TERCICA INC
Form 10-Q
May 10, 2006
Table of Contents

UNITED STATES

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, 2006

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)**

2000 Sierra Point Parkway, Suite 400

Brisbane, San Francisco, CA 94005

(650) 624-4900

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. (Check one):

Large accelerated filer ¨ Accelerated filer x Non-accelerated filer ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x

As of April 28, 2006, there were 37,537,030 shares of the Registrant s Common Stock outstanding.

Table of Contents

TERCICA, INC.

FORM 10-Q FOR THE QUARTER ENDED MARCH 31, 2006

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, 2006	December 31, 2005
Assets		
Current assets:		
Cash and cash equivalents	$ 38,618	$ 14,817
Short-term investments	40,553	43,809
Accounts receivable	35	
Inventories, net	2,318	1,636
Prepaid expenses and other current assets	2,390	1,673
Total current assets	83,914	61,935
Property and equipment, net	4,047	4,021
Restricted cash	340	340
Other assets	20	20
Total assets	$ 88,321	$ 66,316
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 2,782	$ 2,245
Accrued expenses	5,951	5,750
Liability for early exercise of stock options	73	70
Total current liabilities	8,806	8,065
Deferred rent	1,526	1,429
Other liabilities	20	24
Total liabilities	10,352	9,518
Commitments and contingencies		
Stockholders equity:		
Common stock	37	32
Additional paid-in capital	257,952	225,100
Deferred stock compensation		(2,591)
Accumulated other comprehensive loss	(10)	(2)
Deficit accumulated during the development stage	(180,010)	(165,741)
Total stockholders equity	77,969	56,798

Total liabilities and stockholders equity	$ 88,321	$ 66,316

See accompanying notes.

Table of Contents

TERCICA, INC.

(A DEVELOPMENT STAGE COMPANY)

CONDENSED STATEMENTS OF OPERATIONS

(In thousands, except per share data)

(Unaudited)

	Three months ended March 31,		Period from October 1, 2000 (inception) through March 31,
	2006	2005	2006
Net product sales	$ 85	$	$ 85
Costs and expenses:			
Cost of product sales	83		83
Research and development*	4,630	4,871	75,842
Selling, general and administrative*	10,504	4,179	56,407
Acquired in-process research and development			8,158
Total costs and expenses	(15,217)	(9,050)	(140,490)
Operating loss	(15,132)	(9,050)	(140,405)
Interest expense		(499)	(1,186)
Interest and other income, net	863	441	4,609
Net loss	(14,269)	(9,108)	(136,982)
Deemed dividend related to beneficial conversion feature of convertible preferred stock			(44,153)
Net loss allocable to common stockholders	$ (14,269)	$ (9,108)	$ (181,135)
Basic and diluted net loss per share allocable to common stockholders	$ (0.40)	$ (0.32)	
Shares used to compute basic and diluted net loss per share allocable to common stockholders	35,641	28,129	

* Includes non-cash stock-based compensation expense as follows:

Research and development	$ 429	$ 320	$ 3,798
Selling, general and administrative	688	326	3,407
Total	$ 1,117	$ 646	$ 7,205

See accompanying notes.

4

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,
	2006	2005	2006
Cash flows from operating activities:			
Net cash used in operating activities	$ (13,578)	$ (10,902)	$ (117,480)
Cash flows from investing activities:			
Purchases of property and equipment	(275)	(260)	(5,953)
Proceeds from sale of equipment			300
Purchases of available-for-sale securities	(18,787)	(50,775)	(306,265)
Proceeds from sales and maturities of available-for-sale securities	22,150	21,020	265,590
Net cash provided by (used in) investing activities	3,088	(30,015)	(46,328)
Cash flows from financing activities:			
Net proceeds from issuance of preferred stock			63,960
Net proceeds from issuance of common stock	34,291	51,190	137,047
Other, net		(75)	1,419
Net cash provided by financing activities	34,291	51,115	202,426
Net increase in cash and cash equivalents	23,801	10,198	38,618
Cash and cash equivalents, beginning of period	14,817	14,126	
Cash and cash equivalents, end of period	$ 38,618	$ 24,324	$ 38,618
Supplemental schedule of noncash activities:			
Issuance of Series A convertible preferred stock to a collaboration partner in exchange for acquired in-process research and development	$	$	$ 4,071
Reversal of deferred stock compensation upon adoption of SFAS No. 123R	$ (2,591)	$	$ (2,591)
Deferred stock compensation, net of forfeitures	$	$ (179)	$ 8,331
Deemed dividend related to beneficial conversion feature of convertible preferred stock	$	$	$ 44,153
Conversion of Series A and B convertible preferred stock into common stock	$	$	$ 68,637
Issuance of common stock for senior credit facility	$	$	$ 1,001
Issuance of warrant in connection with committed equity financing facility	$	$	$ 1,196
Other, net	$ 25	$ 768	$ 1,216

See accompanying notes.

5

Table of Contents

TERCICA, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO THE CONDENSED FINANCIAL STATEMENTS

(Unaudited)

1. Company and Summary of Significant Accounting Policies

Organization and Business

Tercica, Inc. (the Company) is a biopharmaceutical company focused on the development and commercialization of new therapeutics for the treatment of short stature and other endocrine disorders. The Company s predecessor, 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. 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. In April 2002, the Company licensed the rights of Genentech to develop, manufacture and commercialize rhIGF-1 products for a broad range of indications, including short stature, worldwide.

The Company s first commercial product is Increlex , a DNA-derived recombinant human insulin-like growth factor-1 (rhIGF-1). The Company obtained approval for the long-term treatment of growth failure in children with severe primary insulin-like growth factor deficiency, or severe Primary IGFD, or with growth hormone gene deletion who have developed neutralizing antibodies to growth hormone from the U.S. Food and Drug Administration (FDA) in August 2005, and Increlex was granted seven years of orphan drug marketing exclusivity for the long-term treatment of growth failure in children with severe Primary IGFD. See the section entitled Risks Related to our Business under Part II, Item 1A below for further details related to the Company s orphan drug marketing exclusivity. In January 2006, the Company launched Increlex in the United States. In December 2005, the Company also submitted a Marketing Authorization application (MAA) in the European Union for the long-term treatment of growth failure in children with severe Primary IGFD or with growth hormone gene deletion who have developed neutralizing antibodies to growth hormone. The Company s current focus is on marketing and selling Increlex for the treatment of severe Primary IGFD, and developing Increlex as a replacement therapy for primary IGF-1 deficiency, or Primary IGFD. The Company defines the indication Primary IGFD to mean a child who has a height standard deviation score (Height SDS) and an IGF-1 standard deviation score (IGF-1 SDS) of less than minus two, and the indication severe Primary IGFD to mean a child who has a Height SDS and IGF-1 SDS of minus three or less, in each case in the presence of normal or elevated levels of growth hormone. The Company is currently conducting two late-stage clinical trials for the use of rhIGF-1 in Primary IGFD.

These development stage financial statements and accompanying notes include the results of operations from the inception of Tercica Limited in October 2000 as both the Company and Tercica Limited were under common control as evidenced by the following factors: (i) all of the investors of Tercica Limited were founding stockholders of the Company, (ii) substantially all of the employees of Tercica Limited became employees of the Company, (iii) the nearly identical business plans adopted by both entities and (iv) the commencement of negotiations to obtain the license for recombinant human insulin-like growth factor-1 (rhIGF-1) from Genentech, Inc. by Tercica Limited, and the completion of those negotiations by the Company.

The Company is in its initial stage of commericialization and is considered to be a development stage company 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 U.S. Securities and Exchange Commission (SEC) for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by U.S. generally accepted accounting principles (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.

6

Table of Contents

TERCICA, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO THE CONDENSED FINANCIAL STATEMENTS (Continued)

(Unaudited)

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 audited financial statements for the year ended December 31, 2005, included in the Company s Annual Report on Form 10-K for the year ended December 31, 2005, filed with the Securities and Exchange Commission on March 16, 2006.

The condensed balance sheet at December 31, 2005 has been derived from the audited financial statements at that date but does not include all of the information and footnotes required by GAAP for complete financial statements.

Follow-on Public Offering

On September 9, 2005, the Company filed a shelf registration statement with the SEC pursuant to which the Company may, from time to time, offer and sell shares of the Company s common stock and preferred stock, various series of debt securities and/or warrants to purchase any of such securities, either individually or in units, in one or more offerings, with a total value of up to $75,000,000, at prices and on terms to be determined by market conditions at the time of any offering made under the shelf registration statement. On January 27, 2006, the Company completed the sale of 5,750,000 shares of its common stock under this shelf registration statement, at a price to the public of $6.40 per share, including the exercise of the over-allotment option by the underwriters. Net cash proceeds from this offering were $34,191,000 after deducting underwriter discounts and other offering expenses.

Use of Estimates

The preparation of 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 the financial statements and accompanying notes. Actual results could differ from those estimates.

Concentrations

Financial instruments that potentially subject the Company to credit risk consist of cash, cash equivalents and short-term investments to the extent of the amounts recorded on the balance sheets. The Company s cash, cash equivalents and short-term investments are placed with high credit-quality financial institutions and issuers. The Company believes its established guidelines for investment of its excess cash maintain safety and liquidity through its policies on diversification and investment maturity.

The Company sources all if its fill-finish manufacturing and testing and final product storage and distribution operations, as well as its bulk manufacturing, testing, and shipping operations, through single-source third-party suppliers and contractors and the Company obtains specific components and raw materials used to manufacture Increlex from either single-source or sole-source suppliers. If these contract facilities, suppliers or contractors become unavailable to the Company for any reason, the Company may be delayed in manufacturing Increlex or may be unable to maintain validation of Increlex , which could delay or prevent the supply of commercial and clinical product, or delay or otherwise adversely affect revenues. The Company believes that it has established guidelines to maintain an adequate level of inventory to mitigate this potential negative impact.

Inventories

Inventories are stated at the lower of cost or market and consist primarily of contract manufacturing costs for the production of Increlex that were incurred subsequent to the approval for marketing by the FDA. Cost is determined using the first-in, first-out basis. The valuation of inventory requires the Company to estimate obsolete or excess inventory based on analysis of future demand for Increlex . If inventory costs exceed expected net realizable value due to obsolescence or lack of demand, inventory write-downs are recorded as deemed necessary by management for the difference between the cost and the net realizable value. These write-downs are determined based on significant estimates by management and will be recorded in the period that impairment is first recognized. The Company recorded write-downs of $44,000 during

the three months ended March 31, 2006.

Table of Contents

TERCICA, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO THE CONDENSED FINANCIAL STATEMENTS (Continued)

(Unaudited)

Inventories consisted of the following (in thousands):

	March 31, 2006	December 31, 2005
Raw materials	$ 987	$ 319
Work-in-process	1,291	1,229
Finished goods	40	88
Total	$ 2,318	$ 1,636

Revenue Recognition

Product sales consist of shipments of Increlex to specialty pharmacy distributors. Product sales are recognized when title passes to the customer, and the customer assumes the risks and rewards of ownership. This is generally at the time product arrives at the customer s location. Product sales consist of gross sales less provisions for discounts to customers, rebates to government agencies, product returns and other adjustments. These provisions are provided for in the same period the related product sales are recorded. The Company began generating revenue from the sale of Increlex , in January 2006.

Research and Product 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 consist primarily of costs associated with manufacturing development activities prior to regulatory approval, clinical and regulatory activities, payroll and related costs, non-cash stock-based compensation, laboratory supplies and certain allocated costs. Manufacturing development expenses include costs associated with the Company s contract manufacturers, including technology transfer, pre-approval product manufacturing, process development, validation and qualification activities, analytical development, and compliance-related support, pre-FDA approval preparations for current good manufacturing practices (cGMP), quality control and assurance activities, as well as personnel and related benefits and depreciation, prior to regulatory approval. Clinical and regulatory activities include the preparation, implementation, management of the Company s clinical trials and assay development, as well as regulatory compliance, data management and biostatistics.

Clinical Trial Expenses

The Company contracts with third-party clinical research organizations to perform various clinical trial activities. The Company recognizes research and development expenses for these contracted activities based upon a variety of factors, including actual and estimated patient enrollment rates, clinical site initiation activities, labor hours and other activity-based factors. The Company matches the recording of expenses in the financial statements to the actual services received and efforts expended. Depending on the timing of payments to the service providers, the Company records prepaid expenses and accruals relating to clinical trials based on the estimate of the degree of completion of the event or events as specified each clinical study or trial contract. The Company monitors each of these factors to the extent possible and adjusts estimates accordingly.

Acquired In-Process Research and Development

Acquired in-process research and development relates to in-licensed technology, intellectual property and know-how. The nature of the remaining efforts for completion of research and development activities surrounding rhIGF-1 generally include completion of clinical trials, completion of manufacturing validation, interpretation of clinical and preclinical data and obtaining marketing approval from the FDA and other

foreign regulatory bodies, the cost, length and success of which are extremely difficult to determine. Numerous risks and uncertainties exist with timely completion of development projects, including clinical trial results, manufacturing process development results, 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.

Table of Contents

TERCICA, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO THE CONDENSED FINANCIAL STATEMENTS (Continued)

(Unaudited)

Stock-Based Compensation

On January 1, 2006, the Company adopted Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-Based Payment* (SFAS No. 123R) which requires the measurement and recognition of non-cash compensation expense for all share-based payment awards made to employees and directors including employee stock options and employee stock purchases related to the 2004 Employee Stock Purchase Plan (Purchase Plan) based on estimated fair values. SFAS No. 123R supersedes the Company s previous accounting under Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees,* for periods beginning in fiscal 2006. In March 2005, the Securities and Exchange Commission issued Staff Accounting Bulletin No. 107 (SAB 107) relating to SFAS No. 123R. The Company has applied the provisions of SAB 107 in its adoption of SFAS No. 123R. See Note 7 Stock-Based Compensation for further detail.

After the adoption of SFAS No. 123R, stock compensation arrangements with non-employee service providers continue to be 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.

Comprehensive Loss

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

	Three months ended March 31,	
	2006	2005
Net loss allocable to common stockholders, as reported	$ (14,269)	$ (9,108)
Change in unrealized gains (losses) on marketable securities	(8)	11
Comprehensive loss	$ (14,277)	$ (9,097)

Table of Contents

TERCICA, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO THE CONDENSED FINANCIAL STATEMENTS (Continued)

(Unaudited)

2. 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 allocable to common stockholders when their effect is dilutive.

	Three months ended March 31,	
	2006	2005
	(In thousands, except per share data)	
Historical		
Numerator:		
Net loss allocable to common stockholders	$ (14,269)	$ (9,108)
Denominator:		
Weighted-average common shares outstanding	35,642	28,175
Less: Weighted-average unvested common shares subject to repurchase	(1)	(46)
Denominator for basic and diluted net loss per share allocable to common stockholders	35,641	28,129
Basic and diluted net loss per share allocable to common stockholders	$ (0.40)	$ (0.32)

	Three months ended March 31,	
	2006	2005
	(In thousands)	
Historical outstanding dilutive securities not included in diluted net loss per share allocable to common stockholders calculation		
Options to purchase common stock	4,118	2,593
Warrants	260	
	4,378	2,593

Table of Contents

TERCICA, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO THE CONDENSED FINANCIAL STATEMENTS (Continued)

(Unaudited)

3. Cash, Cash Equivalents and Short-Term Investments

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

	March 31, 2006			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Available-for-sale debt securities maturing within 1 year:				
Auction market preferred	$ 28,150	$	$	$ 28,150
Commercial paper	29,833	5		29,838
Corporate bonds	1,426		(4)	1,422
Federal agency bonds	9,801		(11)	9,790
Repurchase agreements	6,750			6,750
Total available-for-sale debt securities	$ 75,960	$ 5	$ (15)	$ 75,950

	December 31, 2005			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Available-for-sale debt securities maturing within 1 year:				
Auction market preferred	$ 36,150	$	$	$ 36,150
Commercial paper	13,468	3		13,471
Federal agency bonds	5,477		(5)	5,472
Repurchase agreements	3,000			3,000
Total available-for-sale debt securities	$ 58,095	$ 3	$ (5)	$ 58,093

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

	March 31, 2006	December 31, 2005
Cash	$ 3,561	$ 873
Cash equivalents	35,057	13,944
Cash and cash equivalents	38,618	14,817
Short-term investments	40,553	43,809
Long-term restricted cash	340	340
Total	$ 79,511	$ 58,966

Realized losses on the sale of available-for-sale securities for the periods presented were immaterial.

4. Litigation

On December 20, 2004, the Company initiated patent infringement proceedings against Avecia Limited and Insmed Incorporated as co-defendants in the High Court of Justice (Chancery Division Patents Court) in the United Kingdom. There is no trial date set for this action. On December 23, 2004, the Company, with Genentech, initiated patent infringement proceedings against Insmed Incorporated in the U.S. District Court for the Northern District of California. The Company initiated these proceedings because it believes that Insmed and Avecia are infringing and/or have infringed on the Company s patents that cover Insmed s product s use and manufacture. The trial date for the proceedings in the U.S. District Court for the Northern District of California is November 6, 2006.

The Company cannot predict the outcome of its litigation against Avecia and Insmed in the United Kingdom or the outcome of its litigation against Insmed in the United States. Moreover, the Company cannot predict the cost of such

Table of Contents

TERCICA, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO THE CONDENSED FINANCIAL STATEMENTS (Continued)

(Unaudited)

litigation, which may require a substantial diversion of the Company s financial assets and other resources and consequently prevent the Company from allocating sufficient resources to the development of its rhIGF-1 programs, and which may have a material adverse effect on the Company s business. In addition, if the outcome of the Company s litigation in the United Kingdom is not favorable to the Company, the Company is likely to be found liable for the opposing parties costs incurred in connection with the litigation, and the Company could be found liable for an award of additional damages to the opposing parties if the court decides that the Company s claims of patent infringement are without sufficient merit or not pursued in good faith. If in the Company s litigation in the United States, the court decides that a defendant prevails, and the defendant establishes by clear and convincing evidence that the case is exceptional (e.g., the Company s claims of patent infringement were not pursued in good faith), the Company could be liable for an award of the opposing party s costs and legal fees incurred in connection with the litigation and/or an award of other damages. Any such award or awards to the opposing parties could substantially increase the Company s costs and exacerbate the negative impact that an unfavorable outcome in the case(s) could have on the Company s business. Further, it is not uncommon in cases of this kind for a defendant to assert counterclaims, which could significantly increase the Company s costs, potential liability for damages, and other risks arising from these lawsuits, and a court could find the Company liable for any such damages caused by Genentech as well.

Insmed and Avecia have challenged the validity of European Patent No. 0 571 417 in our litigation in the United Kingdom, and Insmed has challenged the validity of U.S. Patent Nos. 5,187,151, 6,331,414 and 5,258,287 in our litigation in the United States. Even if we voluntarily drop our claims of patent infringement in our litigation in the United States and/or the United Kingdom, the opposing party or parties may pursue counterclaims for a declaratory judgement of invalidity against the asserted patent or patents in such action(s). If in our litigation in the United States the court awards a declaratory judgement finding invalid one or more of the claims of U.S. Patent No. 5,187,151, one or more of the claims of U.S. Patent No. 5,258,287, and/or one or more of the claims of U.S. Patent No. 6,331,414, and if the court s finding of invalidity in such declaratory judgment is upheld in whole or in part on appeal or if no appeal is taken, we would be unable to exclude others from using the affected claim or claims in the United States, which may decrease our ability to generate significant revenue from our rhIGF-1 programs and/or render any further development and commercialization of rhIGF-1 commercially infeasible for us. If in our litigation in the United Kingdom, the court awards a declaratory judgment finding invalid one or more of the claims of European Patent No. 0 571 417, and if the court s finding of invalidity in such declaratory judgment is upheld in whole or in part on appeal or if no appeal is taken, we would be unable to exclude others from using the affected claim or claims in the United Kingdom, and any such finding of invalidity may have a similar adverse impact on the enforceability of the affected claim or claims in one or more of the other European countries in which European Patent No. 0 571 417 would otherwise be in force, which may decrease our ability to generate significant revenue from our rhIGF-1 programs and/or render any further development and commercialization of rhIGF-1 commercially infeasible for us.

On December 6, 2005, the Company filed a complaint against Insmed for False Advertising and Unfair Competition, Case No. C-05-5027 SBA, in the U.S. District Court for the Northern District of California. The complaint alleges that Insmed made false, misleading and deceptive statements about Increlex and its product. The Company is seeking monetary and injunctive relief. The Company filed an amended complaint on December 15, 2005. Defendant Insmed filed a Motion to Dismiss on January 13, 2006. The motion was scheduled to be heard on March 28, 2006; however, on April 14, 2006, the Court ordered that no hearing is required and scheduled the Case Management Conference for June 14, 2006. Discovery has not commenced, and no trial date has been set.

From time to time, the Company may become involved in claims and other legal matters arising in the ordinary course of business. Management is not currently aware of any other matters that may have a material adverse affect on the financial position, results of operations or cash flows of the Company.

5. Senior Credit Facility

On January 21, 2005, the Company entered into a Loan Agreement (the Loan Agreement) with Venture Leasing & Lending IV, Inc. (VLL) under which the Company had the option to draw down funds in the aggregate principal amount of up to $15,000,000 through December 31, 2005. The Company paid a $75,000 fee as part of this Loan Agreement and issued a total of 112,500 shares of its common stock to an affiliate of VLL. The 112,500 shares of common stock issued were recorded at fair market value of $1,002,000 on the dates of issuance. As of December 31, 2005, the entire amount was recognized as interest expense. The facility expired on December 31, 2005, and the Company did not

borrow any funds under this facility.

6. Committed Equity Financing Facility

On October 14, 2005, the Company entered into a committed equity financing facility (CEFF) with Kingsbridge Capital Limited (Kingsbridge), which entitles the Company to sell and obligates Kingsbridge to purchase, a maximum of approximately 6.0 million newly issued shares of the Company s common stock over a period of three years for cash up to an aggregate of $75,000,000, subject to certain conditions and restrictions. The Company may draw down under the CEFF in tranches of up to the lesser of $7,000,000 or 2% of the Company s market capitalization at the time of the draw down of such tranche, subject to certain conditions. The common stock to be issued for each draw down will be issued and priced over an eight-day pricing period at discounts ranging from 6% to 10% from the volume weighted average price of the Company s common stock during the pricing period. During the term of the CEFF, Kingsbridge may not short the Company s stock, nor may it enter into any derivative transaction directly related to the Company s stock. The minimum acceptable purchase price, prior to the application of the appropriate discount for any shares to be sold to Kingsbridge during the eight-day pricing period, is determined by the greater of $3.00 or 90% of the Company s closing share price on the trading day immediately prior to the commencement of each draw down. In connection with the CEFF, the Company issued a warrant to Kingsbridge to purchase up to 260,000 shares of the Company s common stock at an exercise price of $13.12 per share. The exercise term of the warrant is five years beginning on April 14, 2006. The warrant was valued on the date of grant using the Black-Scholes method using the following assumptions: a risk-free interest rate of 4.1%, a life of 5.5 years, no dividend yield and a volatility factor of 0.5. The estimated value of this warrant was $1,196,000 and was recorded as a contra-equity amount in additional paid-in capital in 2005.

Table of Contents

TERCICA, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO THE CONDENSED FINANCIAL STATEMENTS (Continued)

(Unaudited)

On November 9, 2005, the Company filed a shelf registration statement with the SEC relating to the resale of up to 6,296,912 shares of common stock that the Company may issue to Kingsbridge pursuant to a common stock purchase agreement and the warrant agreement noted above. The Company will not sell common stock under this registration statement and will not receive any of the proceeds from the sale of shares by the selling stockholder.

During the quarter ending March 31, 2006, the Company did not draw down any funds under the CEFF and had not issued any shares pursuant to the CEFF as of March 31, 2006.

7. Stock-Based Compensation

On January 1, 2006, the Company adopted the provisions of SFAS No. 123R, *Share-Based Payment*. SFAS No. 123R establishes accounting for stock-based awards made to employees and directors. Accordingly, stock-based compensation expense is measured at grant date, based on the fair value of the award, and is recognized as expense over the remaining requisite service period. The Company previously applied APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and related interpretations and provided the required pro forma disclosures of SFAS No. 123, *Accounting for Stock-Based Compensation*. Total stock-based compensation of $1,117,000 was recorded during the three months ended March 31, 2006.

The Company has four active stock-based compensation plans, which are described below.

2004 Stock Plan

The Company s Board of Directors adopted the 2004 Stock Plan (formerly the 2003 Stock Plan) in September 2003 and the Company s stockholders approved it in October 2003. The 2004 Stock Plan became effective on March 16, 2004. The 2004 Stock Plan provides for the grant of incentive stock options to employees and for the grant of nonstatutory stock options, stock purchase rights, restricted stock, stock appreciation rights, performance units and performance shares to the Company s employees, directors and non-employee service providers. Shares reserved under the 2004 Stock Plan include (a) shares reserved but unissued under the Company s 2002 Executive Stock Plan and the Company s 2002 Stock Plan, (b) shares returned to the 2002 Executive Stock Plan and the 2002 Stock Plan as the result of cancellation or forfeiture of options or the repurchase of shares issued under the 2002 Executive Stock Plan and the 2002 Stock Plan, and (c) annual increases in the number of shares available for issuance on the first day of each year beginning on January 1, 2005 equal to the lesser of:

4% of the outstanding shares of common stock on the first day of the Company s fiscal year,

1,250,000 shares, or

an amount the Company s board may determine.

Incentive stock options must be granted with exercise prices not less than 100% of fair market value of the common stock on the date of grant. Nonqualified stock options may be granted with an exercise price as determined by the Company s board; however, nonstatutory stock options intended to qualify as performance-based compensation within the meaning of Section 162(m) of the Internal Revenue Code must be granted with exercise prices not less than 100% of fair market value. The exercise price of any incentive stock option granted to a 10% stockholder will not be less than 110% of the fair market value of the common stock on the date of grant. Options granted under the 2004 Stock Plan expire no later than 10 years from the date of grant; however, incentive stock options granted to individuals owning over 10% of the total combined voting power of all classes of stock expire no later than five years from the date of grant. Options granted under the 2004 Stock Plan vests over periods determined by the Company s board, generally over four years. The 2004 Stock Plan has a term of 10 years.

2002 Stock Plan and 2002 Executive Stock Plan

The terms of the 2002 Stock Plan and 2002 Executive Stock Plan (the Plans) are similar to those of the Company s 2004 Stock Plan. The shares reserved but unissued under the Plans as of March 15, 2004 were reserved for issuance under the 2004 Stock Plan. In addition, any shares returned to the Plans as a result of cancellation or forfeiture of options or repurchases of shares after March 16, 2004 that were issued under the Plans are added to the shares reserved for the 2004 Stock Plan. Effective March 16, 2004, no additional stock options are issuable under these Plans.

There are a total of 6,453,834 shares authorized for issuance under the 2004 Stock Plan and the Plans.

Table of Contents

TERCICA, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO THE CONDENSED FINANCIAL STATEMENTS (Continued)

(Unaudited)

2004 Employee Stock Purchase Plan

The Company s Board of Directors adopted the 2004 Employee Stock Purchase Plan (formerly the 2003 Stock Purchase Plan) in September 2003 and the Company s stockholders approved it in October 2003. The 2004 Employee Stock Purchase Plan (the Purchase Plan) became effective on March 16, 2004. There are a total of 347,797 shares reserved for issuance under the Purchase Plan. In addition, the Purchase Plan provides for annual increases in the number of shares available for issuance under the Purchase Plan on the first day of each year, beginning with January 1, 2005 equal to the lesser of:

- 0.5% of the outstanding shares of common stock on the first day of the Company s fiscal year,
- 125,000 shares, or
- such other amount as may be determined by the Company s board.

The Purchase Plan permits eligible employees to purchase common stock at a discount through payroll deductions during defined offering periods. The price at which the stock is purchased is equal to the lower of 85% of the fair market value of the common stock at the beginning of an offering period or after a purchase period end. No shares were issued under the Purchase Plan during the three months ended March 31, 2006 and 2005.

Adoption of SFAS No. 123R

On January 1, 2006, the Company adopted SFAS No. 123R using the modified prospective transition method. Under that transition method, non-cash compensation expense was recognized in the first quarter of fiscal 2006 and included the following: (a) compensation expense related to any share-based payments granted through, but not yet vested as of January 1, 2006, and (b) compensation expense for any share-based payments granted subsequent to January 1, 2006, based on the grant-date fair value estimated in accordance with the provisions of SFAS No. 123R. The Company recognizes non-cash compensation expense for the fair values of these share-based awards on a straight-line basis over the requisite service period of each of these awards. Because non-cash stock compensation expense is based on awards ultimately expected to vest, it has been reduced by an estimate for future forfeitures. SFAS No. 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The Company s financial statements as of and for the three months ended March 31, 2006 reflect the impact of SFAS No. 123R. In accordance with the modified prospective transition method, the Company s financial statements for prior periods have not been restated to reflect, and do not include, the impact of SFAS No. 123R.

During the period from February 1, 2003 through January 31, 2004, certain stock options were granted with exercise prices that were below the reassessed fair value of the common stock at the date of grant. Total deferred stock compensation of $10,873,000 was recorded in accordance with APB Opinion No. 25, and was being amortized to expense over the related vesting period of the options. From inception through December 31, 2005, stock-based compensation expense of $5,740,000 was recognized and $2,542,000 was reversed as a result of employee terminations. The remaining deferred stock compensation balance of $2,591,000 as of December 31, 2005 was reversed on January 1, 2006 upon adoption in accordance with the provisions of SFAS No. 123R.

The non-cash stock-based compensation expense related to SFAS No. 123R for the three months ended March 31, 2006 was $1,117,000. If the Company had continued to account for stock-based compensation expense under APB Opinion No. 25, the non-cash stock-based compensation expense for the three months ended March 31, 2006 would have been $420,000. As a result of adopting SFAS No. 123R on January 1, 2006, net loss and basic and diluted loss per share for the three months ended March 31, 2006 were $697,000 and $0.02 higher, respectively, than if the Company had continued to account for stock-based compensation expense under APB Opinion No. 25.

14

Table of Contents

TERCICA, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO THE CONDENSED FINANCIAL STATEMENTS (Continued)

(Unaudited)

The following table presents the pro forma effect on net loss allocable to common stockholders and net loss per share if the Company had applied the fair value recognition provisions of SFAS No. 123 to options granted under the Company s share-based compensation arrangements during the first quarter of fiscal 2005 (in thousands, except per share amounts):

(In thousands, except per share data)	Three months ended March 31, 2005
Net loss allocable to common stockholders, as reported	$ (9,108)
Plus: Employee stock compensation expense based on intrinsic value method	618
Less: Stock-based compensation expense determined under the fair value method for all awards	(964)
Pro forma net loss allocable to common stockholders	$ (9,454)
Net loss per share allocable to common stockholders:	
Basic and diluted, as reported	$ (0.32)
Basic and diluted, pro forma	$ (0.34)

Other than options granted to non-employee service providers and a grant of certain stock options to employees with exercise prices that were below the reassessed fair value of the common stock as the date of the grant, there was no other stock-based compensation recognized during the three months ended March 31, 2005.

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

	Three months ended March 31,	
	2006	2005
Expected volatility	64%	50%
Expected term (years)	6.3	4.0
Risk-free interest rate	4.7%	3.7%
Dividend yield		

The Company s computation of expected volatility for the three months ended March 31, 2006 is based on an average of the historical volatility of the Company s stock and the historical volatility of a peer-group of similar companies. The Company s computation of expected term in the three months ended March 31, 2006 utilizes the simplified method in accordance with SAB 107. The risk-free interest rate for periods within the contractual life of the option is based on the U.S. Treasury yield curve in effect at the time of grant. The Company recognizes stock-based compensation expense for the fair values of these awards on a straight-line basis over the requisite service period of each of these awards.

Table of Contents

TERCICA, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO THE CONDENSED FINANCIAL STATEMENTS (Continued)

(Unaudited)

A summary of activity of all options are as follows (in thousands, except per share data and contractual term):

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2005	2,945	$ 7.49		
Options granted	1,386	7.21		
Options exercised	(137)	0.74		
Options forfeited	(5)	11.12		
Outstanding at March 31, 2006	4,189	$ 7.62	9.1	$ 2,629
Exercisable at March 31, 2006	3,111	$ 7.29	9.0	$ 2,295

The aggregate intrinsic value in the table above represents the total pre-tax intrinsic value, based on the Company s closing stock price of $6.70 as of March 31, 2006, which would have been received by the option holders had all option holders exercised their options on March 31, 2006. This amount changes based on the fair market value of the Company s stock. Total intrinsic value of options exercised for the three months ended March 31, 2006 was $842,000. During the three months ended March 31, 2006, the Company granted 1,385,720 stock options with an estimated total grant-date fair value of $6,357,000. Total fair value of options vested for the three months ended March 31, 2006 was $686,000.

As of March 31, 2006, unrecognized stock-based compensation expense related to stock options of $10,845,000 is expected to be recognized over a weighted-average period of 3.0 years.

A summary of activity of all nonvested stock options are as follows (in thousands, except per share data):

	Shares	Weighted-Average Grant Date Fair Value
Nonvested stock options at December 31, 2005	2,259	$ 8.01
Granted	1,386	7.21
Vested	(293)	6.34
Forfeited	(11)	11.10
Nonvested stock options at March 31, 2006	3,341	$ 7.81

Disclosures Pertaining to All Stock-Based Compensation Plans

Cash received from option exercises under all share-based payment arrangements for the quarters ended March 31, 2006 and 2005 was $100,000 and $4,000, respectively. Because of the Company s net operating losses, the Company did not realize any tax benefits for the tax deductions from share-based payment arrangements during each of the quarters ended March 31, 2006 and 2005.

16

Table of Contents

ITEM 2. 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 under Part II, Item 1A 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 and commercialization of new therapeutics for the treatment of short stature and other endocrine disorders. Our predecessor, Tercica Limited, a New Zealand Company, was formed in October 2000. Tercica Medica, Inc. was incorporated in Delaware in December 2001 and subsequently changed its name to Tercica, Inc. 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 Bio Science Baltimore, Inc., or Cambrex Baltimore. In July 2003, we signed an international license and collaboration agreement with Genentech obtaining the rights to develop and commercialize rhIGF-1 products outside of the United States for all indications other than diseases and conditions of the central nervous system. In addition, we must enter into a written agreement with another company if we desire to commercialize Increlex for the treatment of diabetes outside of the United States.

Our first commercial product is Increlex , a DNA-derived recombinant human insulin-like growth factor-1, or rhIGF-1. We obtained approval of long-term Increlex replacement therapy for severe primary insulin-like growth factor deficiency, or severe Primary IGFD, from the FDA in August 2005, and Increlex was granted seven years of orphan drug marketing exclusivity for the long-term treatment of growth failure in children with severe Primary IGFD. See the section entitled Risks Related to our Business under Part II, Item 1A below for further details related to our orphan drug marketing exclusivity. In January 2006, we launched Increlex in the United States. In December 2005, we also submitted a Marketing Authorization Application, or MAA, to the European Medicines Agency, or EMEA, for approval to market Increlex in the European Union for the long-term treatment of growth failure in children with severe Primary IGFD or with growth hormone gene deletion who have developed neutralizing antibodies to growth hormone, or GH. Our current focus is on marketing and selling Increlex for the treatment for severe Primary IGFD, and developing Increlex as a replacement therapy for primary IGF-1 deficiency, or Primary IGFD. We define the indication Primary IGFD to mean a child who has a height standard deviation score, or Height SDS, and an IGF-1 standard deviation score, or IGF-1 SDS, of less than minus two, and the indication severe Primary IGFD to mean a child who has a Height SDS and IGF-1 SDS of minus three or less, in each case in the presence of normal or elevated levels of growth hormone. We are currently conducting two late-stage clinical trials for the use of rhIGF-1 in Primary IGFD.

In October 2005, we entered into a committed equity financing facility, or CEFF, with Kingsbridge Capital Limited, or Kingsbridge, which entitles us to sell and obligates Kingsbridge to purchase a maximum of approximately 6.0 million newly issued shares of our common stock over a three-year period for cash up to an aggregate of $75.0 million, subject to certain conditions and restrictions. See the discussion below under Committed Equity Financing Facility for further details on the CEFF. As of March 31, 2006, we had not issued any shares under this facility.

As of March 31, 2006, we had approximately $79.2 million in cash, cash equivalents and short-term investments. We have funded our operations since inception through the private placement of equity securities and public offerings of our common stock, including a follow-on public offering of common stock completed on January 27, 2006 in which we raised net cash proceeds of approximately $34.2 million.

Table of Contents

Net Product Sales

Product sales consist of shipments of Increlex to specialty pharmacy distributors. Product sales are recognized when title passes to the customer. Product sales consist of gross sales less provisions for discounts to customers, rebates to government agencies, product returns and other adjustments. These provisions are provided for in the same period the related product sales are recorded. We began generating revenue from the sale of Increlex , in January 2006.

Research and Development Expenses

Research and development expenses consist primarily of costs associated with manufacturing development activities prior to regulatory approval and clinical and regulatory activities. Manufacturing development expenses include costs associated with our contract manufacturers including technology transfer, pre-approval product manufacturing, process development, validation and qualification activities, analytical development, and compliance-related support, pre-FDA approval preparations for current good manufacturing practices (cGMP), quality control and assurance activities, as well as personnel and related benefits and depreciation, prior to regulatory approval. Clinical and regulatory activities include the preparation, implementation, management of our clinical trials and assay development, as well as regulatory compliance, data management and biostatistics. Prior to receiving regulatory approval, we charged all drug supply production costs to research and development. Some of these drug supply costs incurred subsequent to August 2005 are included in inventory since our product received regulatory approval that month, and the subsequent cost of product sales of these inventories may not be indicative of future costs of product sales.

Because we licensed non-clinical, clinical and manufacturing data and know-how related to rhIGF-1 from Genentech in 2002, we did not incur significant development expenses prior to 2002. During 2003, our research and development activities were primarily focused on two projects: the transfer of our rhIGF-1 manufacturing process and the development project for Primary IGFD. At the end of 2003, we began to manage the development project for severe Primary IGFD as a separate project from the development project for Primary IGFD and completed the technology transfer of our manufacturing process to our contract manufacturers. Our primary focus in research and development in 2004 was associated with the establishment and validation of our rhIGF-1 manufacturing process at our contract manufacturers and preparations for the anticipated New Drug Application, or NDA, filing for severe Primary IGFD. During 2005, our research and development activities primarily centered around our NDA filing, process validation, quality control and assurance, and analytical services in preparations for FDA inspections at our contract manufacturers and development projects for severe Primary IGFD and Primary IGFD. Development projects for severe Primary IGFD and Primary IGFD consist primarily of clinical and regulatory activities, including costs associated with clinical trials. The FDA approved our NDA for severe Primary IGFD in August 2005. We expect our project costs for the remainder of 2006 to be primarily focused on clinical and regulatory activities, our MAA filing, and new product development activities in both severe Primary IGFD and Primary IGFD. Our projects or intended projects may be subject to change from time to time as we evaluate our research and development priorities and available resources.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of payroll and related costs associated with sales and marketing personnel, executive management, corporate administration, legal fees, commercial planning activities, facility costs, insurance, information technology, medical education and accounting services. During 2004, we expanded our corporate staffing and infrastructure and initiated planning for sales and marketing activities. During 2005, we continued to expand our corporate and sales staffing and infrastructure, increased our pre-launch activities and implemented Section 404 of the Sarbanes-Oxley Act of 2002. We expect total selling, general and administrative expenses in 2006 to increase primarily due to commercial activities associated with marketing Increlex for severe Primary IGFD, which may be partially offset by decreased legal costs associated with our litigation with Insmed Incorporated and Avecia Limited.

Critical Accounting Policies and the Use of Estimates

Our management s discussion and analysis of our financial condition and results of operations are based on our financial statements which have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP, for interim financial information. The preparation of our financial statements 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:

Table of Contents

Revenue Recognition

Product sales consist of shipments of Increlex to specialty pharmacy distributors. Product sales are recognized when title passes to the customer, and the customer assumes the risks and rewards of ownership. This is generally at the time product arrives at the customer s location. Product sales consist of gross sales less provisions for discounts to customers, rebates to government agencies, product returns and other adjustments. These provisions are provided for in the same period the related product sales are recorded. We began generating revenue from the sale of Increlex , in January 2006.

Stock-Based Compensation

On January 1, 2006, we adopted Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-Based Payment*, or SFAS No. 123R, which requires the measurement and recognition of non-cash compensation expense for all share-based payment awards made to employees and directors including employee stock options and employee stock purchases related to our 2004 Employee Stock Purchase Plan based on estimated fair values. SFAS No. 123R supersedes our previous accounting under Accounting Principles Board, or APB, Opinion No. 25, *Accounting for Stock Issued to Employees,* for periods beginning in fiscal 2006. In March 2005, the Securities and Exchange Commission issued Staff Accounting Bulletin No. 107, or SAB 107, relating to SFAS No. 123R. We have applied the provisions of SAB 107 in our adoption of SFAS No. 123R.

Prior to the adoption of SFAS No. 123R, we previously accounted for our stock-based compensation plans under the recognition and measurement provisions of APB Opinion No. 25 and related interpretations, and provided the disclosure-only provisions of SFAS No. 123, *Accounting for Stock-Based Compensation*. During the period from February 1, 2003 through January 31, 2004, 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 stock compensation, from inception through January 31, 2004, of $10.9 million was recorded in accordance with APB Opinion No. 25, and was being amortized to expense over the related vesting period of the options. From inception through December 31, 2005, stock-based compensation expense of $5.7 million was recognized and $2.6 was reversed as a result of employee terminations. The remaining deferred stock compensation balance of $2.6 million as of December 31, 2005 was reversed on January 1, 2006 upon adoption in accordance with the provisions of SFAS No. 123R.

We adopted SFAS No. 123R using the modified prospective transition method. Under that transition method, non-cash compensation expense was recognized in the first quarter of fiscal 2006 and included the following: (a) compensation expense related to any share-based payments granted through, but not yet vested as of January 1, 2006, and (b) compensation expense for any share-based payments granted subsequent to January 1, 2006, based on the grant-date fair value estimated in accordance with the provisions of SFAS No. 123R. We recognize non-cash compensation expense for the fair values of these share-based awards on a straight-line basis over the requisite service period of each of these awards. Because non-cash stock compensation expense is based on awards ultimately expected to vest, it has been reduced by estimated forfeitures. SFAS No. 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Our financial statements as of and for the three months ended March 31, 2006 reflect the impact of SFAS No. 123R. In accordance with the modified prospective transition method, our financial statements for prior periods have not been restated to reflect, and do not include, the impact of SFAS No. 123R.

As a result of adopting SFAS No. 123R, we recognized stock-based compensation expense of $1.1 million during the three months ended March 31, 2006, which primarily affected our reported research and development and selling, general, and administrative expenses. Approximately $0.4 million and $0.7 million are included in research and development expenses and selling, general and administrative expenses, respectively. We calculated this expense based on the fair values of the stock-based compensation awards as estimated using the Black-Scholes model. Use of this model requires us to make assumptions about expected future volatility of our stock price and the expected term of the options that we grant. Calculating stock-based compensation expense under SFAS No. 123R also requires us to make assumptions about expected future forfeiture rates for our option awards. As of March 31, 2006, total unrecognized compensation expense related to unvested share-based compensation arrangements previously granted under our various plans was $10.8 million, which we expect to recognize over a weighted-average period of 3.0 years. However, it is difficult to predict the actual amount of share-based compensation expense that we will recognize in future periods as that expense can be affected by changes in the amount or terms of our share-based compensation awards issued in the future, changes in the assumptions used in our model to value those future awards, changes in our stock price, and changes in interest rates, among other factors.

For more information on stock-based compensation expense recorded for the quarter ended March 31, 2006, please refer to Note 7 Stock Based Compensation in the notes to our condensed financial statements.

Table of Contents

Inventories

Inventories are stated at the lower of cost or market. Cost is determined using the first-in, first-out method. The valuation of inventory requires us to estimate potential obsolete or excess inventory. The determination of obsolete or excess inventory requires us to estimate the future demands for our products; however, if our current assumptions about future production or inventory levels, demand or competition were to change or if actual market conditions are less favorable than those we have projected, inventory write-downs may be required that could negatively impact our results of operations

Clinical Trial Expenses

We contract with third-party clinical research organizations to perform various clinical trial activities. We recognize research and development expenses for these contracted activities based upon a variety of factors, including actual and estimated patient enrollment rates, clinical site initiation activities, labor hours and other activity-based factors. We match the recording of expenses in our financial statements to the actual services received and efforts expended. Depending on the timing of payments to the service providers, we record prepaid expenses and accruals relating to clinical trials based on our estimate of the degree of completion of the event or events as specified in each clinical study or trial contract. We monitor each of these factors to the extent possible and adjust estimates accordingly. However such adjustments to date have not been material to our results of operations or financial position.

Results of Operations

Three Months Ended March 31, 2006 and 2005

Net Product Sales. We began shipment of Increlex to specialty pharmacy distributors in January 2006. Product sales less product returns and cash discounts were $85,000 for the quarter ended March 31, 2006. There were no government rebates to state Medicaid agencies in the first quarter of 2006, and we do expect to pay such rebates in the future. As Increlex is generally ordered by our distributors against specific prescriptions, we believe that our distributors carry minimal levels of inventory.

Cost of Product Sales. Cost of product sales were $83,000 for the quarter ended March 31, 2006. Cost of product sales represents the cost of production, shipping, distribution and handling costs, and a royalty owed to Genentech based on sales of Increlex . Prior to regulatory approval of Increlex in August 2005, drug supply production costs were charged to research and development. Beginning in the fourth quarter of 2005, with the marketing approval of Increlex by the FDA, we began capitalizing these production costs to inventory and began to charge cost of product sales in the first quarter of 2006 as these units of Increlex were sold. In addition to these capitalized drug supply production costs, there are also certain variable and fixed shipping, distribution and handlings costs charged to cost of product sales. Our cost of product sales as a percentage of net product sales may fluctuate over time as the drug supply produced prior to August 2005 is sold and as the mix of the fixed versus variable costs change over time.

Research and Development Expenses. Research and development expenses decreased to $4.6 million for the quarter ended March 31, 2006, from $4.9 million for the same period in 2005. Total research and development expenses decreased $0.2 million in the first quarter of 2006 compared to the first quarter of 2005 due primarily to lower project costs of $0.6 million, partially offset by higher personnel expenses of $0.3 million and $0.1 million of other internal costs. Our project costs in the quarter ended March 31, 2006 were lower than the same quarter in 2005 primarily due to completion of our manufacturing activities in preparation for our NDA filing which was completed in 2005. The $4.6 million in expenses during the quarter ended March 31, 2006 were comprised of internal personnel costs of $2.6 million, external project costs associated with our clinical and regulatory activities in Primary IGFD, and MAA filing related costs of $2.0 million.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased to $10.5 million for the quarter ended March 31, 2006, from $4.2 million for the same period in 2005. The increase of $6.3 million was primarily attributable to additional expenditures associated with sales and marketing activities of $2.8 million, increased expenses associated with litigation of $2.2 million, and increased expenses associated with medical education of $0.5 million.

Interest expense. There was no interest expense for the quarter ended March 31, 2006. Interest expense was $0.5 million for the quarter ended March 31, 2005. In January 2005, we entered into a loan agreement with Venture Leasing & Lending IV, Inc., or VLL, under which we issued 75,000 shares of our common stock to VLL. The common stock was valued at $720,000 on the date of issuance, and was amortized over the period of the initial loan commitment, through April 30, 2005, as interest expense.

Interest and Other Income, net. Interest and other income, net, increased to $0.9 million for the quarter ended March 31, 2006, from $0.4 million for the same period in 2005. The increase was due to an increase in interest rates and interest on higher average cash, cash equivalents and

short-term investment balances as a result of the cash proceeds received from our follow-on public offerings in February 2005 and January 2006.

Table of Contents

Liquidity and Capital Resources

Sources of Liquidity

On January 27, 2006, we completed a public offering of our common stock sold under a shelf registration, in which we raised net cash proceeds of approximately $34.2 million.

As of March 31, 2006, we had an accumulated deficit of $180.0 million, which was primarily comprised of $137.0 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. We have funded our operations and growth from inception through March 31, 2006 with net cash proceeds of $66.0 million in private equity financings and $135.4 million from our public offerings of common stock.

Committed Equity Financing Facility

Under the terms of the CEFF, Kingsbridge committed to purchase a maximum of approximately 6.0 million newly issued shares of our common stock over a three-year period beginning in October 2005, for cash up to an aggregate of $75.0 million, subject to certain conditions. We may draw down under the CEFF in tranches of up to the lesser of $7.0 million or 2% of our market capitalization at the time of the draw down of such tranche, subject to certain conditions. The common stock to be issued for each draw down will be issued and priced over an eight-day pricing period at discounts ranging from 6% to 10% from the volume weighted average price of our common stock during the pricing period. During the term of the CEFF, Kingsbridge may not short our stock, nor may it enter into any derivative transaction directly related to our stock. The minimum acceptable purchase price, prior to the application of the appropriate discount for any shares to be sold to Kingsbridge during the eight-day pricing period, is determined by the greater of $3.00 or 90% of our closing share price on the trading day immediately prior to the commencement of each draw down. In connection with the CEFF, we issued a warrant to Kingsbridge to purchase up to 260,000 shares of our common stock at an exercise price of $13.12 per share. We may exercise our right to draw down amounts under the CEFF, if and to the extent available, at such times as we have a need for additional capital and when we believe that sales of our common stock under the CEFF provide an appropriate means of raising capital. However, we are not obligated to sell any of the $75.0 million of common stock available under the CEFF, and there are no minimum commitments or minimum use penalties. During the quarter ended March 31, 2006, the Company did not draw down any funds under the CEFF and had not issued any shares pursuant to the CEFF as of March 31, 2006.

Cash Flow

Cash, cash equivalents and short-term investments totaled $79.2 million at March 31, 2006, compared to $58.6 million at December 31, 2005. The increase was primarily due to net proceeds of $34.2 million from the issuance of common stock from our January 2006 follow-on public offering, partially offset by cash used in operating activities of $13.6 million. The uses of cash in operations, during the first quarter of 2006, were primarily related to sales, marketing and related support personnel and activities associated with severe Primary IGFD, as well as clinical and regulatory activities related to severe Primary IGFD and Primary IGFD. The increase in cash used in operations of $2.7 million in the quarter ended March 31, 2006, compared to the same period in 2005, was due primarily to increases in sales, marketing and litigation activities. We expect an increase in net cash used in operations for the remainder of 2006, primarily to support the commercial activities associated with marketing Increlex for severe Primary IGFD and clinical, regulatory, and new product development activities in severe Primary IGFD and Primary IGFD.

Net cash provided from investing activities totaled $3.1 million in the quarter ended March 31, 2006, compared to net cash used of $30.0 million in the same period in 2005. Net cash provided from (used in) investing activities represented purchases, sales and maturities of investments and purchases of property and equipment. Net proceeds from short-term investments were $3.4 million in the quarter ended March 31, 2006, compared to net purchases of short-term investments of $29.8 million for the same period in 2005. The decrease of $33.1 million in net purchases of short-term investments in the quarter ended March 31, 2006, compared to the same period in 2005, was primarily due to the timing of maturities, sales and purchases of short-term investments, as well as the increased cash in-flow from our February 2005 follow-on public offering, resulting in higher net purchases of short-term investments.

Table of Contents

Net cash provided by financing activities for the quarter ended March 31, 2006 was $34.3 million, compared to $51.1 million for the same period in 2005. Net cash provided by financing activities primarily related to net proceeds received from our public offerings of common stock which totaled $34.2 million and $51.2 million in the quarters ended March 31, 2006 and 2005, respectively.

Litigation

On December 20, 2004, we initiated patent infringement proceedings against Avecia Limited and Insmed Incorporated as co-defendants in the High Court of Justice (Chancery Division Patents Court) in the United Kingdom. There is no date set for this action. On December 23, 2004, we, with Genentech, initiated patent infringement proceedings against Insmed Incorporated in the U.S. District Court for the Northern District of California. We initiated these proceedings because we believe that Insmed and Avecia are infringing on our patents that cover Insmed s product s use and manufacture. The trial date for the proceedings in the U.S. District Court for the Northern District of California is November 6, 2006.

We cannot predict the outcome of our litigation against Avecia and Insmed in the United Kingdom or the outcome of our litigation against Insmed in the United States. Moreover, we cannot predict the cost of such litigation, which may require a substantial diversion of our financial assets and other resources and consequently prevent us from allocating sufficient resources to the development of our rhIGF-1 programs, and which may have a material adverse effect on our business. In addition, if the outcome of our litigation in the United Kingdom is not favorable to us, we are likely to be found liable for the opposing parties costs incurred in connection with the litigation, and we could be found liable for an award of additional damages to the opposing parties if the court decides that our claims of patent infringement are without sufficient merit or not pursued in good faith. If in our litigation in the United States, the court decides Insmed prevails, and Insmed establishes by clear and convincing evidence that the case is exceptional (e.g., our claims of patent infringement were not pursued in good faith), we could be liable for an award of the opposing party s costs and legal fees incurred in connection with the litigation and/or an award of other damages. Any such award or awards to the opposing party or parties could substantially increase our costs and exacerbate the negative impact that an unfavorable outcome in the case(s) could have on our business. Further, it is not uncommon in cases of this kind for a defendant to assert counterclaims, which could significantly increase our costs, potential liability for damages, and other risks arising from these lawsuits, and a court could find us liable for any such damages caused by Genentech as well.

Insmed and Avecia have challenged the validity of European Patent No. 0 571 417 in our litigation in the United Kingdom, and Insmed has challenged the validity of U.S. Patent Nos. 5,187,151, 6,331,414 and 5,258,287 in our litigation in the United States. Even if we voluntarily drop our claims of patent infringement in our litigation in the United States and/or the United Kingdom, the opposing party or parties may pursue counterclaims for a declaratory judgment of invalidity against the asserted patent or patents in such action(s). If in our litigation in the United States the court awards a declaratory judgment finding invalid one or more of the claims of U.S. Patent No. 5,187,151, one or more of the claims of U.S. Patent No. 5,258,287, and/or one or more of the claims of U.S. Patent No. 6,331,414, and if the court s finding of invalidity in such declaratory judgment is upheld in whole or in part on appeal or if no appeal is taken, we would be unable to exclude others from using the affected claim or claims in the United States, which may decrease our ability to generate significant revenue from our rhIGF-1 programs and/or render any further development and commercialization of rhIGF-1 commercially infeasible for us. If in our litigation in the United Kingdom, the court awards a declaratory judgment finding invalid one or more of the claims of European Patent No. 0 571 417, and if the court s finding of invalidity in such declaratory judgment is upheld in whole or in part on appeal or if no appeal is taken, we would be unable to exclude others from using the affected claim or claims in the United Kingdom, and any such finding of invalidity may have a similar adverse impact on the enforceability of the affected claim or claims in one or more of the other European countries in which European Patent No. 0 571 417 would otherwise be in force, which may decrease our ability to generate significant revenue from our rhIGF-1 programs and/or render any further development and commercialization of rhIGF-1 commercially infeasible for us.

On December 6, 2005, we filed a complaint against Insmed for False Advertising and Unfair Competition, Case No. C-05-5027 SBA, in the U.S. District Court for the Northern District of California. The complaint alleges that Insmed made false, misleading and deceptive statements about Increlex and its product. We are seeking monetary and injunctive relief. We filed an amended complaint on December 15, 2005. Defendant Insmed filed a Motion to Dismiss on January 13, 2006. The motion was scheduled to be heard on March 28, 2006; however, on April 14, 2006, the Court ordered that no hearing is required and scheduled the Case Management Conference for June 14, 2006. Discovery has not commenced, and no trial date has been set.

Table of Contents

Operating Capital and Capital Expenditure Requirements

We believe that our cash, cash equivalents and short-term investments as of March 31, 2006 of $79.2 million, together with the funds available under the CEFF, will be sufficient to meet our projected operating and capital expenditure requirements through at least the end of 2007 based on our current business plan. We plan to make significant expenditures to support our marketing, sales, clinical trial, regulatory, and manufacturing development activities. We expect to focus on commercial launch activities for severe Primary IGFD, and we expect to continue to expand our development projects for severe Primary IGFD and Primary IGFD. We also expect significant legal expenditures for our ongoing litigation.

We obtained approval for the long-term treatment of growth failure in children with severe Primary IGFD or with growth hormone gene deletion who have developed neutralizing antibodies to growth hormone from the FDA in August 2005, and we are marketing Increlex for those indications. In addition, we submitted an MAA to the EMEA seeking approval to market Increlex in the European Union for a similar indication. We are also conducting two late-stage clinical trials for the use of rhIGF-1 in Primary IGFD as well as other clinical activities. Our projects may be subject to change from time-to-time as we evaluate our research and development priorities and available resources. These projects may also yield varying results that could delay, limit or change the timing of a project s advancement through various stages of product development and could significantly impact the costs to be incurred in bringing a project to completion. As a result, the costs to complete such projects, as well as the timing of net cash outflows, are not reasonably estimable.

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

- our ability to market and sell sufficient quantities of Increlex ;
- the status of competing products;
- the commercial status of the Increlex bulk drug manufacturing operations at Cambrex Baltimore, including the success of our cGMP production activities;
- the success of Increlex final drug product manufacturing;
- the costs, timing and scope of additional regulatory approvals for Increlex ;
- the rate of progress and cost of our future clinical trials and other research and development activities; and
- the pace of expansion of administrative and legal expenses.

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

We expect that we will require and attempt to raise additional funds through equity or debt financings, collaborative arrangements with corporate partners or from other sources, including the CEFF. However, there is no assurance that additional funding will be available to finance our operations when needed or on acceptable terms. Additional funding may also result in dilution to our stockholders.

23

Table of Contents

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our market risk disclosures set forth in Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2005 have not changed significantly.

ITEM 4. CONTROLS AND PROCEDURES.

Evaluation of Disclosure Controls and Procedures

Based on their evaluation as of March 31, 2006, 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) are effective to ensure that the information required to be disclosed by us in the reports that we file or submit under the Securities and Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended March 31, 2006 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 control over financial reporting can or 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.

Table of Contents

Part II Other Information

ITEM 1. LEGAL PROCEEDINGS

On December 20, 2004, we initiated patent infringement proceedings against Avecia Limited and Insmed Incorporated as co-defendants in the High Court of Justice (Chancery Division Patents Court) in the United Kingdom. On December 23, 2004, we, with Genentech, initiated patent infringement proceedings against Insmed Incorporated in the U.S. District Court for the Northern District of California. We initiated these proceedings because we believe that Insmed and Avecia are infringing and/or have infringed on our patents that cover Insmed s product s use and manufacture. Please refer to our disclosures under Part I, Item 3 of our Annual Report on Form 10-K for the year ended December 31, 2005, filed with the SEC on March 16, 2006, for more information regarding our litigation against Avecia and Insmed in the United Kingdom and our litigation against Insmed in the United States. There were no material developments in our litigation against Avecia and Insmed in the United Kingdom and our litigation against Insmed in the United States during the quarter ended March 31, 2006. We cannot predict the outcome of our litigation against Avecia and Insmed in the United Kingdom or the outcome of our litigation against Insmed in the United States. Moreover, we cannot predict the cost of such litigation, which has required and will continue to require a substantial diversion of our financial assets and other resources, and which may have a material adverse effect on our business. In addition, if the outcome of our litigation in the United Kingdom is not favorable to us, we are likely to be found liable for the opposing parties costs incurred in connection with the litigation, and we could be found liable for an award of additional damages to the opposing parties if the court decides that our claims of patent infringement are without sufficient merit or not pursued in good faith. If in our litigation in the United States, the court decides that a defendant prevails, and the defendant establishes by clear and convincing evidence that the case is exceptional (e.g., our claims of patent infringement were not pursued in good faith), we could be liable for an award of the opposing party s costs and legal fees incurred in connection with the litigation and/or an award of other damages. Any such award or awards to the opposing parties could substantially increase our costs and exacerbate the negative impact that an unfavorable outcome in the case(s) could have on our business. Further, it is not uncommon in cases of this kind for a defendant to assert counterclaims, which could significantly increase our costs, potential liability for damages, and other risks arising from these lawsuits, and a court could find us liable for any such damages caused by Genentech as well.

Insmed and Avecia have challenged the validity of European Patent No. 0 571 417 in our litigation in the United Kingdom, and Insmed has challenged the validity of U.S. Patent Nos. 5,187,151, 6,331,414 and 5,258,287 in our litigation in the United States. Even if we voluntarily drop our claims of patent infringement in our litigation in the United States and/or the United Kingdom, the opposing party or parties may pursue counterclaims for a declaratory judgment of invalidity against the asserted patent or patents in such action(s). If in our litigation in the United States the court awards a declaratory judgment finding invalid one or more of the claims of U.S. Patent No. 5,187,151, one or more of the claims of U.S. Patent No. 5,258,287, and/or one or more of the claims of U.S. Patent No. 6,331,414, and if the court s finding of invalidity in such declaratory judgment is upheld in whole or in part on appeal or if no appeal is taken, we would be unable to exclude others from using the affected claim or claims in the United States, which may decrease our ability to generate significant revenue from our rhIGF-1 programs and/or render any further development and commercialization of rhIGF-1 commercially infeasible for us. If in our litigation in the United Kingdom, the court awards a declaratory judgment finding invalid one or more of the claims of European Patent No. 0 571 417, and if the court s finding of invalidity in such declaratory judgment is upheld in whole or in part on appeal or if no appeal is taken, we would be unable to exclude others from using the affected claim or claims in the United Kingdom, and any such finding of invalidity may have a similar adverse impact on the enforceability of the affected claim or claims in one or more of the other European countries in which European Patent No. 0 571 417 would otherwise be in force, which may decrease our ability to generate significant revenue from our rhIGF-1 programs and/or render any further development and commercialization of rhIGF-1 commercially infeasible for us.

On December 6, 2005, we filed a complaint against Insmed for False Advertising and Unfair Competition, Case No. C-05-5027 SBA, in the U.S. District Court for the Northern District of California. The complaint alleges that Insmed made false, misleading and deceptive statements about Increlex and its product. We are seeking monetary and injunctive relief. We filed an amended complaint on December 15, 2005. Defendant Insmed filed a Motion to Dismiss on January 13, 2006. The motion was scheduled to be heard on March 28, 2006; however, on April 14, 2006, the Court ordered that no hearing is required and scheduled the Case Management Conference for June 14, 2006. Discovery has not commenced, and no trial date has been set.

ITEM 1A. RISK FACTORS.

We have identified the following additional risks and uncertainties that may have a material adverse effect on our business, financial condition or results of operations. Investors should carefully consider the risks described below before making an investment decision. The risks described below are not the only ones we face. Additional risks not presently known to us or that we currently believe are immaterial may also significantly impair our business operations. Our business could be harmed by any of these risks. The trading price of our common stock could decline due to any of these risks, and investors may lose all or part of their investment.

We have marked with an asterisk (*) those risks described below that reflect substantive changes from the risks described under Item 1A. Risk Factors included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 16, 2006.

Risks Related to Our Business

We are a development stage company with a limited operating history and may not be able to successfully market and sell any products, generate significant revenues or attain profitability.*

We are a development stage company focused on the development and commercialization of Increlex for the treatment of short stature and other endocrine disorders. From our inception in October 2000 through March 31, 2006, we have an accumulated deficit of $180.0 million. We may not be able to generate significant revenues from operations and may not be able to attain profitability. We incurred a net loss of $14.3 million during the three months ended March 31, 2006. We expect to incur substantial net losses, in the aggregate and on a per share basis, for the foreseeable future as we attempt to develop, market and sell Increlex for severe Primary IGFD and Primary IGFD. We are unable to predict the extent of these future net losses, or when we may attain profitability, if at all. These net losses, among other things, have had and will continue to have an adverse effect on our stockholders equity and net current assets.

Table of Contents

We anticipate that for the foreseeable future our ability to generate revenues and achieve profitability will be solely dependent on the successful commercialization of Increlex for the treatment of severe Primary IGFD and Primary IGFD. There is no assurance that we will be able to obtain or maintain governmental regulatory approvals to market Increlex in the United States or rest of the world for either or both of these indications or any other indication. If we are unable to generate significant revenue from Increlex or attain profitability, we will not be able to sustain our operations.

If there are fewer children with severe Primary IGFD or Primary IGFD than we estimate, we may not generate sufficient revenues to continue development of other products or to continue operations, or we may not be able to complete our clinical trials.

If there are fewer children with severe Primary IGFD or Primary IGFD than we estimate, we may not generate sufficient revenues to continue development of other indications or products and may need to cease operations. We estimate that the number of children in the United States with short stature is approximately one million, of which approximately 380,000 are referred to pediatric endocrinologists for evaluation. We believe that approximately 30,000 of these children have Primary IGFD, of which approximately 6,000 have severe Primary IGFD. Our estimate of the size of the patient population is based on published studies as well as internal data, including our interpretation of a study conducted as part of Genentech s National Cooperative Growth Study program. This study reported results of the evaluation of the hormonal basis of short stature in approximately 6,450 children referred to pediatric endocrinologists over a four-year period. We believe that the aggregate numbers of children in Western Europe with Primary IGFD and severe Primary IGFD are substantially equivalent to the numbers in the United States. If the results of Genentech s study or our interpretation and extrapolation of data from the study do not accurately reflect the number of children with Primary IGFD or severe Primary IGFD, our assessment of the market may be incorrect, making it difficult or impossible for us to meet our revenue goals or to enroll a sufficient number of patients in our clinical trials on a timely basis, or at all.

Increlex may fail to achieve market acceptance, which could harm our business.*

Prior to our January 2006 commercial launch of Increlex in the United States for the treatment of severe Primary IGFD, rhIGF-1 had never been commercialized in the United States or Europe for any indication. Even though the FDA has approved Increlex for sale in the United States, physicians may choose not to prescribe it, and third-party payers may choose not to pay for it, in which event we may be unable to generate significant revenue or become profitable.

Acceptance of Increlex will depend on a number of factors including:

- acceptance of Increlex by physicians and patients as a safe and effective treatment;
- reimbursement adoption;
- product price;
- the effectiveness of our sales and marketing efforts;
- storage requirements and ease of administration;
- dosing regimen;
- safety and efficacy;

prevalence and severity of side effects; and

competitive products.

Reimbursement may not be available for Increlex , which could diminish our sales and impact our ability to achieve profitability.*

Market acceptance, our sales of Increlex and our profitability will depend on reimbursement policies and health care reform measures. The levels at which government authorities and third-party payers, such as private health insurers and health maintenance organizations, reimburse the price patients pay for Increlex , and the timing of reimbursement decisions by these payers, will affect the commercialization of Increlex . We believe that Increlex will be reimbursed to a similar extent that growth hormone therapy is reimbursed for growth hormone deficiency. If our assumptions regarding the timing of reimbursement decisions or the level of reimbursement for Increlex are incorrect, our expected revenues may be delayed or substantially reduced. Since Increlex is approved by the FDA for severe Primary IGFD, only prescriptions for that indication may be reimbursable. Also, we cannot be sure that reimbursement amounts will not reduce the demand for, or the price of, Increlex . If reimbursement is not available or is available only to limited levels, we may not be able to market and sell Increlex .

Table of Contents

We believe that the annual wholesale acquisition cost of Increlex therapy for the treatment of severe Primary IGFD for a 24 kilogram child is approximately $23,000 per year. The actual cost per year per patient for Increlex will depend on the weight of the child, the treatment dose prescribed and compliance. In addition, it is possible that the children receiving Increlex therapy during the first few years of our launch are younger and/or smaller than those children receiving the drug in ensuing years, and the price per patient could be less than in subsequent years. If our assumptions regarding the price per patient of Increlex therapy for the treatment of severe Primary IGFD and Primary IGFD are incorrect, the market opportunity for Increlex therapy for the treatment of severe Primary IGFD and Primary IGFD may be substantially reduced.

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

As a result of legislative proposals and the trend towards managed health care in the United States, third-party payers 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, or require patients to pay co-insurance for Increlex . As a result, significant uncertainty exists as to whether and how much third-party payers will reimburse patients for their use of newly approved drugs, which, in turn, could put pressure on the pricing of drugs and/or the adoption of new products based on reimbursement policies.

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

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

We cannot predict the relative competitive position of Increlex . However, we expect that the following factors, among others, will determine our ability to compete effectively:

- acceptance of Increlex by physicians and patients as a safe and effective treatment;
- reimbursement adoption;
- product price;
- manufacturing costs;
- the effectiveness of our sales and marketing efforts;
- storage requirements and ease of administration;
- dosing regimen;

safety and efficacy;

prevalence and severity of side effects; and

competitive products.

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 Increlex . 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 Increlex .

Insmed Incorporated s combination product, when launched commercially, will compete directly with Increlex for the treatment of patients with severe Primary IGFD. Insmed s combination product was recently approved by the FDA for the treatment of patients with severe Primary IGFD or with growth hormone gene deletion who have developed neutralizing antibodies to growth hormone.

Table of Contents

Growth hormone products will likely compete with Increlex for the treatment of patients with Primary IGFD if Increlex is also approved for that indication. The major suppliers of commercially available growth hormone products in the United States are Genentech, Eli Lilly and Company, Teva Pharmaceutical Industries Ltd., Novo Nordisk A/S, Pfizer Inc and Serono S.A. Investigators from a Novo Nordisk clinical trial presented data that demonstrated growth hormone was effective in a population that included children with Primary IGFD. In addition, children with Primary IGFD may be diagnosed as having idiopathic short stature, or ISS. Eli Lilly and Company and Genentech have received FDA approval for their respective growth hormone products for the treatment of children with ISS. Accordingly, we expect that growth hormone products will compete directly with Increlex for the treatment of children with Primary IGFD who may be diagnosed as having ISS.

In addition, we are aware that Chiron Corporation has developed a process to manufacture rhIGF-1 using yeast expression and has intellectual property with respect to that process. We use bacterial expression, which differs from yeast expression, to manufacture Increlex .

We believe that Bristol-Meyers Squibb Company, Genentech, Merck & Co., Inc., Novo Nordisk and Pfizer Inc have conducted research and development of orally available small molecules that cause the release of growth hormone, known as growth hormone secretagogues. We believe that Rejuvenon Corporation has licensed certain rights to Novo Nordisk s growth hormone secretagogues and is actively developing one of these compounds for use in cancer cachexia, a wasting disorder affecting some cancer patients.

Many companies are seeking to develop products and therapies for the treatment of diabetes. These competitors include multinational pharmaceutical companies, specialized biotechnology firms, and universities and other research institutions. 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 Increlex .

Our inability to enter into commercial agreements on commercially reasonable terms with single-source manufacturers to fill-finish our approved product could adversely affect our commercial supply and ability to grow revenues.*

We currently source all of our fill-finish manufacturing and portions of release testing through a single-source third-party supplier. This supplier is the only FDA-approved manufacturer currently available to us, and could only be replaced by qualification of a new site for the same operations. We are currently negotiating a short-term commercial agreement with this fill-finish manufacturer, which has agreed to provide commercial product under an existing agreement. However, if we are unable to enter into such a short-term commercial agreement that has sufficient longevity with this single-source third-party supplier, we may be unable to fill-finish our commercial product until we move our process to another fill-finish manufacturer. It will take a significant amount of time and expense to arrange for an alternative manufacturer. Even if we enter into such a short-term agreement that has sufficient longevity with this manufacturer, we plan to engage another manufacturer for long-term fill-finish manufacturing. For us to change to another commercial fill-finish manufacturer, such manufacturer s facilities and processes, prior to our use, will need to undergo pre-approval and/or cGMP compliance inspections. In addition, we would need to transfer and validate the processes and certain analytical methods necessary for the production and testing of rhIGF-1 to this new manufacturer. Such a transfer may also result in a shortage of our commercial product and a loss of revenues.

If we do not receive additional regulatory marketing approvals of Increlex , our business will be harmed.*

We are currently developing Increlex for the treatment of Primary IGFD. The FDA has substantial discretion in the approval process and may decide that the data from our clinical trials is insufficient to allow approval of Increlex for Primary IGFD. If we do not receive regulatory marketing approval in the United States for Primary IGFD, our business will be harmed. We will also need to file applications with regulatory authorities in foreign countries to market Increlex for Primary IGFD in foreign countries. Although we have submitted a marketing authorization application in Europe for severe Primary IGFD, there is no assurance that we will receive marketing approval in Europe for either severe Primary IGFD or Primary IGFD. If we fail to obtain European marketing approval for Increlex , the geographic market for Increlex would be limited. If such approvals are delayed, it would postpone our ability to generate revenues in Europe.

If our contract manufacturers facilities and operations do not maintain satisfactory cGMP compliance, we may be unable to market and sell Increlex .

The facilities used by and operations of our contract manufacturers to manufacture and test Increlex must undergo continuing inspections by the FDA for compliance with cGMP regulations in order to maintain our Increlex approval for the treatment of severe Primary IGFD. As an example, Cambrex Bio Science Baltimore, Inc. is our sole provider of bulk rhIGF-1. We have no alternative manufacturing facilities or plans for additional facilities at this time. We do not know if the

28

Table of Contents

Cambrex Baltimore facilities or their operations required for the commercial manufacture of Increlex will continue to receive satisfactory cGMP inspections. In the event these facilities or operations do not continue to receive satisfactory cGMP inspections for the manufacture of our product, or for the operation of their facilities in general, we may need to invest in significant compliance improvement programs, fund additional modifications to our manufacturing processes, conduct additional validation studies, or find alternative manufacturing facilities, any of which would result in significant cost to us as well as result in a delay or prevention of commercialization, and may result in our failure to maintain approval. In addition, Cambrex Baltimore, 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 cGMP regulations and similar foreign standards. We do not have direct control over our contract manufacturers compliance with these regulations and standards. Any of these factors could delay or suspend clinical trials, regulatory submissions or regulatory approvals, entail higher costs and result in our being unable to effectively market and sell Increlex or maintain Increlex in the marketplace, which would adversely affect our ability to generate revenues.

We rely solely on single-source third parties in the manufacture, testing, storage and distribution of our products.*

We source all of our fill-finish manufacturing and testing and final product storage and distribution operations, as well as all of our bulk manufacturing, testing, and shipping operations, through single-source third-party suppliers and contractors. Single-source suppliers are the only approved suppliers currently available to us, and could only be replaced by qualification of new sites for the same operations.

If our contract facilities, contractors or suppliers become unavailable to us for any reason, including as a result of the failure to comply with cGMP regulations, manufacturing problems or other operational failures, such as equipment failures or unplanned facility shutdowns required to comply with cGMP, damage from any event, including fire, flood, earthquake or terrorism, business restructuring or insolvency, or if they fail to perform under our agreements with them, such as failing to deliver commercial quantities of bulk drug substance or finished product on a timely basis and at commercially reasonable prices, we may be delayed in manufacturing Increlex or may be unable to maintain validation of Increlex . This could delay or prevent the supply of commercial and clinical product, 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 cGMP or are unable or refuse to perform under our licenses and/or 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 cGMP 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 pre-approval and/or cGMP 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.

We rely in certain cases on single-source and sole-source materials suppliers to manufacture Increlex .

Certain specific components and raw materials used to manufacture Increlex at our third-party manufacturers are obtained and made available through either single-source or sole-source suppliers. Single-source suppliers are the only approved suppliers currently available to us, and could only be supplemented by qualification of new sources for the material required. Sole-source suppliers are the only source of supply available to us, and could only be replaced through qualification of an alternate material after demonstrating suitability. Supply interruption of these materials could result in a significant delay to our manufacturing schedules and ability to supply product, and would likely be required to undergo lengthy regulatory approval procedures prior to product distribution. Limits or termination of supply of these materials could significantly impact our ability to manufacture Increlex , cause significant supply delays while we qualified, at significant expense, new suppliers or new materials, and would consequently cause harm to our business.

Difficulties or delays in product manufacturing due to advance scheduling requirements and/or capacity constraints at our third-party manufacturers could harm our operating results and financial performance.

The manufacture of Increlex requires successful coordination between us and all of our suppliers, contractors, service-providers, and manufacturers. Coordination failures with these different elements of our supply chain could require us to delay shipments and/or impair our ability to supply product. Furthermore, uncertainties in estimating future demand for new products such as Increlex may result in manufacture of surplus inventory requiring us to record charges for any expired, unused product, or may result in inadequate manufacturing of product inventory, causing delays to shipments or no shipments at all. Additionally, our reliance on third-party manufacturing requires long lead times from order to delivery of product, and may be hampered by available capacity at those manufacturers, making our ability to supply product supplies in excess of our forecast extremely difficult. As a consequence, we may have inadequate capacity to meet unexpected demand, which could negatively affect our operating results.

Table of Contents

Claims and concerns may arise regarding the safety and efficacy of Increlex , which could require us to perform additional clinical trials, could slow introduction into the marketplace, or cause reduced sales or product withdrawal after introduction.

Increlex was approved in the United States for the treatment of severe Primary IGFD based on long-term and extensive studies and clinical trials conducted to demonstrate product safety and efficacy. Discovery of previously unknown problems with the raw materials, product or manufacturing processes, such as loss of sterility, contamination, new data suggesting an unacceptable safety risk or previously unidentified side effects for the product, could result in a voluntary or mandated withdrawal of the product from the marketplace, either temporarily or permanently. Studies may result in data or evidence suggesting another product is safer, better tolerated, or more efficacious than Increlex , which could lead to reduced sales. Additionally, discovery of unknown problems with our product or manufacturing processes for our product could negatively impact the established safety and efficacy profile and result in possible reduced sales or product withdrawal. Such outcomes could negatively and materially affect our product sales, operating results, and financial condition.

If other companies overcome our U.S. orphan drug marketing exclusivity or obtain marketing exclusivity in Europe, they will be able to compete with us, and our revenues will be diminished.*

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States. The company that obtains the first FDA approval for a designated orphan drug for a rare disease receives marketing exclusivity for use of that drug for the designated condition for a period of seven years. Increlex has received from the FDA orphan drug marketing exclusivity for the long-term treatment of patients with severe Primary IGFD. However, more than one product may be approved by the FDA for the same orphan indication or disease. As a result, even though our product has been approved and has received marketing exclusivity for severe Primary IGFD, the FDA can still approve other drugs for use in treating the same indication or disease covered by our product, which would create a more competitive market for us. For example, the FDA recently approved Insmed Incorporated s combination product for the treatment of severe Primary IGFD and granted Insmed s product orphan drug designation. Accordingly, notwithstanding our orphan drug designation for rhIGF- 1, Insmed s combination product for rhIGF-1 and BP-3 was deemed by the FDA to be a different drug than ours, and therefore, it will compete directly with Increlex for the treatment of patients with severe Primary IGFD, when it is launched commercially.

Furthermore, drugs considered to be the same as Increlex that are clinically superior or provide a major contribution to patient care may be approved for marketing by the FDA despite our initial orphan drug marketing exclusivity. If other companies are able to overcome our U.S. orphan drug exclusivity, they will be able to compete with us, and our revenues will be diminished.

We believe that Insmed s drug has also received an orphan drug designation in Europe from the European Medicines Agency, or EMEA, that covers the treatment of severe Primary IGFD. If Insmed s or another company s drug product is granted orphan drug marketing exclusivity for severe Primary IGFD in Europe before ours and is considered to be the same drug as ours, we would not be able to market or sell Increlex for severe Primary IGFD in Europe, and our revenues would be diminished.

We will not be able to sell our products if we are not able to maintain our regulatory approval due to changes to existing regulatory requirements.

Although we have obtained regulatory approval for Increlex in the United States for the treatment of severe Primary IGFD, this product and our manufacturing processes are subject to continued review and ongoing regulation by the FDA post approval, including, for example, changes to manufacturing process standards or good manufacturing practices, changes to product labeling, revisions to existing requirements or new requirements for manufacturing practices, or changing interpretations regarding regulatory guidance. Such changes in the regulatory environment and requirements could occur at any time during the commercialization of Increlex . This could adversely affect our ability to maintain our approval or require us to expend significant resources to maintain our approval, which could result in the possible withdrawal of Increlex from the marketplace, which would harm our business and negatively impact our financial performance.

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

In the future, rhIGF-1 manufactured by other parties may be approved for use in the United States. For example, we are aware that Chiron Corporation has developed a process to manufacture rhIGF-1 using yeast expression and has intellectual property with respect to that process. In the event there are other rhIGF-1 products approved by the FDA to treat indications other than those covered by Increlex , physicians may elect to prescribe a competitor s product containing rhIGF-1 to treat

30

Table of Contents

the indications for which Increlex has received and may receive 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 product containing rhIGF-1 to prescribe to their patients. As a result, we would have limited ability to prevent off-label use of a competitor s product containing rhIGF-1 to treat any diseases for which we have received FDA approval even if it violates our method of use patents and/or we have orphan drug exclusivity for the use of rhIGF-1 to treat such diseases.

Competitors could challenge our patents and file an Abbreviated New Drug Application (ANDA) or a 505(b)(2) new drug application for an IGF-1 product and adversely affect the competitive position of Increlex .

Products approved for commercial marketing by the FDA are subject to the provisions of the Drug Price Competition and Patent Term Restoration Act of 1984, or Hatch-Waxman Act. The Hatch-Waxman Act provides companies with marketing exclusivity for varying time periods during which generic or modified versions of a drug may not be marketed and allows companies to apply to extend patent protection for up to five additional years. It also provides a means for approving generic versions of a drug once the marketing exclusivity period has ended and all relevant patents have expired. The period of exclusive marketing, however, may be shortened if a patent is successfully challenged and defeated. Competitors with a generic IGF-1 product or a modified version of IGF-1 may attempt to file an ANDA or a 505(b)(2) NDA and challenge our patents and marketing exclusivity. Such applications would have to certify that one of the patents in the Increlex NDA is invalid or not infringed by the manufacture, use, or sale of the product described in that ANDA or 505(b)(2) application under the Hatch-Waxman Act. If successful, a competitor could come to market at an earlier time than expected. We can provide no assurances that we can prevail in a challenge or litigation related to our patents or exclusivity.

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. Patent litigation is very expensive, and we therefore may be unable to pursue patent litigation to its conclusion because currently we do not generate revenues.

We do not have patent composition coverage on the rhIGF-1 protein alone. 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 composition alone. 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 United States and foreign courts use to interpret patents, are not the same and are not always applied predictably or uniformly and can change, particularly as new technologies develop. As such, the degree of patent protection obtained in the United States may differ substantially from that obtained in various foreign countries. In some instances, patents have issued in the United States while substantially less or no protection has been obtained in Europe or other countries. Our United States Patent No. 6,331,414 B1 licensed from Genentech is directed to methods for bacterial expression of rhIGF-1 and expires in 2018. We have no equivalent European patent. The European Patent Office has determined that the claims of Genentech s corresponding European patent application are not patentable under European patent law in view of public disclosures made before the application was filed.

We are uncertain of the level of protection, if any, that will be provided by our licensed patents if we attempt to enforce them, and they are challenged in court where our competitors may raise defenses such as invalidity, unenforceability or possession of a valid license. For example, we initiated patent infringement proceedings against Avecia Limited and Insmed Incorporated in the United Kingdom and against Insmed Incorporated in the United States to enforce patent rights we licensed from Genentech. The United States action, among other things, alleges infringement of United States Patent No. 6,311,414 B1 identified above. If the court finds any of the patents at issue in those litigations, including United States Patent No. 6,311,414 B1, to be invalid or unenforceable, we would be prevented from enforcing such patents against third parties in the future, thus preventing us from using the affected patents to exclude others from competing with us. In addition, the type and extent of patent claims that will be issued to us in the future are uncertain. Any patents that are issued may not contain claims that will permit us to stop competitors from using similar technology.

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 Increlex . 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.

31

Table of Contents

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

In December 2004, we initiated patent infringement proceedings against Avecia Limited and Insmed Incorporated in the United Kingdom and against Insmed in the United States to enforce patent rights we licensed from Genentech. We cannot predict the outcome of such litigation. These actions have required a substantial diversion of financial and personnel resources and could expose us to liability for costs or other awards of damages. Declaratory judgments of invalidity against our patents asserted in such actions could prevent us from using the affected patents to exclude others from competing with us.

In addition, a third party may claim that we are using its inventions covered by its patents and may initiate litigation to stop us from engaging in our 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 are aware of a U.S. patent of Chiron Corporation related to processes of manufacturing rhIGF-1 in yeast host cells, to fusion proteins, DNA, and yeast host cells useful in such processes of manufacturing rhIGF-1 in yeast host cells, and to rhIGF-1 made as a product of such processes. While we use bacterial expression, not yeast expression, in our process for manufacturing Increlex , we cannot predict whether our activities relating to the development and commercialization of Increlex in the United States will be found to infringe Chiron s patent in the event Chiron brings patent infringement proceedings against us. We may not be able to obtain a license to Chiron s patent under commercially reasonable terms, if at all. If we are unable to obtain a license to Chiron s patent, and if in any patent infringement proceeding Chiron brings against us the court decides that our activities relating to the development and commercialization of Increlex in the United States infringe Chiron s patent, the court may award damages and/or injunctive relief to Chiron. Any such damages, injunctive relief and/or other remedies the court may award could render any further development and commercialization of Increlex commercially infeasible for us or otherwise curtail or cease any further development and commercialization of Increlex .

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

- some patent applications in the United States may be maintained in secrecy until the patents are issued,
- patent applications in the United States and many foreign jurisdictions are typically not published until 18 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 United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful, resulting in a loss of our United States patent position with respect to such inventions.

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

32

Table of Contents

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

We have licensed intellectual property rights and technology from Genentech, under our U.S. and International License and Collaboration agreements with Genentech. Under each agreement, Genentech has the right to terminate our license if we are in material breach of our obligations under that agreement and fail to cure that breach. Under the terms of the agreements, we are obligated, among other things, to use reasonable business efforts to meet specified milestones, including filing for regulatory approval in the United States for either a diabetes indication or a substitute indication by December 31, 2008. 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 lose our rights to utilize the technology and intellectual property covered by that agreement to develop, manufacture, market and sell Increlex for any indication. This may prevent us from continuing our business.

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

Under our U.S. license and collaboration agreement with Genentech, Genentech has the option to elect to jointly commercialize rhIGF-1 for all diabetes and non-orphan indications in the United States. 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 United States. With respect to those non-orphan and diabetes indications in the United States, once Genentech has exercised its option to jointly develop and commercialize, Genentech has the final decision on disputes relating to development and commercialization of such indications. Our ability to sublicense the development and commercialization of such products requires the consent of Genentech.

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

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

- the FDA or other regulatory authorities either do not approve a clinical trial protocol or place a clinical trial on clinical hold;
- patients do not enroll in clinical trials at the rate we expect (for example, in our current Phase III clinical trials of rhIGF-1 in Primary IGFD, patients have not enrolled at the rate we expected);
- patients experience adverse side effects;
- patients develop medical problems that are not related to our products or product candidates;
- third-party clinical investigators do not perform our clinical trials on our anticipated schedule or consistent with the clinical trial protocol and good clinical practices, or other third-party organizations do not perform data collection and analysis in a timely or accurate manner;
- contract laboratories fail to follow good laboratory practices;
- interim results of the clinical trial are inconclusive or negative;
- sufficient quantities of the trial drug may not be available, or available drug may become unusable;

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

re-evaluation of our corporate strategies and priorities; and

limited financial resources.

In addition, we may choose to cancel, change or delay certain planned clinical trials, or replace one or more planned clinical trials with alternative clinical trials. Our clinical trials or intended clinical trials may be subject to further change from time to time as we evaluate our research and development priorities and available resources. Our development costs will increase if we need to perform more or larger clinical trials than planned. Significant delays for our current or planned clinical trials may harm the commercial prospects for Increlex and our prospects for profitability.

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

To gain approval to market a product for treatment of a specific disease, we must provide the FDA and foreign regulatory authorities with clinical data that demonstrate the safety and statistically significant efficacy of that product for the

Table of Contents

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

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 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 contractors do not successfully carry out their contractual duties, satisfy FDA requirements for the conduct of clinical trials, or meet expected deadlines, we may be unable to obtain or maintain required approvals and may be unable to market and sell Increlex on a timely basis, if at all.

We may need others to market and sell Increlex in Europe and other regions of the world.*

We may need others to market and sell Increlex in Europe and other regions of the world . If we receive marketing approval for Increlex in Europe and decide to sell Increlex in Europe through one or more third parties, we will need to enter into marketing arrangements with them. We may not be able to enter into marketing arrangements with third parties on favorable terms, or at all. In addition, these arrangements could result in lower levels of income to us than if we marketed Increlex entirely on our own. In the event that we are unable to enter into a marketing arrangement for Increlex in Europe, we may not be able to develop an effective sales force to successfully market and sell our product in 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 discovery 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 additional products.

In addition, we may need additional intellectual property from other third parties to market and sell Increlex for indications other than severe Primary IGFD or Primary IGFD. We cannot be certain that we will be able to obtain a license to any third-party technology we may require to conduct our business.

The committed equity financing facility that we entered into with Kingsbridge Capital Limited may not be available to us if we elect to make a draw down, and may require us to pay certain liquidated damages.

In October 2005, we entered into a committed equity financing facility, or CEFF, with Kingsbridge Capital Limited, or Kingsbridge, which entitles us to sell and obligates Kingsbridge to purchase, from time to time over a period of three years, newly issued shares of our common stock for cash consideration of up to an aggregate of $75.0 million, subject to certain conditions and restrictions. Kingsbridge will not be obligated to purchase shares under the CEFF unless certain conditions are met, which include:

- a minimum price for our common stock;
- the accuracy of representations and warranties made to Kingsbridge;
- compliance with laws;

effectiveness of the registration statement, filed by us with the U.S. Securities and Exchange Commission, or SEC, for the resale of the shares of common stock issuable in connection with the CEFF and the shares of common stock underlying the warrant we issued to Kingsbridge in connection with the entering into of the CEFF; and

the continued listing of our stock on the Nasdaq Stock Market.

In addition, Kingsbridge is permitted to terminate the CEFF if it determines that a material and adverse event has occurred affecting our business, operations, properties or financial condition. If we are unable to access funds through the CEFF, or if the CEFF is terminated by Kingsbridge, we may be unable to access capital on favorable terms or at all.

Table of Contents

The terms of the CEFF require us to pay certain liquidated damages in the event that the registration statement filed by us with the SEC is not available for the resale of securities purchased by Kingsbridge under the CEFF or upon exercise of the warrant we issued to Kingsbridge. Except for certain periods of ineffectiveness permitted under the CEFF, we are obligated to pay to Kingsbridge an amount equal to the number of shares purchased under the CEFF and held by Kingsbridge at the date the registration statement becomes unavailable, multiplied by any positive difference in price between the volume weighted average price on the trading day prior to such period of unavailability and the volume weighted average price on the first trading day after the period of unavailability. In addition, we are entitled in certain circumstances to deliver a blackout notice to Kingsbridge to suspend the use of the registration statement and prohibit Kingsbridge from selling shares under the registration statement. If we deliver a blackout notice in the 15 trading days following a settlement of a draw down, then we must make a blackout payment to Kingsbridge as liquidated damages, or issue Kingsbridge additional shares in lieu of this payment, calculated by means of a varying percentage of an amount based on the number of shares purchased and held by Kingsbridge and the change in the market price of our common stock during the period in which the use of the registration statement is suspended. If the trading price of our common stock declines during a suspension of the registration statement, the blackout payment could be significant and could adversely affect our liquidity and our ability to raise capital.

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, cash equivalents and short-term investments as of March 31, 2006, together with the funds available under the CEFF, will be sufficient to meet our projected operating and capital expenditure requirements through at least the end of 2007 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.

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

- our ability to market and sell sufficient quantities of Increlex ;
- the status of competing products;
- the commercial status of the Increlex bulk drug manufacturing operations at Cambrex Baltimore, including the success of our cGMP production activities;
- the success of Increlex final drug product manufacturing;
- the costs, timing and scope of additional regulatory approvals for Increlex ;
- the rate of progress and cost of our future clinical trials and other research and development activities; and
- the pace of expansion of administrative and legal expenses.

We expect that we will require and attempt to raise additional funds through equity or debt financings, collaborative arrangements with corporate partners or from other sources, and the CEFF. However, there can be no assurance that 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 March 31, 2006, we had 103 full-time employees, and we expect to hire 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 believe that our anticipated future growth may strain our management, systems and resources. To manage the anticipated growth of our operations, we may need to increase management resources and implement additional financial and management controls, reporting systems and procedures. If we are unable to manage our growth, we may be unable to execute our business strategy.

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

One potential risk of using growth factors like 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. Increlex 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 study results from the treatment of 76 children with severe Primary IGFD with Increlex for an average of 4.4 years, with some patients being treated for over 12 years. None of the children withdrew from the study due to adverse events. However, some patients experienced hypoglycemia, or low blood glucose levels. Other side effects noted in some patients include hearing deficits, enlargement of the tonsils and intracranial hypertension.

Table of Contents

There may also be other adverse events associated with the use of Increlex , which may result in product liability suits being brought against us. While we have licensed the rights to develop, market and sell Increlex in certain indications, we are not indemnified by any third party, including our contract manufacturers, for any liabilities arising out of the development or use 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 Increlex 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.

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

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

We must implement additional finance and accounting systems, procedures and controls as we grow our business and organization and to satisfy new reporting requirements.

As a public reporting company, we must comply with the Sarbanes-Oxley Act of 2002 and the related rules and regulations of the Securities and Exchange Commission, including expanded disclosures and accelerated reporting requirements and more complex accounting rules. Compliance with Section 404 of the Sarbanes-Oxley Act of 2002 and other requirements will increase our costs and require additional management resources. We have upgraded our finance and accounting systems, procedures and controls and will need to continue to implement additional procedures and controls as we grow our business and organization and to satisfy new reporting requirements. Section 404 requires annual management assessments of the effectiveness of our internal control over financial reporting and a report by our independent registered public accountants attesting to and reporting on these assessments. If we are unable to complete the required assessment as to the adequacy of our internal control reporting or if our independent registered public accounting firm is unable to provide us with an unqualified report as to the effectiveness of our internal control over financial reporting, investors could lose confidence in the reliability of our internal control over financial reporting, which could adversely affect our stock price.

If we are unable to attract and retain additional qualified personnel, our ability to market and sell Increlex 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 and Dr. Ross G. Clark, our Chief Technical Officer, whose knowledge of our industry and technical expertise would be extremely difficult to replace. We have at will employment contracts with all of our executive officers. They may terminate their employment without cause or good reason and without notice to us.

Risks Related to Our Common Stock

If our results do not meet analysts forecasts and expectations, our stock price could decline.

While research analysts and others have published forecasts as to the amount and timing of our future revenues and earnings, we have stated that we will not be providing any forecasts of the amount and timing of our future revenues and earnings until after the assessment of two quarters of product sales. Analysts who cover our business and operations provide valuations regarding our stock price and make recommendations whether to buy, hold or sell our stock. Our stock price may be dependent upon such valuations and recommendations. Analysts valuations and recommendations are based primarily on our reported results and their forecasts and expectations concerning our future results regarding, for example, expenses, revenues, clinical trials, regulatory marketing approvals and competition. Our future results are subject to substantial

36

Table of Contents

uncertainty, and we may fail to meet or exceed analysts forecasts and expectations as a result of a number of factors, including those discussed under the section entitled Risks Related to Our Business above. If our results do not meet analysts forecasts and expectations, our stock price could decline as a result of analysts lowering their valuations and recommendations or otherwise.

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

As of March 31, 2006, our directors, executive officers and principal stockholders and their affiliates beneficially owned approximately 42% of our common stock. Our greater than five percent beneficial owners include; entities affiliated with MPM Capital, which beneficially owned 18.3%; entities affiliated with Prospect Management Co. II, LLC, which beneficially owned 8.2%; MedImmune, Inc., which beneficially owned 8%; entities affiliated with Rho Ventures, which beneficially owned 8%; and The Bank of New York, Co., Inc. which beneficially owned 5%. Our directors, executive officers and principal stockholders and their affiliates collectively 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.

The committed equity financing facility that we entered into with Kingsbridge may result in dilution to our stockholders.

Pursuant to the CEFF, Kingsbridge committed to purchase, subject to certain conditions and at our election, up to $75.0 million of our common stock. Should we sell shares to Kingsbridge under the CEFF, or issue shares in lieu of any blackout payment, it will have a dilutive effect on the holdings of our current stockholders, and may result in downward pressure on the price of our common stock. If we draw down amounts under the CEFF, we will issue shares to Kingsbridge at a discount of up to ten percent from the volume weighted average price of our common stock. If we draw down amounts under the CEFF when our share price is decreasing, we will need to issue more shares to raise the same amount than if our stock price was higher. Issuances in the face of a declining share price will have an even greater dilutive effect than if our share price were stable or increasing, and may further decrease our share price.

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

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

- announcements by us or our competitors of regulatory developments, clinical trial results, clinical trial enrollment, regulatory filings, new products and product launches, significant acquisitions, strategic partnerships or joint ventures;

- estimates of our business potential and earnings prospects;

- deviations from analysts projections regarding business potential, costs and/or earnings prospects;

Table of Contents

quarterly variations in our operating results;

significant developments in the businesses of biotechnology companies;

changes in financial estimates by securities analysts;

changes in market valuations or financial results of biotechnology companies;

additions or departures of key personnel;

changes in the structure of healthcare payment or reimbursement systems, regulations or policies;

activities of short sellers and risk arbitrageurs;

future sales of our common stock;

general economic, industry and market conditions; and

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

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

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 or issued pursuant to the CEFF, the market price of our common stock may decline. In addition, the perceived risk of dilution from sales of our common stock to or by Kingsbridge in connection with the CEFF may cause holders of our common stock to sell their shares, or it may encourage short selling by market participants, which could contribute to a decline in our stock price. 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 March 31, 2006, we had 37,537,030 outstanding shares of common stock. Of these shares, the 18,975,000 shares sold in our public offerings were freely tradable without restriction or further registration unless purchased by our affiliates. Of the remaining 18,562,030 shares outstanding as of March 31, 2006, substantially all of these shares were eligible for sale in the public market (subject to certain restrictions on sales by affiliates and vesting in the case of early exercised options). As of March 31, 2006, we had 3,110,896 shares subject to outstanding options granted under our equity compensation plans.

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 September 2005, we filed a shelf registration statement pursuant to which we may, from time-to-time, sell shares of our common stock and preferred stock, various series of debt securities and/or warrants to purchase any of such securities, either individually or in units, in one or more offerings. In November 2005, we also filed a registration statement for the resale of the shares of common stock issuable in connection with the CEFF and the shares of common stock underlying the warrant we issued to Kingsbridge in connection with our entering into the CEFF. In addition, certain holders of shares of our common stock that are parties to our amended and restated investors rights agreement are entitled to registration rights.

Table of Contents

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

On March 22, 2004, we completed our initial public offering of 5,500,000 shares of our common stock at a public offering price of $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 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. The aggregate purchase price of the offering was $56,925,000. The net offering proceeds to us after deducting total expenses and underwriting discounts and commissions were $50,021,000. None of the expenses were paid, directly or indirectly, to directors, officers or persons owning ten percent or more of our common stock or to their associates, or to our affiliates

We are using, and intend to continue to use, these proceeds for general corporate purposes, including research and development expenses, manufacturing expenses, clinical trials and selling, general and administrative expenses. No such payments were made to directors, officers of persons owning ten percent or more of our common stock or to their associates, or to our affiliates, other than payments in the ordinary course of business to officers for salaries and to non-employee directors as compensation for Board or Board committee service.

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 6. EXHIBITS

3.1	Certificate of Incorporation (1)
3.2	By-laws (2)
4.1	Form of Specimen Stock Certificate (2)
4.2	Reference is made to Exhibits 3.1 and 3.2
4.3	Warrant issued to Kingsbridge Capital Limited, dated October 14, 2005(3)
10.9W	Tercica, Inc. Incentive Compensation Plan (4)
10.9X	Employment letter to Ajay Bansal, dated February 27, 2006
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).

(1) Incorporated by reference to the Registrant s quarterly report on Form 10-Q (File No. 000-50461) filed on May 13, 2004.
(2) Incorporated by reference to the Registrant s registration statement on Form S-1 (File No. 333-108729) and amendments thereto, declared effective on March 16, 2004.
(3) Incorporated by reference to the Registrant s quarterly report on Form 10-Q (File No. 000-50461) filed on November 4, 2005.
(4) Incorporated by reference to the Registrant s current report on Form 8-K (File No. 000-50461) filed on February 28, 2006.

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 10, 2006

TERCICA, INC.

(Registrant)

/s/ Ajay Bansal
Ajay Bansal

Chief Financial Officer
(Authorized Officer and Principal Accounting and Financial Officer)