TERCICA INC
Form 10-Q
May 13, 2004
Table of Contents

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 March 31, 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 ¨ No x

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

As of April 30, 2004 there were 24,530,503 shares of the Registrant s Common Stock outstanding.

Table of Contents

TERCICA, INC.

(A DEVELOPMENT STAGE COMPANY)

INDEX

Table of Contents

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

TERCICA, INC.

(A DEVELOPMENT STAGE COMPANY)

CONDENSED BALANCE SHEETS

(In thousands)

(Unaudited)

	March 31, 2004	December 31, 2003
Assets		
Current assets:		
Cash and cash equivalents	$ 28,709	$ 12,049
Short-term investments	44,442	25,264
Stock subscription receivable	6,905	
Prepaid expenses and other current assets	1,195	2,772
Total current assets	81,251	40,085
Property and equipment, net	2,380	2,314
Other assets	50	85
Total assets	$ 83,681	$ 42,484
Liabilities and stockholders equity (deficit)		
Current liabilities:		
Accounts payable	$ 3,856	$ 5,351
Accrued expenses	657	1,214
Liability for early exercise of stock options	198	174
Total current liabilities	4,711	6,739
Liability for early exercise of stock options noncurrent portion	298	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	174,056	51,308
Deferred stock compensation	(9,215)	(5,984)
Accumulated other comprehensive income (loss)	3	(18)
Deficit accumulated during the development stage	(86,196)	(78,506)
Total stockholders equity (deficit)	78,672	(33,198)
Total liabilities and stockholders equity (deficit)	$ 83,681	$ 42,484

See accompanying notes.

Table of Contents

TERCICA, INC.

(A DEVELOPMENT STAGE COMPANY)

CONDENSED STATEMENTS OF OPERATIONS

(In thousands, except share and per share data)

(Unaudited)

	Three Months Ended March 31,		Period from October 1, 2000 (inception) through March 31,
	2004	2003	2004
Costs and expenses:			
Research and development*	$ 5,674	$ 2,255	$ 27,380
Selling, general and administrative*	1,881	699	9,320
Acquired in-process research and development	250		6,990
Total costs and expenses	(7,805)	(2,954)	(43,690)
Interest expense			(106)
Interest and other income, net	115	44	629
Net loss	(7,690)	(2,910)	(43,167)
Deemed dividend related to beneficial conversion feature of convertible preferred stock			(44,153)
Net loss allocable to common stockholders	$ (7,690)	$ (2,910)	$ (87,320)
Basic and diluted net loss per share allocable to common stockholders	$ (1.47)	$ (1.77)	
Shares used to compute basic and diluted net loss per share allocable to common stockholders	5,235,759	1,644,182	
Pro forma basic and diluted net loss per share allocable to common stockholders	$ (0.42)	$ (0.36)	
Shares used to compute pro forma basic and diluted net loss per share allocable to common stockholders	18,179,635	8,070,842	
* Includes non-cash stock-based compensation expense as follows:			
Research and development	$ 390	$ 34	$ 1,039

Selling, general and administrative	392		647
Total	$ 782	$ 34	$ 1,686

See accompanying notes.

Table of Contents

TERCICA, INC.

(A DEVELOPMENT STAGE COMPANY)

CONDENSED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Three Months Ended March 31,		Period from October 1, 2000 (inception) through March 31,
	2004	2003	2004
Cash flows from operating activities:			
Net loss	$ (7,690)	$ (2,910)	$ (43,167)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	94	8	205
Property and equipment written-off			8
Amortization of deferred stock compensation	755	10	1,659
Amortization of premiums relating to available-for-sale securities	283		753
Stock compensation to consultants in exchange for services	27	24	177
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	1,611	275	(1,245)
Accounts payable	(1,495)	617	3,856
Accrued expenses	(558)	33	657
Net cash used in operating activities	(6,973)	(1,943)	(32,791)
Cash flows from investing activities:			
Purchases of property and equipment	(160)	(498)	(2,593)
Purchases of available-for-sale securities	(19,440)		(48,693)
Proceeds from sale of available-for-sale securities			3,500
Net cash used in investing activities	(19,600)	(498)	(47,786)
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		206	88

Proceeds from early exercised options	40		551
Net proceeds from initial public offering of common stock	43,193		43,192
Net cash provided by financing activities	43,233	206	109,286
Net increase (decrease) in cash and cash equivalents	16,660	(2,235)	28,709
Cash and cash equivalents, beginning of period	12,049	15,871	
Cash and cash equivalents, end of period	$ 28,709	$ 13,636	$ 28,709
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	$ 24	$	$ 126
Deferred stock compensation	$ 3,986	$ 307	$ 10,873
Deemed dividend related to beneficial conversion feature of convertible preferred stock	$	$	$ 44,153
Issuance of common stock for stock subscription receivable	$ 6,905	$	$ 6,905
Conversion of Series A and B convertible preferred stock into common stock	$ 68,636	$	$ 68,636
Issuance of common stock upon net exercise of warrants	$ 140	$	$ 140

See accompanying notes.

Table of Contents

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. (Genentech) 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 Pediatric 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 U.S. GAAP 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.

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

Table of Contents

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 March 31,	
	2004	2003
Risk-free interest rate	2.6%	2.3%
Dividend yield		
Volatility factors	0.8	0.8
Weighted-average expected life of options (years)	3.9	4.0

During the three months ended March 31, 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 $4.0 million and $0.3 million for the three months ended March 31, 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 $0.8 million and $10,000 for the three months ended March 31, 2004 and 2003, respectively.

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:

(In thousands, except per share data)	Three Months Ended March 31, 2004	Three Months Ended March 31, 2003	Period from October 1, 2000 (inception) through March 31, 2004
Net loss allocable to common stockholders, as reported	$ (7,690)	$ (2,910)	$ (87,320)
Plus: Employee stock compensation expense based on intrinsic value method	755	10	1,658
Less: Employee stock compensation expense determined under the fair value method for all awards	(673)	(19)	(1,670)
Pro forma net loss allocable to common stockholders	$ (7,608)	$ (2,919)	$ (87,332)
Net loss per share allocable to common stockholders:			
Basic and diluted, as reported	$ (1.47)	$ (1.77)	
Basic and diluted, pro forma	$ (1.45)	$ (1.78)	

Table of Contents

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 upon issuance.

Comprehensive Income (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*. For the three months ended March 31, 2004 and 2003, comprehensive loss was $7.7 million and $2.9 million, respectively. For the three months ended March 31, 2004 and 2003, unrealized gains (losses) on available-for-sale securities were $21,000 and $0, respectively.

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 $43.2 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 and commissions. The amount is recorded as a stock subscription receivable in the accompanying condensed balance sheet at March 31, 2004.

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.

Table of Contents

The unaudited pro forma basic and diluted net loss per share allocable to common stockholders calculations assume the conversion of all outstanding shares of convertible preferred stock into shares of common stock using the as-if-converted method as of the beginning of the period presented or the date of issuance, if later.

	Three Months Ended March 31,	
(In thousands, except share and per share data)	**2004**	**2003**
Historical		
Numerator:		
Net loss allocable to common stockholders	$ (7,690)	$ (2,910)
Denominator:		
Weighted-average common shares outstanding	5,328,661	1,813,737
Less: Weighted-average unvested common shares subject to repurchase	(92,902)	(169,555)
Denominator for basic and diluted net loss per share allocable to common stockholders	5,235,759	1,644,182
Basic and diluted net loss per share allocable to common stockholders	$ (1.47)	$ (1.77)
Pro forma		
Pro forma net loss allocable to common stockholders	$ (7,690)	$ (2,910)
Denominator for pro forma basic and diluted net loss per share allocable to common stockholders:		
Shares used above	5,235,759	1,644,182
Pro forma adjustment to reflect assumed weighted-average effect of conversion of preferred stock	12,943,876	6,426,660
Shares used to compute pro forma basic and diluted net loss per share allocable to common stockholders	18,179,635	8,070,842
Pro forma basic and diluted net loss per share allocable to common stockholders	$ (0.42)	$ (0.36)

	Three Months Ended March 31,	
	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	1,712,222	848,537

	1,712,222	7,421,449

4. Cash, Cash Equivalents and Short-Term Investments

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

	March 31, 2004			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Available-for-sale debt securities maturing within 1 year:				
Auction market preferred stock	$ 14,449	$	$	$ 14,449
Corporate bonds	14,571	10		14,581
Federal agency bonds	7,886		(1)	7,885
Floating rate bonds	26,475			26,475
Municipal bonds	6,131		(6)	6,125
Total available-for-sale debt securities	$ 69,512	$ 10	$ (7)	$ 69,515

Table of Contents

	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):

	March 31, 2004	December 31, 2003
Cash	$ 3,636	$ 1,949
Cash equivalents	25,073	10,100
Cash and cash equivalents	28,709	12,049
Short-term investments	44,442	25,264
Total	$ 73,151	$ 37,313

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

Table of Contents

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.

Table of Contents

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 Genentech s rights to rhIGF-1 for a broad range of indications, including for short stature worldwide and diabetes in the U.S. We have Phase III clinical data for the use of rhIGF-1 in children with Severe Pediatric IGFD. We intend to complete the validation of our rhIGF-1 manufacturing process and submit an NDA with the FDA by early 2005 for this indication. We plan to initiate late-stage clinical trials for the use of rhIGF-1 in other indications.

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 U.S. for all indications other than diseases and conditions of the central nervous system and diabetes.

As of March 31, 2004, we had approximately $73.2 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 $43.2 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.

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 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, using that process to make drug product suitable for clinical use and sale, and development activities related to Pediatric IGFD. Because we licensed non-clinical, clinical and chemistry, manufacturing and controls data and know-how from Genentech, we did not incur significant development expenses prior to 2002. However, we expect to fund our own development activities and will continue to incur

Table of Contents

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 Pediatric IGFD. At the end of 2003, we began to manage the development project for Severe Pediatric IGFD as a separate project from the development project for Pediatric 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 quarter 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 Pediatric IGF-1 deficiency (IGFD). We expect the remainder of 2004 to be focused on the establishment and validation of our rhIGF-1 manufacturing process at our contract manufacturer and completion of our development project for Severe Pediatric IGFD.

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 quarter 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 March 31, 2004, we recorded amortization of deferred stock compensation of $1.7 million. At March 31, 2004, we had a total of $9.2 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 March 31, 2004 will be amortized as follows: $2.8 million for the year ending December 31, 2004; $2.7 million for the year ending December 31, 2005; $2.8 million for the year ending December 31, 2006 and $1.7 million for the year ending December 31, 2007.

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, Accounting for Stock Issued to Employees, and generally would require such transactions be accounted for using a fair-value-based method and the resulting cost recognized in the financial statements. We are closely monitoring developments related to the Exposure Draft and will adopt the final standard upon issuance.

Table of Contents

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 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.

Results of Operations

Three Months Ended March 31, 2004 and 2003

Research and Development Expenses. Research and development expenses increased to $5.7 million for the three months ended March 31, 2004 from $2.3 million for the three months ended March 31, 2003. For the three months ended March 31, 2004, project costs associated with the establishment of our rhIGF-1 manufacturing process at Cambrex Baltimore totaled $2.9 million, internal personnel and other costs totaled $2.0 million, and our rhIGF-1 development project costs for Pediatric IGFD totaled $0.8 million.

In the first quarter of 2004, project costs for the establishment of our rhIGF-1 manufacturing process increased $1.3 million from the first quarter of 2003, and were driven primarily by production activities at Cambrex Baltimore. Production activities involve making 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). We incurred $0.8 million in costs associated with our rhIGF-1 development project for Severe Pediatric IGFD and to prepare and submit an NDA filing for the three months ended March 31, 2004 which increased by approximately $655,000 from March 31, 2003. The Severe Pediatric IGFD project costs related primarily to the review and analyses of the Phase III clinical trial data in preparation for the NDA filing. Other costs for the three months ended March 31, 2004 increased $1.5 million from the three-months ended March 31, 2003, which was substantially related to increased personnel costs.

We estimate the remaining costs to complete the establishment of our rhIGF-1 manufacturing process will be approximately $10.0 to $13.0 million through the end of 2004. We estimate the remaining 2004 costs to prepare and submit a NDA filing for Severe Pediatric IGFD will be approximately $1.7 to $2.2 million. In late 2004 we intend to initiate a Phase III clinical trial for Pediatric IGFD, which we estimate will cost approximately $6.0 to $10.0 million to complete. In late 2004 we also intend to initiate a Phase II clinical trial for Type A diabetes (which will include patients with extreme insulin resistance), which we estimate will cost approximately $4.0 to $5.0 million to complete during the course of the study, which will likely be initiated in the fourth quarter of 2004 or early 2005.

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 and changes that may significantly impact cost projections and timelines.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased to $1.9 million for the three months ended March 31, 2004 from $699,000 for the three months ended March 31, 2003. The increase was primarily attributable to increased headcount (there were 15 and 4 employees in selling, general and administrative positions as of March 31, 2004 and 2003, respectively) and non-cash stock compensation expenses of approximately $880,000, creation of a new marketing infrastructure, legal, consulting and professional fees of approximately $150,000, and general office expenses of $143,000. 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 $250,000 for the three months ended March 31, 2004. The costs in 2004 resulted from the execution of a patent license.

Table of Contents

Interest and Other Income, net. Interest income increased to $115,000 for the three months ended March 31, 2004 from $44,000 for the three months ended March 31, 2003. The increase was due to interest on higher average cash and cash equivalents 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 March 31, 2004, we had an accumulated deficit of $86.2 million, which is comprised of $42.0 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. From inception through March 31, 2004, we raised net cash proceeds of $66.1 million in private equity financings and $43.2 million from our initial public offering of common stock which we have used to fund our operating activities and growth. The remainder of the net cash proceeds from our private equity financings and from the closing of our initial public offering of common stock were invested in cash, cash equivalents and short-term investments as of March 31, 2004.

Cash, cash equivalents and short term investments increased to $73.2 million at March 31, 2004 from $37.3 million at December 31, 2003 primarily due to net proceeds of $43.2 from the issuance our common stock in our initial public offering, partially offset by cash used to in operating activities of $7.0 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 to Cambrex, Baltimore, and our development project for Pediatric IGFD.

Net cash used in investing activities increased to $19.6 million in the first quarter of 2004 as a result of net purchases of short-term investments. Net cash provided by financing activities for the first quarter of 2004 increased by $43.0 million as a result of net proceeds received from our initial public offering of common stock.

Contractual Obligations and Commercial Commitments

Our commitments for operating leases relate to two subleases and one lease for real estate covering our present facility. The real estate subleases and lease expire in December 2004.

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 Pediatric IGFD in the U.S. and Europe are achieved. Additional milestone payments would be due for subsequent indication approvals, in both the U.S. and Europe. We also expect to make a $1.1 million payment associated with license rights for rhIGF-1 in combination with IGF binding protein-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 $10.0 million through December 31, 2005.

Operating Capital and Capital Expenditure Requirements

We believe that our cash, cash equivalents and short-term investments as of March 31, 2004 of $73.2 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 clinical trial activities. 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.

Table of Contents

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.

Table of Contents

RISK FACTORS

You should carefully consider the risks described below together with the other information included in this prospectus before deciding to invest in shares of our common stock. If any of the following risks occur, the value of our common stock could decline.

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 $86.2 million as of March 31, 2004 and have not generated any revenue from operations. We incurred a net loss of $7.7 million during the three months ended March 31,2004. 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 U.S. 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 U.S.

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 U.S. Orphan indications are designated by the FDA under the Orphan Drug Act, and are generally rare diseases or conditions that affect fewer than 200,000 individuals in the U.S. With respect to those rhIGF-1 indications in the U.S., 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 U.S. 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 regulatory approvals, we will not be able to develop and commercialize rhIGF-1.

We need FDA approval to market rhIGF-1 for therapeutic uses in the U.S. We are currently developing rhIGF-1 for the treatment of Severe Pediatric IGFD, Pediatric IGFD and diabetes. We have Phase III clinical data using rhIGF-1 replacement therapy for Severe Pediatric IGFD, which we plan to submit in support of an NDA in the U.S. If we fail to obtain FDA approval for the marketing of rhIGF-1 for this indication, or any other indication, we will be unable to sell rhIGF-1 in the U.S. and our business will be harmed.

The regulatory review and approval process in the U.S., which includes evaluation of preclinical studies and clinical trials of our rhIGF-1, 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 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 each indication. We have limited experience in filing and pursuing applications necessary to gain regulatory approvals.

The FDA has substantial discretion in the approval process and may either refuse to accept our application, or may decide after review of our application that our data is insufficient to allow approval of rhIGF-1. If the FDA does not accept or approve our application, it may require that we conduct additional clinical, preclinical or manufacturing studies and submit that data before it will reconsider our application. 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 applications may be delayed by

Table of Contents

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 applications approvable. If any of these outcomes occur, we may be forced to abandon our applications for approval, which might cause us to cease operations.

In addition, the FDA could require us to include in our rhIGF-1 labeling specific diagnostic tests that would confirm the diagnosis of Severe Pediatric IGFD or Pediatric IGFD. Such a requirement could add additional complexity in making the diagnosis of Severe Pediatric IGFD or Pediatric IGFD, which includes children with a less severe form of IGFD, and, as a result, could limit the number of patients for whom our product is prescribed.

We will need to file similar applications with regulatory authorities in foreign countries to market rhIGF-1 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. Numerous press releases have been issued following this event, which 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 conduct 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;
- 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.

Table of Contents

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 good manufacturing practice, or 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 U.S. 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 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 original plan was to obtain rhIGF-1 orphan drug designation for the treatment of growth hormone insensitivity syndrome, or GHIS. The Phase III clinical trial results we obtained from Genentech were for GHIS. Everywhere in this document where we discuss existing Phase III clinical trial results such results were from patients identified at the time as having GHIS. Since we now believe that Severe Pediatric IGFD, which is we believe substantially equivalent to GHIS, more accurately describes the patient population which we intend to treat with rhIGF-1, we plan to amend our current designation, but may as a result of comments from the FDA reconsider the GHIS designation, which may be a smaller patient population. 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 Pediatric IGFD or Pediatric 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.

Table of Contents

We face significant competition from large pharmaceutical, biotechnology and other companies which 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 U.S. or Europe is approved as replacement therapy for the treatment of Severe Pediatric IGFD, Pediatric 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 Pediatric 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 Pediatric IGFD and Adult IGFD. Although patients with Pediatric 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 Pediatric 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 U.S. for any human therapeutic indication, rhIGF-1 manufactured by other parties may be approved for use in the U.S. 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.

Table of Contents

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 Pediatric IGFD and Pediatric IGFD. Although we have Phase III clinical data for the use of rhIGF-1 replacement therapy in Severe Pediatric IGFD, there is no assurance we will be able to obtain FDA approval to market rhIGF-1 in the U.S. 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 Pediatric 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 U.S.

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 U.S. Patent and Trademark Office and foreign patent offices use to grant patents, and the standards that U.S. 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 U.S. may differ substantially from that obtained in various foreign countries. In some instances, patents have issued in the U.S. while substantially less or no protection has been obtained in Europe or other countries. Our U.S. 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 U.S. 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 U.S. 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 U.S. 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 Pediatric 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 Pediatric 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 U.S. with short stature is approximately one million, of which approximately 360,000 are referred to pediatric endocrinologists for evaluation. We

Table of Contents

believe that approximately 30,000 of these children have Pediatric 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 U.S. We believe that the aggregate number of children in the U.S. and Western Europe with Pediatric IGFD is approximately 60,000, of which approximately 12,000 have Severe Pediatric 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 Pediatric IGFD or Severe Pediatric 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 U.S. 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 U.S. 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 Pediatric 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 Pediatric IGFD is incorrect, the market opportunity for rhIGF-1 therapy for the treatment of Pediatric IGFD may be substantially reduced.

In recent years, officials have made numerous proposals to change the health care system in the U.S. 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 U.S., 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.

Table of Contents

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

We currently do not have a sales organization. If rhIGF-1 is approved by the FDA for Severe Pediatric IGFD, we intend to market that therapy directly to pediatric endocrinologists in the U.S. 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 U.S., 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 Pediatric 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 will need additional intellectual property from other third parties to commercialize rhIGF-1 for type A diabetes and we may need additional intellectual property from other third parties to commercialize rhIGF-1 for type 2 diabetes with Severe Insulin Resistance. 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 April 30, 2004, we only had 48 employees and 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.

Table of Contents

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 Pediatric 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 Pediatric 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.

Table of Contents

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 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 U.S. may be maintained in secrecy until the patents are issued,
- patent applications in the U.S. 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 U.S. patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the U.S. Patent and Trademark Office to determine priority of invention in the U.S. 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.

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, Mr. Thomas H. Silberg, our Chief Operating Officer and Mr. Timothy P. Lynch, our Chief Financial Officer and Treasurer, 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.

Table of Contents

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.

Prior to our offering, there had been no public market for our common stock, and an active public market for our common stock may not develop or be sustained after our offering. The initial public offering price of our common stock was determined by negotiations between the representatives of the underwriters and us and may not be indicative of future market prices. The following factors were considered in

determining the initial public offering price of our common stock:

prevailing market conditions;

estimates of our business potential and earnings prospects; and

an assessment of our management.

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.

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 April 30, 2004, we have 24,530,503 outstanding shares of common stock. Of these shares, the 6,325,000 shares sold in our offering are freely tradable without restriction or further regulation, other than

Table of Contents

shares purchased by our officers, directors or other affiliates within the meaning of Rule 144 under the Securities Act of 1933. The remaining 18,205,503 shares of common stock were issued prior to the offering or pursuant to options or warrants granted prior to the 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 the 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 20,201,538 shares 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 March 31, 2004, the holders of 17,296,568 shares of common stock are entitled to registration rights.

Table of Contents

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 March 31, 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 March 31, 2004.

Item 4. Controls and Procedures

Evaluation of disclosure controls and procedures

Based on their evaluation as of March 31, 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 March 31, 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.

28

Table of Contents

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 $50,098,000. We incurred total estimated expenses in connection with the offering of $6,827,000, which consisted of:

(i) $2,693,000 in legal, accounting and printing fees;

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

(iii) $149,000 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 March 31, 2004, we had cash, cash equivalents and short-term investments of $73.2 million, which includes the net cash proceeds from our initial public offering of 5,500,000 shares of common stock. On April 2, 2004, we received net cash proceeds of $6.9 million from 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 March 31, 2004.

We expect to use the net proceeds from our offering, and our existing cash, cash equivalents and short-term investments as follows:

- Approximately $43 million for general corporate purposes, including launch and post-launch sales and marketing activities for rhIGF-1 for Severe Pediatric IGFD and the possible acquisition of new products or product candidates;

Approximately $25 million for late-stage clinical trials of rhIGF-1 for additional indications; and

Approximately $13 million for transfer and validation of the rhIGF-1 manufacturing process

We have no present understandings, commitments or agreements with respect to any acquisitions, investments or joint ventures and no portion of the net proceeds has been allocated for any specific acquisition.

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.

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

In February 2004, in connection with our initial public offering, we sent a written consent to our preferred stockholders requesting their election to convert all of their shares of our preferred stock into share of our common stock, effective immediately prior to the closing of the offering. A total of 13,949,993 shares of our preferred stock out of a total of 15,297,308 shares of our preferred stock then issued and outstanding voted in favor of the conversion.

Also in February 2004, we sent a written consent to our stockholders requesting approval of (i) an increase in the number of shares available under our 2002 Stock Plan of 2,470,000 shares, and (ii) an increase in the number of shares available under our 2002 Executive Stock Plan, and a corresponding decrease in the number of shares available under our 2002 Stock Plan, of 750,000 shares. A total of 15,687,877 shares of our stock out of 18,065,753 shares then issued and outstanding voted in favor of these matters.

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.
3.2	By-laws of Tercica*

Table of Contents

4.1	Form of Specimen Stock Certificate*
10.9K	Employment letter to Thomas H. Silberg dated April 14, 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

None

* Incorporated by reference to Tercica 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.

Table of Contents

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: May 13, 2004

TERCICA, INC.
(Registrant)

/s/ Timothy P. Lynch

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