market for rhIGF-1 would be limited.

Delays in validating the Genentech rhIGF-1 manufacturing process at our contract manufacturers may delay our NDA submission to the FDA.

Genentech developed a large-scale manufacturing process utilizing an *E. coli* fermentation process for the manufacture of rhIGF-1. We licensed this technology from Genentech and have transferred it to our contract manufacturer, Cambrex Bio Science Baltimore, Inc., a subsidiary of Cambrex Corporation. If our contract manufacturer experiences delays in the validation of this technology, our NDA submission to the FDA may be delayed. Because Genentech has not manufactured rhIGF-1 for at least five years, the manufacturing know-how that has been transferred may be inaccurate and/or incomplete. If we fail to validate our rhIGF-1 manufacturing process, we will not be able to commercialize rhIGF-1. If we are unable to replicate Genentech s manufacturing process in a timely manner, or at all, our commercialization of rhIGF-1 will be delayed or prevented.

As part of the NDA submission to the FDA, we have contracted with AAI Development Services, Inc. (AAI) to perform some of the testing and characterization work on our product. The Board of Directors of aaiPharma, the parent company of AAI, announced on March 1, 2004 that it appointed an independent committee to conduct an inquiry into unusual sales recorded in 2003. In a press release issued on April 27, 2004, aaiPharma identified financial adjustments relating to the recognition of revenue on certain transactions in 2003, and announced that it expected the reduction of revenue recognized for 2003 to be a material amount. On June 15, 2004, aaiPharma filed its annual report on Form 10-K for the year ended December 31, 2003 with the Securities and Exchange Commission reflecting restated financial statements for the fiscal year 2002 and each of the three quarters of 2002 and 2003. Numerous press releases have been issued since March 1, 2004 that provided updates on aaiPharma s financial condition. If aaiPharma s financial position results in business interruptions at AAI, our NDA submission may be delayed, while this work is re-assigned to an alternative contractor.

If we are unable to establish that our rhIGF-1 is comparable to that produced by Genentech, our ability to commercialize rhIGF-1 may be prevented or delayed.

All of our clinical trials were conducted using rhIGF-1 manufactured by Genentech. Our rhIGF-1 must be approved by the FDA or we will not be able to sell it. In order to obtain this approval, we intend to complete a comprehensive assessment program to demonstrate structural and functional comparability between the Genentech-manufactured rhIGF-1 and our rhIGF-1. If the FDA determines that this approach is insufficient to assess whether the manufacturing changes have affected the final product safety, identity, purity or potency of our rhIGF-1 compared to the rhIGF-1 used in the existing clinical studies, then the FDA could require us to conduct additional clinical trials. Repeating clinical trials would require us to incur significant expenses and would significantly delay the commercialization of rhIGF-1.

The differences between the production of the Genentech-manufactured rhIGF-1 and our rhIGF-1 include:

relocation of the manufacturing facility for bulk rhIGF-1 product from Genentech to Cambrex Baltimore;

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use of a new master cell bank derived from the Genentech master cell bank;

change of some of the raw material suppliers;

change of the final vial size, configuration and site of manufacture;

process changes;

analytical methods changes;

equipment used; and

a solvent used in the purification process.

Our comparability assessment will also require the evaluation of a number of technical parameters, such as the impurity profile and stability. Any of these factors could affect the comparability of the Genentech-manufactured rhIGF-1 and our rhIGF-1 and, as a result, delay our ability to commercialize rhIGF-1.

If our contract manufacturers facilities do not achieve a satisfactory good manufacturing practice inspection or if our contract manufacturers facilities become unavailable, we may be unable to sell rhIGF-1.

The facilities used by our contract manufacturers, including Cambrex Baltimore, to manufacture rhIGF-1 must undergo an inspection by the FDA for compliance with GMP regulations before rhIGF-1 can be approved. In the event these facilities do not receive a satisfactory GMP inspection for the manufacture of our product, we may need to fund additional modifications to our manufacturing process, conduct additional validation studies, or find alternative manufacturing facilities, any of which would result in significant cost to us as well as a delay of up to several years in obtaining approval for rhIGF-1. In addition, our contract manufacturers, and any alternative contract manufacturer we may utilize, will be subject to ongoing periodic inspection by the FDA and corresponding state and foreign agencies for compliance with GMP regulations and similar foreign standards. We do not have direct control over our contract manufacturers compliance with these regulations and standards.

Currently, Cambrex Baltimore is our sole provider of bulk rhIGF-1. We have no alternative manufacturing facilities or plans for additional facilities at this time. Cambrex Baltimore has never commercially manufactured rhIGF-1 for any party, including us. We do not know if the Cambrex Baltimore facility for the manufacture of rhIGF-1 will receive a satisfactory GMP inspection. If Cambrex Baltimore s facilities or any of our other contract manufacturers facilities become unavailable to us for any reason, including failure to comply with GMP regulations, damage from any event, including fire, flood, earthquake, or terrorism or if they fail to perform under our agreement with them, we may be unable to complete validation of rhIGF-1 or manufacture rhIGF-1. This could delay the approval of our NDA and our clinical trials, or delay or otherwise adversely affect revenues. If the damage to any of these facilities is extensive, or, for any reason, they do not operate in compliance with GMP or are unable or refuse to perform under our agreements, we will need to find alternative facilities. The number of contract manufacturers with the expertise and facilities to manufacture rhIGF-1 bulk drug substance on a commercial scale in accordance with GMP regulations is extremely limited, and it would take a significant amount of time and expense to arrange for alternative manufacturers. If we need to change to other commercial manufacturers, these manufacturers facilities and processes, prior to our use, would likely have to undergo GMP compliance inspections. In addition, we would need to transfer and validate the processes and analytical methods necessary for the production and testing of rhIGF-1 to these new manufacturers.

Any of these factors could delay or suspend clinical trials, regulatory submissions, regulatory approvals or commercialization of rhIGF-1, entail higher costs and result in our being unable to effectively commercialize rhIGF-1. Furthermore, if our contract manufacturers fail to deliver commercial quantities of bulk drug substance or finished product on a timely basis and at commercially reasonable prices, and we are unable to promptly find one or more replacement manufacturers capable of production at a substantially equivalent cost, in substantially equivalent volume and on a timely basis, we will likely be unable to meet demand for rhIGF-1, and we would lose potential revenues.

If another party obtains orphan drug and pediatric exclusivity for rhIGF-1 for children with IGFD, we may be precluded from commercializing rhIGF-1 in that indication.

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States. The company that obtains the first FDA approval for a designated orphan drug for a rare disease receives marketing exclusivity for use of that drug for the designated condition for a period of seven years. Pediatric exclusivity can provide an additional six months of market exclusivity. Although we intend to file for orphan drug designation and obtain pediatric exclusivity where appropriate, we have not yet sought

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pediatric exclusivity for any indication. If a competitor obtains approval of the same drug for the same indication or disease before us, we would be blocked from obtaining approval for our product for seven years, or seven and one-half years if pediatric exclusivity applies, unless our product can be shown to be clinically superior. In addition, more than one product may be approved by the FDA for the same orphan indication or disease as long as the products are different drugs. As a result, if our product is approved and receives orphan drug status, the FDA can still approve other drugs for use in treating the same indication or disease covered by our product, which could create a more competitive market for us.

Our rhIGF-1 has received from the FDA orphan drug designation for the treatment of growth hormone insufficiency (i.e., insensitivity) syndrome, or GHIS. We believe that the disease described by the term Severe Primary IGFD is substantially equivalent to the disease described by the term GHIS, relates to approximately the same number of pediatric patients, and more accurately describes the pediatric patient population for which we will be filing our NDA and seeking regulatory marketing approval. However, with respect to orphan drug designation, the FDA may determine that Severe Primary IGFD is not substantially equivalent to GHIS and/or that the number of children who have GHIS are less than those with Severe Primary IGFD. Accordingly, even if we were to receive an FDA marketing approval and rhIGF-1 labeling for Severe Primary IGFD, our orphan drug marketing designation and exclusivity may be limited to a small subset of children with Severe Primary IGFD. We cannot predict the size of the subset of children with Severe Primary IGFD to which our orphan drug marketing exclusivity may be limited. If we do not obtain orphan drug marketing exclusivity for Severe Primary IGFD, we could face competition for these patients and our business would be harmed.

We are aware of one other drug being developed by Insmed Incorporated, which we believe is a combination product containing rhIGF-1, that is in development for treatment of GHIS. This product has received an orphan drug designation from the FDA for the treatment of GHIS. The FDA could determine that this other product is the same drug as our product and is used for the same indication. If the FDA makes this determination and the other product is approved first, the approval of our rhIGF-1 for either Severe Primary IGFD or Primary IGFD could be blocked for up to seven and one-half years, which could force us to curtail or cease our operations. Even if our product is approved first, we may not be able to benefit from the orphan drug marketing exclusivity because products that are clinically superior may be approved for marketing by the FDA notwithstanding our initial approval and our initial orphan drug marketing exclusivity.

Clinical development is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our clinical trials.

To gain approval to market a product for treatment of a specific disease, we must provide the FDA and foreign regulatory authorities with clinical data that demonstrate the safety and statistically significant efficacy of that product for the treatment of the disease. Clinical development is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our clinical trials. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful. If a clinical trial failed to demonstrate statistically significant efficacy, we would likely abandon the development of that product, which could harm our business and may result in a precipitous decline in our stock price.

We do not know whether our planned clinical trials will begin on time, or at all, or will be completed on schedule, or at all.

The commencement or completion of any of our clinical trials may be delayed or halted for numerous reasons, including, but not limited to, the following:

the FDA or other regulatory authorities do not approve a clinical trial protocol or place a clinical trial on clinical hold;

patients do not enroll in clinical trials at the rate we expect;

patients experience adverse side effects;

patients could develop medical problems that are not related to our products or product candidates;

third-party clinical investigators do not perform our clinical trials on our anticipated schedule or consistent with the clinical trial protocol and good clinical practices, or other third-party organizations do not perform data collection and analysis in a timely or accurate manner;

our contract laboratories fail to follow good laboratory practices;

the interim results of the clinical trial are inconclusive or negative;

sufficient quantities of the trial drug may not be available;

our trial design, although approved, is inadequate to demonstrate safety and/or efficacy;

re-evaluation of our corporate strategies and priorities.

In addition, we may choose to cancel, change or delay certain planned clinical trials, or replace one or more planned clinical trials with alternative clinical trials. For example, we have previously stated our intention to initiate a Phase II clinical trial for Adult Primary IGFD in early 2005. While we still intend to pursue a clinical program in Adult IGFD, we do not intend to initiate a clinical trial in this area in early 2005, and cannot be sure as to when, if at all, we may initiate clinical trials in this area. We are currently evaluating multiple, existing trial results from the use of rhIGF-1 in diabetes in order to refine our conclusions and potential development plans and timelines for diabetes. Our clinical trials or intended clinical trials may be subject to further change from time to time as we evaluate our research and development priorities and available resources. Our development costs will increase if we need to perform more or larger clinical trials than planned. Significant delays for our current or planned clinical trials may harm the commercial prospects for our products and product candidates and our prospects for profitability.

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We face significant competition from large pharmaceutical, biotechnology and other companies that could harm our business.

The biotechnology industry is intensely competitive and characterized by rapid technological progress. In each of our potential product areas, we face significant competition from large pharmaceutical, biotechnology and other companies. Most of these companies have substantially greater capital resources, research and development staffs, facilities and experience at conducting clinical trials and obtaining regulatory approvals. In addition, many of these companies have greater experience and expertise in developing and commercializing products.

Since our product is under development, we cannot predict the relative competitive position of our product if it is approved for use. However, we expect that the following factors will determine our ability to compete effectively: safety and efficacy; product price; ease of administration; and marketing and sales capability.

We believe that many of our competitors spend significantly more on research and development-related activities than we do. Our competitors may discover new treatments, drugs or therapies or develop existing technologies to compete with our rhIGF-1. Our commercial opportunities will be reduced or eliminated if these competing products are more effective, have fewer or less severe side effects, are more convenient or are less expensive than our product.

Currently, no drug in the United States or Europe is approved as replacement therapy for the treatment of Severe Primary IGFD, Primary IGFD or Adult IGFD. To date, we believe that rhIGF-1 is the only treatment that has been specifically shown to be useful in treating children with Severe Primary IGFD. However, we believe Insmed has initiated clinical trials using a product containing rhIGF-1 in patients with a similar IGFD disorder. In addition, we are aware that Chiron Corporation has developed a process to manufacture rhIGF-1 using yeast expression, and have intellectual property with respect to that process. We use bacterial expression, which differs from yeast expression, to manufacture rhIGF-1.

Growth hormone may also be a competitive product for the treatment of some patients with Primary IGFD and Adult IGFD. Although patients with Primary IGFD and Adult IGFD are resistant to growth hormone, higher doses of growth hormone may be effective in these patients. The major suppliers of commercially available growth hormone are Genentech, Eli Lilly and Company, Novo Nordisk A/S, Pfizer Inc. and Serono S.A. We believe that Novo Nordisk is conducting clinical trials for the use of its growth hormone in Primary IGFD.

In addition, we believe that Genentech, Merck & Co., Inc., Novo Nordisk and Pfizer have previously conducted research and development of orally-available small molecules that cause the release of growth hormone, known as growth hormone secretagogues. We are not aware of any continued clinical development of these molecules by these companies. We believe that Rejuvenon Corporation has licensed certain rights to Novo Nordisk s growth hormone secretagogues, which are in preclinical development.

Many companies are seeking to develop products and therapies for the treatment of diabetes. Our competitors include multinational pharmaceutical companies, specialized biotechnology firms, and universities and other research institutions. Our largest competitors include Amylin Pharmaceuticals, Inc., Bristol-Myers Squibb Company, Eli Lilly, GlaxoSmithKline plc, Merck, Novartis AG, Novo Nordisk and Takeda Chemical Industries, Ltd. Various products are currently available to treat type 2 diabetes, such as insulin and oral hypoglycemic drugs.

In addition, several companies are developing various new approaches to improve the treatments of type 1 and type 2 diabetes. Specifically, Amylin Pharmaceuticals has conducted and is continuing to conduct clinical trials for two products, Symlin and Exenatide, for the treatment of

type 2 diabetes. Insmed has also conducted clinical trials using a product that contains rhIGF-1 for the treatment of diabetes. It is possible that there are other products currently in development or that exist on the market that may compete directly with rhIGF-1.

Competitors could develop and gain FDA approval of rhIGF-1, which could adversely affect our competitive position.

Although we are not aware of any other company currently marketing rhIGF-1 in the United States for any human therapeutic indication, rhIGF-1 manufactured by other parties may be approved for use in the United States in the future. In the event there are other rhIGF-1 products approved by the FDA to treat indications other than those covered by our product, physicians may elect to prescribe a competitor s rhIGF-1 to treat the indications for which our product has received approval. This is commonly referred to as off label use. While under FDA regulations a competitor is not allowed to promote off label use of its product, the FDA does not regulate the practice of medicine and as a result cannot direct physicians as to what rhIGF-1 to prescribe to their patients. As a result, we would have limited ability to prevent off label use of a competitor s rhIGF-1 to treat short stature even if it violates our method of use patents and/or we have orphan drug exclusivity for the use of rhIGF-1 to treat short stature.

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If we are unable to commercialize rhIGF-1, we will be unable to generate revenues, and our stock price will decline.

We have invested a significant portion of our time and financial resources since our inception in the development of rhIGF-1 for the treatment of short stature and diabetes. We anticipate that for the foreseeable future our ability to generate revenues and achieve profitability will be solely dependent on the successful commercialization of rhIGF-1 for the treatment of Severe Primary IGFD and Primary IGFD. Although we have Phase III clinical data for the use of rhIGF-1 replacement therapy in Severe Primary IGFD, there is no assurance we will be able to obtain FDA approval to market rhIGF-1 in the United States for this indication or any other indication. In addition, if we do receive FDA approval for rhIGF-1, we may receive approval for an indication which relates to a smaller patient population than Severe Primary IGFD, our initial target indication, which could limit our revenues significantly. We also intend to pursue the use of rhIGF-1 to treat particular diabetes indications. We will need additional intellectual property to commercialize rhIGF-1 for type A diabetes and we may need additional intellectual property to commercialize rhIGF-1 for type 2 diabetes with Severe Insulin Resistance. There can be no assurance we will obtain this intellectual property on reasonable terms, if at all. In addition, we need the consent of another company to commercialize rhIGF-1 for diabetes outside of the United States.

If we fail to protect our intellectual property rights, competitors may develop competing products, and our business will suffer.

lf we are not able to protect our proprietary technology, trade secrets and know-how, our competitors may use our inventions to develop competing products. We have licensed intellectual property rights, including patent rights, relating to rhIGF-1 technologies from Genentech. However, these patents may not protect us against our competitors, and patent litigation is very expensive. If we spend a significant portion of our cash, including the proceeds from this offering, we may be unable to pursue litigation to its conclusion because currently we do not generate revenues.

We do not have patent coverage on the rhIGF-1 protein. Although we have licensed from Genentech its rights to its methods of use and manufacturing patents, it may be more difficult to establish infringement of such patents as compared to a patent directed to the rhIGF-1 protein. Our licensed patents may not be sufficient to prevent others from competing with us. We cannot rely solely on our patents to be successful. The standards that the United States Patent and Trademark Office and foreign patent offices use to grant patents, and the standards that United States and foreign courts use to interpret patents, are not the same and are not always applied predictably or uniformly and can change, particularly as new technologies develop. As such, the degree of patent protection obtained in the United States may differ substantially from that obtained in various foreign countries. In some instances, patents have issued in the United States while substantially less or no protection has been obtained in Europe or other countries. Our United States patent No. 6,331,414 B1 licensed from Genentech is directed to methods for bacterial expression of rhIGF-1 and expires in 2018. We have no equivalent European patent. The European Patent Office has determined that the claims of Genentech s corresponding European patent application are not patentable under European patent law in view of public disclosures made before the application was filed.

We are uncertain of the level of protection, if any, that will be provided by our licensed patents if we attempt to enforce them and they are challenged in court where our competitors may raise defenses such as invalidity, unenforceability or possession of a valid license. In addition, the type and extent of patent claims that will be issued to us in the future are uncertain. Any patents which are issued may not contain claims that will permit us to stop competitors from using similar technology.

Applications to obtain additional patents are being pursued with the United States Patent and Trademark Office and the European Patent Office. Other than this activity, we are not aware of any pending legal or governmental proceedings, including interferences, involving any of the United States or European patent applications or patents owned by or licensed to us. We have not received any threats of litigation or other challenges to our owned or licensed United States or European patent rights from any governmental authority or third-party. In Japan, certain claims of one of the Japanese patents licensed to us have been revoked. We do not believe that the revocation of these claims will adversely affect our business.

In addition to the patented technology licensed from Genentech, we also rely on unpatented technology, trade secrets and confidential information, such as the proprietary information we use to manufacture rhIGF-1. We may not be able to effectively protect our rights to this technology or information. Other parties may independently develop substantially equivalent information and techniques or otherwise gain access to or disclose this technology. We generally require each of our employees, consultants, collaborators, and certain contractors to execute a confidentiality agreement at the commencement of an employment, consulting or collaborative relationship with us. However, these agreements may not provide effective protection of this technology or information or, in the event of unauthorized use or disclosure, they may not provide adequate remedies.

If there are fewer children with Severe Primary IGFD or Primary IGFD than we estimate, we may not generate sufficient revenues to continue development of other products or to continue operations.

If there are fewer children with Severe Primary IGFD or Primary IGFD than we estimate, we may not generate sufficient revenues to continue development of other indications or products and may cease operations. We estimate that the number of children in the United States

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with short stature is approximately one million, of which approximately 380,000 are referred to pediatric endocrinologists for evaluation. We believe that approximately 30,000 of these children have Primary IGFD. Our estimate of the size of the patient population is based on published studies as well as internal data, including our interpretation of a study conducted as part of Genentech s National Cooperative Growth Study program. This study reported results of the evaluation of the hormonal basis of short stature in approximately 6,450 children referred to pediatric endocrinologists over a four-year period. We believe that the population in Western Europe is comparable to that of the United States. We believe that the aggregate number of children in the United States and Western Europe with Primary IGFD is approximately 60,000, of which approximately 12,000 have Severe Primary IGFD. If the results of this study or our interpretation of and extrapolation from the study do not accurately reflect the number of children with Primary IGFD or Severe Primary IGFD, our assessment of the market may be wrong, making it difficult or impossible for us to meet our revenue goals.

rhIGF-1 may fail to achieve market acceptance, which could harm our business.

The use of rhIGF-1 has never been commercialized in the United States or Western Europe for any indication. Even if approved for sale by the appropriate regulatory authorities, physicians may not prescribe rhIGF-1, in which event we may be unable to generate significant revenue or become profitable.

Acceptance of rhIGF-1 will depend on a number of factors including:

- acceptance of rhIGF-1 by physicians and patients as a safe and effective treatment;
- adequate reimbursement by third-parties;
- relative convenience and ease of administration of rhIGF-1;
- prevalence and severity of side effects; and
- competitive product approvals.

Reimbursement may not be available for rhIGF-1, which could diminish our sales and impact our ability to achieve profitability.

Market acceptance, our sales of rhIGF-1 and our profitability may depend on reimbursement policies and health care reform measures. The levels at which government authorities and third-party payors, such as private health insurers and health maintenance organizations, reimburse the price patients pay for our product could affect whether we are able to commercialize our product. We believe that rhIGF-1 replacement therapy will be reimbursed to a similar extent that growth hormone therapy is reimbursed. If our assumption regarding reimbursement for rhIGF-1 replacement therapy is incorrect, our expected revenues may be substantially reduced. We cannot be sure that reimbursement in the United States or elsewhere will be available for our product. Also, we cannot be sure that reimbursement amounts will not reduce the demand for, or the price of, our product. We have not commenced efforts to have rhIGF-1 replacement treatment reimbursed by governments or third-party payors. If reimbursement is not available or is available only to limited levels, we may not be able to commercialize our product.

We believe that the price per patient of rhIGF-1 therapy for the treatment of Primary IGFD will not be less than the price per patient for growth hormone treatment of growth hormone deficiency in children. We believe that the price per patient for growth hormone treatment of growth hormone deficiency in children is approximately $20,000 per year. If our assumption regarding the price per patient of rhIGF-1 therapy for the treatment of Primary IGFD is incorrect, the market opportunity for rhIGF-1 therapy for the treatment of Primary IGFD may be substantially reduced.

In recent years, officials have made numerous proposals to change the health care system in the United States. These proposals include measures that would limit or prohibit payments for certain medical treatments or subject the pricing of drugs to government control. In addition, in many foreign countries, particularly the countries of the European Union, the pricing of prescription drugs is subject to government control. If our product becomes subject to government legislation that limits or prohibits payment for our product, or that subjects the price of our product to governmental control, we may not be able to generate revenues, attain profitability or commercialize our product. Because these initiatives are subject to substantial political debate which we cannot predict, the trading price of biotechnology stocks, including ours, may become more volatile as this debate proceeds.

As a result of legislative proposals and the trend towards managed health care in the United States, third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement of new drugs. They may also refuse to provide any coverage of uses of approved products for medical indications other than those for which the FDA has granted market approvals. As a result, significant uncertainty exists as to whether and how much third-party payors will reimburse patients for their use of newly approved drugs, which, in turn, will put pressure on the pricing of drugs.

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If we are unable to establish a direct sales force in the United States, our business may be harmed.

We currently do not have a sales organization. If rhIGF-1 is approved by the FDA for Severe Primary IGFD, we intend to market that therapy directly to pediatric endocrinologists in the United States through our own sales force. We will need to incur significant additional expenses and commit significant additional management resources to establish this sales force. We may not be able to establish these capabilities despite these additional expenditures. If we elect to rely on third-parties to sell rhIGF-1 in the United States, we may receive less revenue than if we sold it directly. In addition, we may have little or no control over the sales efforts of those third-parties. In the event we are unable to sell rhIGF-1, either directly or through third-parties, the commercialization of rhIGF-1 may be delayed and our business may be harmed.

We may need others to market and commercialize rhIGF-1 in international markets.

We currently intend to market our product in Europe through our own sales force. If, however, we decide to sell rhIGF-1 in Europe through a third-party, we will need to enter into marketing arrangements with them. We may not be able to enter into marketing arrangements with them on favorable terms, or at all. In addition, these arrangements could result in lower levels of income to us than if we marketed rhIGF-1 entirely on our own. In the event that we are unable to enter into a marketing arrangement for rhIGF-1 in international markets, we may not be able to develop an effective international sales force to successfully commercialize our product in Western Europe. If we fail to enter into marketing arrangements for our product and are unable to develop an effective international sales force, our revenues could be limited.

If we fail to identify and in-license other patent rights, products or product candidates, we may be unable to grow our revenues.

We do not conduct any preclinical laboratory research. Our strategy is to in-license products or product candidates and further develop them for commercialization. The market for acquiring and in-licensing patent rights, products and product candidates is intensely competitive. If we are not successful in identifying and in-licensing other patent rights, products or product candidates, we may be unable to grow our revenues with sales from new products. If the FDA only approves rhIGF-1 for Severe Primary IGFD, only our sales for that indication may be reimbursable. In this event, we would need to invest significant resources in discovery research and preclinical development to obtain new product candidates.

In addition, we may need additional intellectual property from other third-parties to commercialize rhIGF-1 for certain diabetes indications. We cannot be sure that we will be able to obtain a license to any third-party technology we may require to conduct our business.

If we fail to obtain the capital necessary to fund our operations, we will be unable to execute our business plan.

We believe that our existing cash and investment securities will be sufficient to meet our capital requirements through at least the end of 2005 based on our current business plan. We expect capital outlays and operating expenditures to increase over the next several years as we expand our operations. We may also need to spend more money than currently expected because we may change our product development plans or acquire additional products or product candidates. We have no committed sources of capital and do not know whether additional financing will be available when needed, or, if available, that the terms will be favorable. If additional funds are not available, we may be forced to curtail or cease operations.

If we are unable to manage our expected growth, we may not be able to implement our business plan.

Our ability to implement our business plan requires an effective planning and management process. As of June 30, 2004, we had 51 employees; however, we will need to hire a significant number of additional employees in the near term. Our offices are located in the San Francisco Bay area, where competition for personnel with biopharmaceutical skills is intense. If we fail to identify, attract, retain and motivate these highly skilled personnel, we may be unable to continue our development and commercialization activities.

We expect that our anticipated future growth will place a significant strain on our management, systems and resources. In particular, to fulfill our strategy to file an NDA by early 2005 and conduct clinical trials necessary to submit supplemental NDAs for additional indications for our rhIGF-1, we will need to hire a significant number of additional employees. To manage the anticipated growth of our operations, we will need to increase management resources and implement new financial and management controls, reporting systems and procedures. If we are unable to manage our growth, we could be unable to execute our business strategy.

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We may be required to conduct broad, long-term clinical trials to address concerns that the long-term use of rhIGF-1 by diabetics might increase the risk of diabetic retinopathy.

During the course of Genentech s clinical trials, concerns were raised that long-term use of rhIGF-1 in diabetic patients might lead to an increased incidence and/or severity of retinopathy, a disease of new blood vessel growth in the eye which results in loss of vision. Partly as a result of the scope and extended timeframe of the clinical trials necessary to address these concerns, Genentech discontinued development of rhIGF-1 for the treatment of diabetes. The FDA may require us to conduct broad, long-term clinical trials to address these concerns prior to receiving FDA approval for diabetes indications. These clinical trials would be expensive and could delay our commercialization of rhIGF-1 for diabetes indications. Adverse results in these trials could prevent our commercialization of rhIGF-1 for diabetes indications.

If product liability lawsuits are brought against us, we may incur substantial liabilities.

The testing, marketing, distributing and sale of drug products entail an inherent risk of product liability. Because our product is a growth factor, one potential risk of using rhIGF-1 is that it may increase the likelihood of developing cancer or, if patients already have cancer, that the cancer may develop more rapidly. Our rhIGF-1 product may also increase the risk that diabetic patients may develop or worsen an existing retinopathy, which could lead to the need for additional therapy such as laser treatment of the eyes or result in blindness. We have Phase III results from the treatment of 65 children with Severe Primary IGFD with rhIGF-1 replacement therapy for an average of 3.5 years, with some patients being treated for as many as 10 years. None of the 65 patients discontinued rhIGF-1 treatment due to safety concerns. However, some patients experienced hypoglycemia, or low blood glucose levels, or enlargement of the tonsils. Minor temporary hearing deficits were also noted in some patients.

There may also be other adverse events associated with the use of rhIGF-1 which may result in product liability suits being brought against us. While we have licensed the rights to develop and commercialize rhIGF-1 in certain indications, we are not indemnified by any third-party, including Genentech, for any liabilities arising out of the development of rhIGF-1.

Whether or not we are ultimately successful in defending product liability litigation, such litigation would consume substantial amounts of our financial and managerial resources, and might result in adverse publicity or reduced acceptance of our product in the market, all of which would impair our business. We have obtained clinical trial insurance and product liability insurance, however, we may not be able to maintain our clinical trial insurance or product liability insurance at an acceptable cost, if at all, and this insurance may not provide adequate coverage against potential claims or losses.

If third-party clinical research organizations do not perform in an acceptable and timely manner, our clinical trials could be delayed or unsuccessful.

We do not have the ability to conduct all of our clinical trials independently. We intend to rely on clinical investigators, third-party clinical research organizations, and consultants to perform a substantial portion of these functions. If we cannot locate acceptable contractors to run our clinical trials or enter into favorable agreements with them, or if these third-parties do not successfully carry out their contractual duties, satisfy FDA requirements for the conduct of clinical trials, or meet expected deadlines, we will be unable to obtain required approvals and will be unable to commercialize rhIGF-1 on a timely basis, if at all.

We may incur substantial costs as a result of litigation or other proceedings relating to orphan drug approvals, patent and other intellectual property rights and we may be unable to protect our intellectual property rights.

If the FDA determines that another company s drug is the same product as our rhIGF-1, and it considers approving that product for Severe Primary IGFD, or a similar indication or disease before our product is approved, we may have no other recourse than to consider legal action against the FDA to prevent the other company s product from being approved and blocking approval of our product. If the FDA considers approving such a drug at the same time or after our product is approved, we may again have no other recourse than to consider legal action against the FDA to prevent the other company s product from being approved and losing our orphan drug marketing exclusivity. There is a risk that the courts may defer to the FDA.

With regard to patent matters, if we choose to go to court to stop someone else from using the inventions claimed in our patents, including those we have licensed from Genentech, which are directed specifically to rhIGF-1 or IGF binding protein-3 (IGFBP-3) technologies, that individual or company has the right to ask the court to rule that these patents are invalid, unenforceable, not infringed or validly licensed to that third-party, and should not be enforced against that third-party. Although we are not involved in any patent litigation, these lawsuits are expensive and would consume time and other resources even if we were successful in stopping the infringement of these patents. In addition, there is a risk that the court will decide that the patents we licensed from Genentech are not valid and that we do not have the right to stop the other party from using the inventions.

In addition, a third-party may claim that we are using its inventions covered by its patents and may go to court to stop us from engaging in our normal operations and activities. Although no third-party has claimed that we are infringing on their patents, patent lawsuits are costly and could affect our results of operations and divert the attention of managerial and technical personnel. There is a

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risk that a court would decide that we are infringing the third-party s patents and would order us to stop the activities covered by the patents. In addition, there is a risk that a court will order us to pay the other party damages for having infringed the other party s patents. The biotechnology industry has produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our products or methods of use do not infringe the patent claims of the relevant patent and/or that the patent claims are invalid, and we may not be able to do so. Proving invalidity, in particular, is difficult since it requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents.

We cannot be certain that others have not filed patent applications for technology covered by our licensor s issued patents or our pending applications or our licensor s pending applications or that we or our licensors were the first to invent the technology because:

- some patent applications in the United States may be maintained in secrecy until the patents are issued,
- patent applications in the United States and many foreign jurisdictions are typically not published until eighteen months after filing, and
- publications in the scientific literature often lag behind actual discoveries and the filing of patents relating to those discoveries.

Patent applications may have been filed and may be filed in the future covering technology similar to ours. Any such patent application may have priority over our patent applications and could further require us to obtain rights to issued patents covering such technologies. In the event that another party has filed a United States patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the United States Patent and Trademark Office to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful, resulting in a loss of our United States patent position with respect to such inventions.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could harm our business.

Budgetary or cash constraints may force us to delay our efforts to develop certain research and development programs in favor of developing others, which may prevent us from meeting our stated timetables and completing these projects through to product commercialization.

Because we are an emerging company with limited resources, and because research and development is an expensive process, we must regularly assess the most efficient allocation of our research and development resources. Accordingly, we may choose to delay or abandon our research and development efforts for the treatment of a particular indication or project to allocate those resources to another indication or project, which could cause us to fall behind our initial timetables for development. As a result, we may not be able to fully realize the value of some of our product candidates in a timely manner, since they will be delayed in reaching the market, or may not reach the market at all.

If we are unable to attract and retain additional qualified personnel, our ability to commercialize rhIGF-1 and develop other product candidates will be harmed.

Our success depends on our continued ability to attract and retain highly qualified management and scientific personnel and on our ability to develop relationships with leading academic scientists and clinicians. We are highly dependent on our current management and key medical, scientific and technical personnel, including Dr. John A. Scarlett, our President and Chief Executive Officer; Dr. Ross G. Clark, our Chief Technical Officer; Thomas H. Silberg, our Chief Operating Officer; Timothy P. Lynch, our Chief Financial Officer and Treasurer; and Stephen N. Rosenfield, our General Counsel and Secretary, whose knowledge of our industry and technical expertise would be extremely difficult to replace. In addition, we have not obtained life insurance benefiting us if any of our key employees left or was seriously injured and unable to work.

We have employment contracts with all of our executive officers. Each of these employment relationships is at will. All of our executive officers may terminate their employment without notice and without cause or good reason, except for Mr. Lynch. Mr. Lynch may terminate his employment with two weeks notice to us and without cause or good reason. We may terminate any of our executive officers without cause, in which event they would be entitled to severance payments. In the event of a change in control, we may be obligated to make severance payments and to accelerate the vesting of certain stock options.

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Risks Related to Our Common Stock

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

Our directors, executive officers and principal stockholders and their affiliates beneficially own approximately 80% of our common stock. As a result, they collectively will have the ability to determine the election of all of our directors and to determine the outcome of most corporate actions requiring stockholder approval. They may exercise this ability in a manner that advances their best interests and not necessarily those of other stockholders.

Anti-takeover provisions in our charter documents and under Delaware law may make an acquisition of us, which may be beneficial to our stockholders, more difficult.

Provisions of our amended and restated certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third-party to acquire us, even if doing so would benefit our stockholders. These provisions:

- establish a classified board of directors so that not all members of our board may be elected at one time;
- authorize the issuance of blank check preferred stock that could be issued by our board of directors to increase the number of outstanding shares and hinder a takeover attempt;
- limit who may call a special meeting of stockholders;
- prohibit stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders; and
- establish advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted upon at stockholder meetings.

In addition, Section 203 of the Delaware General Corporation Law, which prohibits business combinations between us and one or more significant stockholders unless specified conditions are met, may discourage, delay or prevent a third-party from acquiring us.

Our stock price may be volatile, and your investment in our stock could decline in value.

The trading price of our common stock has fluctuated significantly since our initial public offering in March 2004, and is likely to remain volatile in the future. The trading price of our common stock could be subject to wide fluctuations in response to many events or factors, including the following:

estimates of our business potential and earnings prospects;

an assessment of our management;

quarterly variations in our operating results;

significant developments in the businesses of biotechnology companies;

changes in financial estimates by securities analysts;

changes in market valuations or financial results of biotechnology companies;

announcements by us or our competitors of new trial results, regulatory developments, new products, or significant acquisitions, strategic partnerships or joint ventures;

any deviation from projections regarding business potential and earnings prospects;

additions or departures of key personnel;

changes in the structure of healthcare payment systems;

activities of short sellers and risk arbitrageurs;

future sales of our common stock;

general economic, industry and market conditions; and

volume fluctuations, which are particularly common among highly volatile securities of biotechnology companies.

In addition, the stock market has experienced volatility that has particularly affected the market prices of equity securities of many biotechnology companies, which often has been unrelated or disproportionate to the operating performance of these companies. These broad market fluctuations may adversely affect the market price of our common stock. If the market price of our common stock declines in value, you may not realize any return on your investment in us and may lose some or all of your investment.

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We are at risk of securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology companies have experienced greater than average stock price volatility in recent years. If we faced such litigation, it could result in substantial costs and a diversion of management s attention and resources, which could harm our business.

Substantial sales of shares may impact the market price of our common stock.

If our stockholders sell substantial amounts of our common stock, including shares issued upon the exercise of outstanding options, the market price of our common stock may decline. 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 that we deem appropriate. We are unable to predict the effect that sales may have on the prevailing market price of our common stock. As of June 30, 2004, we have 24,550,442 outstanding shares of common stock. Of these shares, the 6,325,000 shares sold in our initial public offering were freely tradable without restriction or further regulation, other than shares purchased by our officers, directors or other affiliates within the meaning of Rule 144 under the Securities Act of 1933. The remaining 18,225,442 shares of common stock were issued prior to our initial public offering or pursuant to options or warrants granted prior to the initial public offering, and may not be sold publicly unless they are registered under the Securities Act or are sold pursuant to Rule 144 or another exemption from registration. These shares will become eligible for public resale at various times over a period of less than one year following the completion of our initial public offering, subject to volume limitations and certain restrictions on sales by affiliates.

We, our executive officers and directors and principal stockholders and their affiliates holding an aggregate of 20,221,477 shares as of June 30, 2004 have entered into agreements not to sell or offer to sell or otherwise dispose of any shares of common stock held by us or them for a period of 180 days after the date of our offering without the prior written consent of Lehman Brothers Inc. which may release any or all of the shares subject to lock-up agreements at any time without notice. We have filed a registration statement covering shares of common stock issuable upon exercise of options and other grants pursuant to our stock plans. In addition, assuming no exercise of outstanding options after June 30, 2004, the holders of 17,296,568 shares of common stock are entitled to registration rights.

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Item 3. Qualitative and Quantitative Disclosures About Market Risk

The primary objective of our investment activities is to preserve our capital for the purpose of funding operations while at the same time maximizing the income we receive from our investments without significantly increasing risk. To achieve these objectives, our investment policy allows us to maintain a portfolio of cash equivalents and short-term investments in a variety of securities, including commercial paper, money market funds and corporate debt securities. Our cash and cash equivalents through June 30, 2004 included liquid money market accounts. Our short-term investments included readily marketable debt securities. Due to the short-term nature of these instruments, a 1% movement in market interest rates would not have a significant impact on the total value of our portfolio as of June 30, 2004.

Item 4. Controls and Procedures

Evaluation of disclosure controls and procedures

Based on their evaluation as of June 30, 2004, our chief executive officer and chief financial officer, with the participation of management, have concluded that our disclosure controls and procedures (as defined in Rules 13a 15(e) and 15d 15(e) of the Securities Exchange Act of 1934) were effective to ensure that the information required to be disclosed by us in this quarterly report on Form 10-Q was recorded, processed, summarized and reported within the time periods specified in the SEC s rules and Form 10-Q.

Changes in internal controls

There were no changes in our internal controls over financial reporting during the quarter ended June 30, 2004 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the effectiveness of controls

Our disclosure controls and procedures provide our Chief Executive Officer and Chief Financial Officer reasonable assurances that our disclosure controls and procedures will achieve their objectives. However, company management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal controls will prevent all human error. A control system, no matter how well designed and implemented, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Furthermore, the design of a control system must reflect the fact that there are internal resource constraints, and the benefit of controls must be weighed relative to their corresponding costs. Because of the limitations in all control systems, no evaluation of controls can provide complete assurance that all control issues and instances of error, if any, within our company are detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur due to human error or mistake. Additionally, controls, no matter how well designed, could be circumvented by the individual acts of specific persons within the organization. The design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated objectives under all potential future conditions.

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Part II. Other Information

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

On March 22, 2004, we completed our initial public offering of 5,500,000 shares of our common stock at $9 per share. On April 2, 2004, we received net cash proceeds from the issuance of 825,000 shares of common stock in connection with the underwriters exercise of the over-allotment option. The managing underwriters in the offering were Lehman Brothers, SG Cowen, Harris Nesbitt Gerard and Robert W. Baird & Co. The shares of common stock sold in the offering were registered under the Securities Act of 1933, as amended, on a Registration Statement on Form S-1 (File No. 333-108729) that was declared effective by the SEC on March 16, 2004. Our offering commenced on March 17, 2004. The aggregate purchase price of the offering was $56,925,000. The net offering proceeds to us after deducting total expenses were $50,021,000. We incurred total estimated expenses in connection with the offering of $6,904,000, which consisted of:

(i) $2,736,000 in legal, accounting and printing fees;

(ii) $3,985,000 in underwriters discounts, fees and commissions; and

(iii) $183,000 in miscellaneous expenses.

Immediately prior to the first closing of the initial public offering, all of our outstanding preferred stock, par value of $0.001 per share, automatically converted into an aggregate of 15,297,308 shares of common stock. In addition, all outstanding warrants were fully exercised which resulted in a net issuance of 139,750 shares of common stock.

No payments for such expenses were made directly or indirectly to (i) any of our directors, officers or their associates, (ii) any person(s) owning 10% or more of any class of our equity securities or (iii) any of our affiliates.

As of June 30, 2004, we had cash, cash equivalents and short-term investments of $69.0 million, which includes the net cash proceeds from our initial public offering of 5,500,000 shares of common stock and the underwriters exercise of their over-allotment option. The net offering proceeds have been invested into short-term investment-grade securities and cash equivalents. We have not used any of the net cash proceeds from the initial public offering for operational purposes as of June 30, 2004.

We will retain broad discretion over the use of the net proceeds received from our offering. The amount and timing of our actual expenditures may vary significantly depending on numerous factors, such as the progress of our product development and commercialization efforts and the amount of cash used by our operations.

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Item 6. Exhibits and Reports on Form 8-K

(a) Exhibits

3.1	Amended and Restated Certificate of Incorporation of Tercica, Inc., dated March 22, 2004. (1)
3.2	By-laws of Tercica (2)
4.1	Form of Specimen Stock Certificate (2)
10.6E	Second Amendment to Lease Agreement between Gateway Center, LLC and Tercica Inc., dated June 28, 2004.
10.9L	Employment letter between Tercica, Inc. and Stephen Rosenfield, dated June 23, 2004.
31.1	Certification of Chief Executive Officer of Tercica, Inc., as required by Rule 13a-14(a) or Rule 15d-14(a).
31.2	Certification of Chief Financial Officer of Tercica, Inc., as required by Rule 13a-14(a) or Rule 15d-14(a).
32.1	Certification by the Chief Executive Officer, as required by Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350).
32.2	Certification by the Chief Financial Officer, as required by Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350).

(b) Reports on Form 8-K

On May 4, 2004, we filed a current report on Form 8-K describing and furnishing the press release announcing our financial results for the quarter ended March 31, 2004. The press release included condensed statements of operations and selected balance sheet data.

(1) Filed as an exhibit to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2004.
(2) Filed as an exhibit to the Registrant s Registration Statement on Form S-1 (File No. 333-108729), initially filed with the Securities and Exchange Commission on September 12, 2003, as amended, as declared effective by the Securities and Exchange Commission on March 16, 2004.

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SIGNATURE

Pursuant to the requirements of the Securities and Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Dated: August 16, 2004

TERCICA, INC.
(Registrant)

/s/ Timothy P. Lynch

Timothy P. Lynch
Chief Financial Officer
(Authorized Officer and Principal Accounting and Financial Officer)