TERCICA INC
Form 10-Q
August 04, 2005
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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 June 30, 2005

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, 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 an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x

As of July 22, 2005, there were 31,572,321 shares of the Registrant s Common Stock outstanding.

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FORM 10-Q FOR THE QUARTER ENDED JUNE 30, 2005

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PART I FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS.

TERCICA, INC.

(A DEVELOPMENT STAGE COMPANY)

CONDENSED BALANCE SHEETS

(In thousands)

(Unaudited)

	June 30, 2005	December 31, 2004
Assets		
Current assets:		
Cash and cash equivalents	$ 29,728	$ 14,126
Short-term investments	53,751	37,875
Prepaid expenses and other current assets	1,503	705
Total current assets	84,982	52,706
Property and equipment, net	3,504	2,266
Restricted cash	790	
Other assets	90	50
Total assets	$ 89,366	$ 55,022
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 5,355	$ 3,967
Accrued expenses	3,691	3,032
Liability for early exercise of stock options	102	165
Total current liabilities	9,148	7,164
Other liabilities	205	181
Total liabilities	9,353	7,345
Commitments and contingencies		
Stockholders equity:		
Common stock	31	24
Additional paid-in capital	225,108	173,621
Deferred stock compensation	(4,085)	(6,388)
Accumulated other comprehensive loss	(24)	(72)

Deficit accumulated during the development stage	(141,017)	(119,508)
Total stockholders equity	80,013	47,677
Total liabilities and stockholders equity	$ 89,366	$ 55,022

See accompanying notes.

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TERCICA, INC.

(A DEVELOPMENT STAGE COMPANY)

CONDENSED STATEMENTS OF OPERATIONS

(In thousands, except per share data)

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,		Period from October 1, 2000 (inception) through June 30,
	2005	2004	2005	2004	2005
Costs and expenses:					
Research and development*	$ 6,320	$ 7,157	$ 11,190	$ 12,830	$ 60,815
Selling, general and administrative*	6,458	3,373	10,638	5,254	30,629
Acquired in-process research and development		1,167		1,417	8,157
Total costs and expenses	(12,778)	(11,697)	(21,828)	(19,501)	(99,601)
Interest expense	(294)		(793)		(899)
Interest and other income, net	671	250	1,112	364	2,511
Net loss	(12,401)	(11,447)	(21,509)	(19,137)	(97,989)
Deemed dividend related to beneficial conversion feature of convertible preferred stock					(44,153)
Net loss allocable to common stockholders	$ (12,401)	$ (11,447)	$ (21,509)	$ (19,137)	$ (142,142)
Basic and diluted net loss per share allocable to common stockholders	$ (0.40)	$ (0.48)	$ (0.72)	$ (1.32)	
Shares used to compute basic and diluted net loss per share allocable to common stockholders	31,257	23,852	29,702	14,544	

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

Research and development	$ 306	$ 361	$ 627	$ 751	$ 2,808
Selling, general and administrative	302	346	628	738	2,341
Total	$ 608	$ 707	$ 1,255	$ 1,489	$ 5,149

See accompanying notes.

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TERCICA, INC.

(A DEVELOPMENT STAGE COMPANY)

CONDENSED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Six Months Ended June 30,		Period from October 1, 2000 (inception) through June 30,
	2005	2004	2005
Cash flows from operating activities:			
Net cash used in operating activities	$ (18,829)	$ (17,534)	$ (79,365)
Cash flows from investing activities:			
Purchases of property and equipment	(1,435)	(234)	(4,276)
Purchases of available-for-sale securities	(69,159)	(105,312)	(245,995)
Proceeds from sales and maturities of available-for-sale securities	53,750	83,305	191,715
Net cash used in investing activities	(16,844)	(22,241)	(58,556)
Cash flows from financing activities:			
Net proceeds from issuance of preferred stock			63,960
Net proceeds from issuance of common stock	51,351	50,126	102,270
Other, net	(76)		1,419
Net cash provided by financing activities	51,275	50,126	167,649
Net increase in cash and cash equivalents	15,602	10,351	29,728
Cash and cash equivalents, beginning of period	14,126	1,949	
Cash and cash equivalents, end of period	$ 29,728	$ 12,300	$ 29,728
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
Deferred stock compensation, net of forfeitures	$ (1,111)	$ 3,986	$ 8,915
Deemed dividend related to beneficial conversion feature of convertible preferred stock	$	$	$ 44,153
Conversion of Series A and B convertible preferred stock into common stock	$	$ 68,636	$ 68,636
Common stock issued for senior credit facility	$ 1,002	$	$ 1,002
Other, net	$ 89	$ 42	$ 1,141

See accompanying notes.

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

These development stage financial statements and accompanying notes include the results of operations from the inception of Tercica Limited in October 2000 as both entities were under common control as evidenced by the following factors: (i) all of the investors of Tercica Limited were founding stockholders of 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 a biopharmaceutical company focused on the development and commercialization of new theraputics for the treatment of short stature and other related metabolic disorders. The Company s current product candidate is Increlex, recombinant human insulin-like growth factor-1 (rhIGF-1). 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 initial focus is on developing Increlex as a replacement therapy for primary IGF-1 deficiency (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 submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in February 2005 seeking approval of long-term rhIGF-1 replacement therapy for Severe Primary IGFD, based on Phase III clinical trial data. The Company s NDA was accepted for filing and granted priority review by the FDA in April 2005. The Company is conducting one late-stage clinical trial for the use of rhIGF-1 in Primary IGFD and initiated another in late July 2005.

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

Basis of Presentation

The accompanying unaudited condensed financial statements have been prepared in accordance with the requirements of the 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 accounting principles generally accepted in the United States (GAAP) can be condensed or omitted. In the opinion of management, the financial statements include all normal and recurring adjustments that are considered necessary for the fair presentation of the Company s financial position and operating results.

The results of the Company s operations can vary during each quarter of the year. Therefore, the results and trends in these interim financial statements may not be the same as those for the full year. The information included in this quarterly report on Form 10-Q should be read in conjunction with the audited financial statements for the year ended December 31, 2004, included in the Company s Annual Report on Form 10-K for the year ended December 31, 2004, filed with the SEC on March 24, 2005.

The condensed balance sheet at December 31, 2004 has been derived from the audited financial statements at that date but does not include all of the information and footnotes required by GAAP in the United States for complete financial statements.

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TERCICA, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO THE CONDENSED FINANCIAL STATEMENTS (continued)

(Unaudited)

Follow-on Public Offering

On February 11, 2005, the Company completed a follow-on public offering of 6,900,000 shares of its common stock, including the exercise of the over-allotment option by the underwriters, at a public offering price of $8.00 per share. Net cash proceeds from this offering were approximately $51,100,000 after deducting underwriter discounts and other offering expenses.

Use of Estimates

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

Research and Development Costs

In accordance with Statement of Financial Accounting Standards (SFAS) No. 2, *Accounting for Research and Development Costs*, research and development costs are expensed as incurred. Research and development expenses consist primarily of contract manufacturing expenses, clinical activities, regulatory activities, payroll and related costs, non-cash stock compensation, laboratory supplies and certain allocated costs.

Stock Compensation

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

The Company has elected to continue to follow the intrinsic value method of accounting as prescribed by APB Opinion No. 25. The information regarding net loss as required by SFAS No. 123 has been determined as if the Company had accounted for its employee stock options under the fair value method of that Statement.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2005	2004	2005	2004
Risk-free interest rate	3.7%	3.1%	3.7%	2.7%
Volatility	0.5	0.8	0.5	0.8
Weighted-average expected life of options (years)	3.3	4.0	3.7	3.8
Dividend yield				

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TERCICA, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO THE CONDENSED FINANCIAL STATEMENTS (continued)

(Unaudited)

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 compensation of $6,888,000 was recorded in accordance with APB Opinion No. 25, and is being amortized over the related vesting period of the options. The Company recorded employee stock-based compensation expense of $593,000 and $680,000 for the three months ended June 30, 2005 and 2004, respectively, and $1,212,000 and $1,434,000 for the six months ended June 30, 2005 and 2004, respectively. During the three and six months ended June 30, 2005, the Company reversed $932,000 and $1,111,000, respectively, of deferred stock compensation due to forfeitures of unvested stock options resulting from employee terminations. There were no reversals of deferred stock compensation due to forfeitures of unvested stock options resulting from employee terminations in the three and six months ended June 30, 2004. The following table illustrates the effect on net loss allocable to common stockholders had the Company applied the fair value provisions of SFAS No. 123 to employee stock compensation:

	Three Months Ended June 30,		Six Months Ended June 30		Period from October 1, 2000 (inception) through June 30,
(In thousand except per share data)	**2005**	**2004**	**2005**	**2004**	**2005**
Net loss allocable to common stockholders, as reported	$ (12,401)	$ (11,447)	$ (21,509)	$ (19,137)	$ (142,142)
Plus: Employee stock compensation expense based on intrinsic value method	593	680	1,212	1,434	4,851
Less: Employee stock compensation expense determined under the fair value method for all awards	(1,649)	(782)	(2,611)	(1,491)	(6,915)
Pro forma net loss allocable to common stockholders	$ (13,457)	$ (11,549)	$ (22,908)	$ (19,194)	$ (144,206)
Net loss per share allocable to common stockholders:					
Basic and diluted, as reported	$ (0.40)	$ (0.48)	$ (0.72)	$ (1.32)	
Basic and diluted, pro forma	$ (0.43)	$ (0.48)	$ (0.77)	$ (1.32)	

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

Clinical Trial Expenses

In the normal course of business, 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. As such, expense accruals related to clinical trials are recognized based on the estimate of the degree of completion of the event or events as specified in the specific clinical study or trial contract.

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 and successful completion of development projects, including clinical trial results, manufacturing process development results, ongoing feedback from regulatory authorities, including obtaining marketing approval, and those risks and uncertainties set forth in Item 2 below under the heading Risk Factors. 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.

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TERCICA, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO THE CONDENSED FINANCIAL STATEMENTS (continued)

(Unaudited)

Comprehensive Loss

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2005	2004	2005	2004
Net loss, as reported	$ (12,401)	$ (11,447)	$ (21,509)	$ (19,137)
Change in unrealized losses on marketable securities	36	(152)	48	(132)
Comprehensive loss	$ (12,365)	$ (11,599)	$ (21,461)	$ (19,269)

Recent Accounting Pronouncement

On December 16, 2004, the FASB issued an amendment to SFAS No. 123, *Share-Based Payment,* (SFAS No. 123R), which is effective for public companies in periods beginning after June 15, 2005. On April 14, 2005, the SEC adopted a rule amendment that delayed the compliance dates for SFAS No. 123R such that the Company is allowed to implement the proposed standard no later than the quarter that begins January 1, 2006. SFAS No. 123R addresses the accounting for transactions in which an enterprise receives employee services in exchange for equity instruments of the enterprise or liabilities that are based on the fair value of the enterprise s equity instruments or that may be settled by the issuance of such equity instruments. SFAS No. 123R eliminates the ability to account for share-based compensation transactions using APB Opinion No. 25, and requires instead that such transactions be accounted for using a fair-value-based method. Companies are required to recognize an expense for compensation cost related to share-based payment arrangements including stock options and employee stock purchase plans. Under SFAS No. 123R, the Company must determine the appropriate fair value model to be used for valuing share-based payments, the amortization method for compensation cost and the transition method to be used at the date of adoption. The transition methods include modified prospective and modified retrospective adoption options. Under the modified prospective method, compensation cost is recognized beginning with the effective date (a) based on the requirements of SFAS No. 123R for all share-based payments granted after the effective date and (b) based on the requirements of SFAS No. 123 for all awards granted to employees prior to the effective date of SFAS No. 123R that remain unvested on the effective date. The modified retrospective method includes the requirements of the modified prospective method described above, but also permits entities to restate based on the amounts previously recognized under SFAS No. 123 for purposes of pro forma disclosures, either (a) all prior periods presented or (b) prior interim periods of the year of adoption. The Company is currently evaluating option valuation methodologies and assumptions and therefore has not fully assessed the impact of adopting SFAS No. 123R. The Company has not yet

determined the method of adoption or the effect of adopting SFAS 123R, and has not determined whether the adoption will result in amounts that are similar to the current pro forma disclosures under SFAS 123. Current estimates of option values using the Black-Scholes method may not be indicative of results from valuation methodologies ultimately adopted by the Company. The Company expects to continue to grant stock-based compensation to employees, and believes that the adoption of the new standard will most likely have a material impact on the Company s results of operations.

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 when their effect is dilutive.

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TERCICA, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO THE CONDENSED FINANCIAL STATEMENTS (continued)

(Unaudited)

(In thousands, except per share data)	Three Months Ended June 30,		Six Months Ended June 30,	
	2005	2004	2005	2004
Historical				
Numerator:				
Net loss allocable to common stockholders	$ (12,401)	$ (11,447)	$ (21,509)	$ (19,137)
Denominator:				
Weighted-average common shares outstanding	31,292	23,933	29,742	14,631
Less: Weighted-average unvested common shares subject to repurchase	(35)	(81)	(40)	(87)
Denominator for basic and diluted net loss per share allocable to common stockholders	31,257	23,852	29,702	14,544
Basic and diluted net loss per share allocable to common stockholders	$ (0.40)	$ (0.48)	$ (0.72)	$ (1.32)

	Six Months Ended June 30,	
	2005	2004
Historical outstanding dilutive securities not included in diluted net loss per share allocable to common stockholders calculation		
Options to purchase common stock	2,758,823	1,999,736

3. Cash, Cash Equivalents and Short-Term Investments

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

	June 30, 2005

	Amortized Cost	Gross Unrealized Losses	Fair Value
Available-for-sale debt securities maturing within 1 year:			
Auction market preferred	$ 23,625	$	$ 23,625
Commercial paper	28,677	(3)	28,674
Federal agency bonds	27,979	(20)	27,959
Total available-for-sale debt securities	$ 80,281	$ (23)	$ 80,258

	December 31, 2004		
	Amortized Cost	Gross Unrealized Losses	Fair Value
Available-for-sale debt securities maturing within 1 year:			
Corporate bonds	$ 5,815	$ (14)	$ 5,801
Commercial paper	9,346	(2)	9,344
Federal agency bonds	19,759	(26)	19,733
Municipal bonds	9,753	(30)	9,723
Total available-for-sale debt securities	$ 44,673	$ (72)	$ 44,601

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TERCICA, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO THE CONDENSED FINANCIAL STATEMENTS (continued)

(Unaudited)

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

	June 30, 2005	December 31, 2004
Cash	$ 4,011	$ 7,400
Cash equivalents	25,717	6,726
Cash and cash equivalents	29,728	14,126
Short-term investments	53,751	37,875
Long-term restricted cash	790	
Total	$ 84,269	$ 52,001

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

4. 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 has the option to draw down funds in the aggregate principal amount of up to $15,000,000. The Company paid a $75,000 fee as part of this Loan Agreement and issued 75,000 shares of its common stock to an affiliate of VLL, which are held in escrow, subject to certain conditions. The $75,000 fee will be refunded to the Company if it borrows a minimum of $1.0 million under this facility. The 75,000 shares of common stock issued were recorded at fair market value on the date of issuance of $720,000. As of June 30, 2005, the entire amount was amortized to interest expense. The option to draw funding under this Loan Agreement is subject to additional issuances of up to a maximum of 112,500 shares of the Company s common stock. Any funding drawn down will have a three-year term from the date of funding. Any borrowings are subject to cash payments of principal and interest at an interest rate of 7.5% per annum, as well as a terminal interest payment at the end of the three-year term equal to 9.2% of the aggregate principal amount borrowed during the term of the loan. Under the terms of the Loan Agreement and an intellectual property security agreement, the Company would grant to VLL a first priority security interest on certain assets, including limited intellectual property assets, in the event any borrowings occur. The Company may terminate this facility at any time without penalty as long as no borrowings have been drawn down from the facility.

In April 2005, the Company exercised its option to extend the period during which it may draw down funds under the facility from April 30, 2005 to December 31, 2005. In connection with this extension, the Company issued 37,500 shares of its common stock to an affiliate of VLL in May 2005. The 37,500 shares of common stock were recorded at fair market value on the date of issuance of $282,000, which is being amortized over the extended eight-month loan commitment period. In connection with this stock issuance, the Company recognized $70,000 of interest expense in the quarter ended June 30, 2005. As of June 30, 2005, the Company has not borrowed any funds under this facility.

5. Lease Agreement

In March 2005, the Company entered into a new lease agreement for a facility in Brisbane, California. The term of the lease is 75 months. This agreement includes scheduled rent increases over the lease term and rent abatement for the first 15 months. In addition, the landlord may contribute up to $1,046,000 towards facility improvements. The Company recognizes rent expense on a straight-line basis over the term that the facility is physically utilized, taking into account the scheduled rent increases, rent abatement, rent holidays and the leasehold improvement allowance. Under the lease agreement, the Company provided the landlord with letters of credit amounting to $790,000, which are collateralized for the same amount by cash, cash equivalents and short-term investments held in a Company bank account. The Company has recorded the collateralized bank account balance as restricted cash.

Under this lease agreement, the future minimum lease commitment for the years ending December 31, 2005, 2006, 2007, 2008 and thereafter are $55,000, $83,000, $677,000, $711,000 and $2,155,000, respectively.

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TERCICA, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO THE CONDENSED FINANCIAL STATEMENTS (continued)

(Unaudited)

6. 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. 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 litigations because it believes that Insmed and Avecia are infringing on the Company s patents that cover Insmed s product s use and manufacture.

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 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.

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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 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 related metabolic disorders. Our current product candidate is Increlex, recombinant human insulin-like growth factor-1, or rhIGF-1. We licensed the rights of Genentech to develop, manufacture and commercialize rhIGF-1 products for a broad range of indications, including short stature, worldwide. Our initial focus is on 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 submitted a New Drug Application, or NDA, to the FDA in February 2005 seeking approval of long-term rhIGF-1 replacement therapy for Severe Primary IGFD, based on Phase III clinical trial data. Our NDA was accepted for filing and granted priority review by the FDA in April 2005. We are conducting one late-stage clinical trial for the use of rhIGF-1 in Primary IGFD and initiated another in late July 2005.

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

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

As of June 30, 2005, we had approximately $83.5 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 common stock. In 2002, we raised $20.0 million

through the sale of shares of our Series A preferred stock. In 2003, we raised $43.8 million through the sale of shares of our Series B preferred stock. On March 22, 2004, we completed our initial public offering of common stock in which we raised net cash proceeds of approximately $43.1 million and received an additional $6.9 million of net cash proceeds on April 2, 2004 in connection with the underwriters exercise of their option to purchase additional shares. On February 11, 2005, we completed our follow-on public offering of common stock in which we raised net cash proceeds of approximately $51.1 million.

On January 21, 2005, we entered into a loan agreement with Venture Leasing & Lending IV, Inc., or VLL, under which we have the option to draw down funds in the aggregate principal amount of up to $15 million. We paid a $75,000 fee as part of this loan agreement and issued 75,000 shares of our common stock to an affiliate of VLL, which are held in escrow, subject to certain conditions. The $75,000 fee will be refunded to us if we borrow a minimum of $1.0 million under this

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facility. The 75,000 shares of common stock issued were recorded at fair market value on the date of issuance of $720,000. As of June 30, 2005, the entire amount was amortized to interest expense. The option to draw funding under this loan agreement is subject to additional issuances of up to a maximum of 112,500 shares of our common stock. Any funding drawn down will have a three-year term from the date of funding. Any borrowings are subject to cash payments of principal and interest at an interest rate of 7.5% per annum, as well as a terminal interest payment at the end of the three year term equal to 9.2% of the aggregate principal amount borrowed during the term of the loan. Under the terms of the loan agreement and an intellectual property security agreement, we would grant to VLL a first priority security interest on certain assets, including limited intellectual property assets, in the event any borrowings occur. We may terminate this facility at any time without penalty as long as no borrowings have been drawn down from the facility. In April 2005, we exercised our option to extend the period during which we may draw down funds under this facility from April 30, 2005 to December 31, 2005. In connection with this extension, we issued 37,500 shares of our common stock to an affiliate of VLL in May 2005. The 37,500 shares of our common stock were recorded at fair market value on the date of issuance of $282,000, which is being amortized over the extended eight-month loan commitment period. In connection with this stock issuance, we recognized $70,000 of interest expense in the quarter ended June 30, 2005. As of June 30, 2005, we have not borrowed any funds under this facility.

Revenues

We have not generated any operating revenues since our inception and do not expect to generate any revenue from the sale of our current product candidate, Increlex, until at least late 2005, if at all.

Research and Development Expenses

Research and development expenses consist primarily of contract manufacturing expenses, clinical activities, regulatory activities, payroll and related costs, non-cash stock compensation, laboratory supplies and certain allocated costs. Our research and development activities are primarily focused on validating our manufacturing process at our contract manufacturers, using that process to make drug product suitable for clinical use and commercial sale and development activities related to Severe Primary IGFD and Primary IGFD. 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. However, we expect to fund our own development activities and will continue to incur significant costs in the future. During 2003, our research and development activities were primarily focused on two projects: the transfer of our rhIGF-1 manufacturing process and the development project for Primary IGFD. At the end of 2003, we began to manage the development project for Severe Primary IGFD as a separate project from the development project for Primary IGFD and completed the 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 NDA filing in Severe Primary IGFD. With our NDA submitted to the FDA in February 2005, we expect the remainder of 2005 to be focused on the preparation for pre-approval inspections at our contract manufacturers, the completion of our development project for Severe Primary IGFD and increased activities associated with our development project for Primary IGFD. In 2005, we expect that our project costs will be focused on FDA inspection preparation activities at our contract manufacturers, manufacturing activities related to product launch preparation and costs related to clinical trials in 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.

When Increlex is approved by the FDA, if at all, and we begin commercial manufacturing, we will no longer expense certain manufacturing costs as research and development for Increlex.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of payroll and related costs, non-cash stock compensation, facility costs, insurance, information technology, legal fees and accounting services. Other costs include sales and marketing activities such as pre-launch planning and medical education activities. During 2004, we continued to expand our corporate staffing and infrastructure and initiated planning for sales and marketing activities. We expect selling, general and administrative expenses in 2005 to increase due to associated costs with the annualized effect of 2004 personnel additions, legal expenses related to litigation, personnel additions in 2005, increased pre-launch activities and activities associated with the implementation of Section 404 of the Sarbanes-Oxley Act of 2002.

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.

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The items in our financial statements requiring significant estimates and judgments are as follows:

Stock Compensation

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

In December 2002, the FASB issued SFAS No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure*. SFAS No. 148 amends SFAS No. 123 to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. We have elected to continue to follow the intrinsic value method of accounting as prescribed by APB No. 25. The information regarding net loss as required by SFAS No. 123 has been determined as if we had accounted for our employee stock options under the fair value method of that statement.

Stock compensation expense, which is a non-cash charge, results from stock option grants at exercise prices below the reassessed fair value of the underlying common stock resulting in our recording stock compensation associated with these grants. Stock compensation expense is amortized over the vesting period of the underlying option, generally four years. From inception through January 31, 2004, we recorded deferred stock compensation of $10.9 million. At June 30, 2005, we had a total of $4.1 million of deferred stock compensation remaining to be amortized over the vesting period of the stock options of approximately three years. In the six months ended June 30, 2005, we reversed $1.1 million of deferred stock compensation due to the forfeiture of unvested stock options from employee terminations. We have not recorded any additional deferred stock compensation subsequent to January 31, 2004.

The total unamortized deferred stock compensation recorded for all option grants through January 31, 2004, net of the amounts reversed associated with forfeited stock options will be amortized as follows: $2.3 million for the year ending December 31, 2005; $2.2 million for the year ending December 31, 2006; and $1.1 million for the year ending December 31, 2007.

Clinical Trial Expenses

In the normal course of business, 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. As such, expense accruals related to clinical trials are recognized based on our estimate of the degree of completion of the event or events as specified in each clinical study or trial contract.

Acquired In-Process Research and Development

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

Recent Accounting Development

On December 16, 2004, the FASB issued an amendment to SFAS No. 123, *Share-Based Payment,* (SFAS No. 123R), which is effective for public companies in periods beginning after June 15, 2005. On April 14, 2005, the SEC adopted a rule amendment that delayed the compliance dates for SFAS No. 123R such that we are allowed to implement the

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proposed standard no later than the quarter that begins January 1, 2006. SFAS No. 123R addresses the accounting for transactions in which an enterprise receives employee services in exchange for equity instruments of the enterprise or liabilities that are based on the fair value of the enterprise s equity instruments or that may be settled by the issuance of such equity instruments. SFAS No. 123R eliminates the ability to account for share-based compensation transactions using APB Opinion No. 25, and requires instead that such transactions be accounted for using a fair-value-based method. Companies are required to recognize an expense for compensation cost related to share-based payment arrangements including stock options and employee stock purchase plans. Under SFAS No. 123R, we must determine the appropriate fair value model to be used for valuing share-based payments, the amortization method for compensation cost and the transition method to be used at the date of adoption. The transition methods include modified prospective and modified retrospective adoption options. Under the modified prospective method, compensation cost is recognized beginning with the effective date (a) based on the requirements of SFAS No. 123R for all share-based payments granted after the effective date and (b) based on the requirements of SFAS No. 123 for all awards granted to employees prior to the effective date of SFAS No. 123R that remain unvested on the effective date. The modified retrospective method includes the requirements of the modified prospective method described above, but also permits entities to restate based on the amounts previously recognized under SFAS No. 123 for purposes of pro forma disclosures, either (a) all prior periods presented or (b) prior interim periods of the year of adoption. We are currently evaluating option valuation methodologies and assumptions and therefore have not fully assessed the impact of adopting SFAS No. 123R. We have not yet determined the method of adoption or the effect of adopting SFAS 123R, and we have not determined whether the adoption will result in amounts that are similar to the current pro forma disclosures under SFAS 123. Current estimates of option values using the Black-Scholes method may not be indicative of results from valuation methodologies ultimately adopted by us. We expect to continue to grant stock-based compensation to employees, and believe that the adoption of the new standard will most likely have a material impact on our results of operations.

Results of Operations

Three Months Ended June 30, 2005 and 2004

Research and Development Expenses. Research and development expenses decreased to $6.3 million for the quarter ended June 30, 2005, from $7.2 million for the same period in 2004. The $6.3 million in expenses were comprised of internal personnel costs of $2.7 million, project costs associated with the establishment, validation and preparations for pre-approval inspections at our manufacturing process at our contract manufacturers totaling $3.0 million and costs related to our development projects for Primary IGFD and Severe Primary IGFD totaling $0.6 million.

In the quarter ended June 30, 2005, project costs for the establishment, validation and preparations for pre-approval inspections at our contract manufacturers decreased by $1.4 million from the same period in 2004, primarily due to production and validation activities at Cambrex Baltimore. Personnel costs for the quarter ended June 30, 2005 increased by $0.6 million from the same period in 2004. The costs associated with our development projects for Primary IGFD and Severe Primary IGFD for the quarter ended June 30, 2005 decreased by $0.1 million from the same period in 2004. The Primary IGFD and Severe Primary IGFD project costs related primarily to NDA filing preparations for Severe Primary IGFD, clinical trials in Primary IGFD, the conduct of several small studies and the analyses of clinical trial data. In 2005, we expect that our project costs will be focused on FDA inspection preparation activities at our contract manufacturers, launch preparation activities and costs related to clinical trials in Primary IGFD.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased to $6.5 million for the quarter ended June 30, 2005, from $3.4 million for the same period in 2004. The increase of $3.1 million was primarily attributable to increased legal fees associated with our litigation with Insmed Incorporated and Avecia Limited of $2.4 million, increased personnel costs of $0.5 million, and increased corporate administration expenses such as consulting, facilities and other expenses of $0.2 million. We expect selling, general and administrative expenses in 2005 to increase due to associated costs with the annualized effect of 2004 personnel additions, personnel additions in 2005, legal expenses related to litigation, increased pre-launch activities and the activities associated with the implementation of Section 404 of the Sarbanes-Oxley Act of 2002.

Acquired In-Process Research and Development. Acquired in-process research and development expense was $1.2 million in the quarter ended June 30, 2004. We did not incur acquired in-process research and development expenses in the comparable quarter in 2005. The costs in 2004 resulted from a $1.2 million payment to Genentech related to the exclusive license to Genentech s worldwide rights, including the United States, to IGF-1 combined with IGFBP-3 for all indications, other than diseases and conditions of the central nervous system.

Interest expense. Interest expense was $0.3 million for the quarter ended June 30, 2005. We did not incur any interest expense in the comparable quarter in 2004. The 75,000 shares of common stock we issued in January 2005 in connection

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with our loan agreement with VLL were valued at $0.7 million on the date of issuance and were amortized over the period of the initial loan commitment, through April 30, 2005, as interest expense. In May 2005, we extended our loan agreement with VLL through December 31, 2005, in connection with which we issued 37,500 shares of our common stock to an affiliate of VLL. The 37,500 shares of common stock were valued at $0.3 million on the date of issuance, and are being amortized over the extended eight-month commitment period through December 31, 2005, as interest expense.

Interest and Other Income, net. Interest and other income, net, increased to $0.7 million for the quarter ended June 30, 2005, from $0.3 million for the same period in 2004. The increase was due primarily to interest on higher average cash, cash equivalents and short-term investment balances as a result of the cash proceeds received from our initial public offering in March 2004 and our follow-on public offering in February 2005.

Six Months Ended June 30, 2005 and 2004

Research and Development Expenses. Research and development expenses decreased to $11.2 million for the six months ended June 30, 2005, from $12.8 million for the same period in 2004. The $11.2 million in expenses were comprised primarily of internal personnel costs of $5.0 million, project costs associated with the establishment, validation and preparations for pre-approval inspections at our contract manufacturers totaling $4.5 million, and costs related to our development projects for Primary IGFD and Severe Primary IGFD totaling $1.7 million.

In the six months ended June 30, 2005, project costs for the establishment, validation and preparations for pre-approval inspections at our contract manufacturers decreased by $2.8 million from the same period in 2004, primarily due to the timing of production and validation activities at Cambrex Baltimore. Personnel costs for the six months ended June 30, 2005 increased by $1.0 million from the same period in 2004. The costs associated with our development projects for Primary IGFD and Severe Primary IGFD for the six months ended June 30, 2005 increased by $0.1 million from the same period in 2004. The Primary IGFD and Severe Primary IGFD project costs related primarily to NDA filing preparations for Severe Primary IGFD, clinical trials in Primary IGFD, the conduct of several small studies and the analyses of clinical trial data. In 2005, we expect that our project costs will be focused on inspection preparation activities at our contract manufacturers, launch preparation activities and costs related to clinical trials in Primary IGFD.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased to $10.6 million for the six months ended June 30, 2005, from $5.3 million for the same period in 2004. The increase of $5.3 million was attributable to increased legal fees associated with our litigation with Insmed and Avecia of $2.8 million, increased personnel costs of $1.3 million and increased corporate administration expenses such as consulting, insurance, facilities and other expenses of $1.3 million. We expect selling, general and administrative expenses in 2005 to increase due to associated costs with the annualized effect of 2004 personnel additions, personnel additions in 2005, legal expenses related to litigation, increased pre-launch activities and the activities associated with the implementation of Section 404 of the Sarbanes-Oxley Act of 2002.

Acquired In Process Research and Development. Acquired in-process research and development expense was $1.4 million in the six months ended June 30, 2004. We did not incur acquired in-process research and development expenses in the comparable period ended in 2005. The costs in 2004 resulted from a $1.2 million payment to Genentech related to the exclusive license to Genentech s worldwide rights, including the United States, to IGF-1 combined with IGFBP-3 for all indications, other than diseases and conditions of the central nervous system, and $250,000 of costs resulting from the execution of a patent license.

Interest expense. Interest expense was $0.8 million for the six months ended June 30, 2005. We did not incur any interest expense in the comparable period in 2004. The 75,000 shares of common stock we issued in January 2005 in connection with our loan agreement with VLL were valued at $0.7 million on the date of issuance and were amortized over the period of the initial loan commitment, through April 30, 2005, as interest expense. In May 2005, we extended our loan agreement with VLL through December 31, 2005, in connection with which we issued 37,500 shares of our common stock to an affiliate of VLL. The 37,500 shares of common stock were valued at $0.3 million on the date of issuance, and are being amortized over the extended eight-month commitment period through December 31, 2005, as interest expense.

Interest and Other Income, net. Interest and other income, net, increased to $1.1 million for the six months ended June 30, 2005, from $0.4 million for the same period in 2004. The increase was due primarily to interest on higher average cash, cash equivalents and short-term investment balances as a result of the cash proceeds received from our initial public offering in March 2004 and our follow-on public offering in February 2005.

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Liquidity and Capital Resources

Sources of Liquidity

As of June 30, 2005, we had an accumulated deficit of $141.0 million, which was primarily comprised of $98.0 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 with net cash proceeds of $66.0 million in private equity financings and $101.2 million from our public offerings of common stock.

Cash Flow

Cash, cash equivalents and short-term investments totaled $83.5 million at June 30, 2005, compared to $52.0 million at December 31, 2004. The increase was primarily due to net proceeds of $51.1 million from the issuance of common stock in our follow-on public offering, partially offset by cash used in operating activities of $18.8 million. The increase in net cash used in operating activities was due to increased personnel and infrastructure costs and our development projects for Severe Primary IGFD and Primary IGFD.

Net cash used in investing activities totaled $16.8 million in the six months ended June 30, 2005, compared to $22.2 million in the same period in 2004. Net cash used in investing activities represent purchases, sales and maturities of investments and purchases of property and equipment. Net purchases of short-term investments were $15.4 million in the six months ended June 30, 2005, a decrease of $6.6 million from the same period in 2004. The decrease in net purchases of short-term investments was due to timing of maturities, sales and purchases of short-term investments. Purchases of property and equipment were $1.4 million and $0.2 million in the six months ended June 30, 2005 and 2004, respectively. The increase in purchases of property and equipment primarily relate to the purchase of leasehold improvements and office furniture for our new offices located in Brisbane, California.

Net cash provided by financing activities for the six months ended June 30, 2005 was $51.3 million, compared to $50.1 million for the same period in 2004. Net cash provided by financing activities primarily relate to net proceeds received from our public offerings of common stock in the six months ended June 30, 2005 and 2004, respectively.

Senior Credit Facility

On January 21, 2005, we entered into a loan agreement with VLL under which we have the option to draw down funds in the aggregate principal amount of up to $15 million. We paid a $75,000 fee as part of this loan agreement and issued 75,000 shares of our common stock to an affiliate of VLL, which are held in escrow, subject to certain conditions. The $75,000 fee will be refunded to us if we borrow a minimum of $1.0 million under this facility. The 75,000 shares of common stock issued were valued at fair market value on the date of issuance of $720,000. As of June 30, 2005 the entire amount was amortized to interest expense. The option to draw funding under this loan agreement is subject to additional issuances of up to a maximum of 112,500 shares of our common stock. Any funding drawn down will have a three-year term from the date of funding. Any borrowings are subject to cash payments of principal and interest at an interest rate of 7.5% per annum, as well as a terminal interest payment at the end of the three-year term equal to 9.2% of the aggregate principal amount borrowed during the term of the loan. Under the terms of the loan agreement and an intellectual property security agreement, we would grant to VLL a first priority security interest on certain assets, including limited intellectual property assets, in the event any borrowings occur. We may terminate this facility at any time

without penalty as long as no borrowings have been drawn down from the facility. In April 2005, we exercised our option to extend the period during which we may draw down funds under this facility from April 30, 2005 to December 31, 2005. In connection with this extension, we issued 37,500 shares of our common stock to an affiliate of VLL in May 2005. The 37,500 shares of common stock were valued at fair market value on the date of issuance of $282,000, which is being amortized over the extended eight-month loan commitment period. In connection with this stock issuance, we recognized $70,000 of interest expense in the quarter ended June 30, 2005. As of June 30, 2005, we have not borrowed any funds under this facility.

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. 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 litigations because we believe that Insmed and Avecia are infringing on our patents that cover Insmed s product s use and manufacture.

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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 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.

Contractual Obligations and Commercial Commitments

Our contractual obligations as of June 30, 2005 were as follows (in thousands):

	Payments due by period				
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Operating lease commitments	$ 3,706	$ 29	$ 1,151	$ 1,497	$ 1,029

Our commitments for operating leases include leases for real estate covering our present and future facility and office equipment.

In March 2005, we entered into a new lease agreement for a facility in Brisbane, California. The term of the lease is 75 months, and rent is abated for the first 15 months. The minimum lease commitment for this lease has been included in the table above.

We have contractual payment obligations, the timing of which is contingent on future events. Under our license agreements with Genentech, aggregate payments of up to $1.5 million would be due if milestones relating to the initial product approvals of rhIGF-1 for Severe Primary IGFD in the United States and Europe are achieved. Additional milestone payments would be due for subsequent indication approvals, including for approvals of products consisting of rhIGF-1 or IGF binding protein 3, in the United States or in Europe.

Under our agreement with Cambrex Baltimore, we are obligated to reimburse Cambrex Baltimore on a time and materials and per batch basis in connection with the establishment and validation of our rhIGF-1 manufacturing process. We estimate that our remaining fiscal 2005 purchase commitment to Cambrex Baltimore as of June 30, 2005 is approximately $1.2 million for the remainder of 2005.

Operating Capital and Capital Expenditure Requirements

We believe that our cash, cash equivalents and short-term investments as of June 30, 2005 of $83.5 million and proceeds available under our senior credit facility will be sufficient to meet our projected operating and capital expenditure requirements through at least the end of 2006 based on our current business plan. We plan to make significant expenditures to support our marketing, sales, regulatory and clinical trial activities. With our NDA submitted to the FDA in February 2005, we expect to be focused on the preparation for pre-approval inspections at our contract manufacturer, the completion of our development project for Severe Primary IGFD, our development project for Primary IGFD, pre-launch activities, legal activities and the implementation of Section 404 of the Sarbanes-Oxley Act of 2002.

As of June 30, 2005, the establishment and validation of our rhIGF-1 manufacturing process and the development projects for Severe Primary IGFD were substantially complete, we filed our NDA for Severe Primary IGFD in February 2005 and are preparing for pre-approval inspections with the FDA. We are conducting one late-stage clinical trial for the use of rhIGF-1 in Primary IGFD and initiated another in late July 2005. 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 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.

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

- the costs, timing and scope of domestic and international regulatory approvals for rhIGF-1;
- our ability to market and sell sufficient quantities of rhIGF-1;
- the commercial readiness of our rhIGF-1 manufacturing operations at Cambrex Baltimore, including the success of our cGMP production activities;
- the success of drug product manufacturing and results of stability and product comparability studies performed at third-party contractors;
- the rate of progress and cost of our future clinical trials and other research and development activities;
- the pace of expansion of administrative expenses; and
- the status of competing products.

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. We have no commitments for any additional financings and additional funding may not be available to finance our operations when needed or on acceptable terms. Additional funding may also result in dilution to our stockholders.

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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.

Risks Related to Our Business

We are a development stage company with a limited operating history and may not be able to commercialize any products, generate revenue 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 June 30, 2005, we have accumulated a deficit of $141.0 million. We have not generated and may not be able to generate any revenues from operations and may not be able to attain profitability. We incurred a net loss of $21.5 million during the six months ended June 30, 2005. 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 and commercialize 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.

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 we will be able to obtain governmental regulatory approval to market Increlex in the United States or Western Europe for 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 we do not receive a regulatory marketing approval of Increlex for Severe Primary IGFD, our business will be harmed.

We need FDA approval to market Increlex for therapeutic uses in the United States. We are currently developing Increlex for the treatment of Severe Primary IGFD and Primary IGFD. We submitted an NDA in the United States for marketing Increlex for the treatment of Severe Primary IGFD in February 2005, which was accepted for filing and granted priority review by the FDA in April 2005. The FDA s Prescription Drug User Fee Act, or PDUFA, date for taking action on our NDA is August 31, 2005.

The FDA has substantial discretion in the approval process and may:

decide after review of our NDA that our data is insufficient to allow approval of Increlex for Severe Primary IGFD;

limit our approval and/or restrict our marketing labeling to a small subset of patients with Severe Primary IGFD; and/or

extend our PDUFA date.

We cannot predict the size of the subset of patients with Severe Primary IGFD to which the FDA may limit any marketing approval and labeling for Increlex. If we fail to obtain the FDA s approval for the marketing of Increlex for this indication, we will not be able to commercialize Increlex in the near term, and our business will be harmed.

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

If the FDA disagrees with us and determines that Severe Primary IGFD is not substantially equivalent to GHIS and/or that the number of children with GHIS are less than those with Severe Primary IGFD, the FDA may:

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not approve our NDA for the treatment of Severe Primary IGFD; and/or

limit our approval and/or restrict our marketing labeling to a small subset of patients with Severe Primary IGFD.

Even if the FDA agrees with us that Severe Primary IGFD is substantially equivalent to GHIS, the FDA may:

not approve our NDA for the treatment of Severe Primary IGFD or GHIS; and/or

limit our approval and/or restrict our marketing labeling to a small subset of patients with Severe Primary IGFD.

Since our marketing approval for Severe Primary IGFD is key to our business plan and development of Increlex, any of the FDA s determinations, requirements or labeling restrictions discussed above would substantially harm our business.

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

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

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

We will need to file similar applications with regulatory authorities in foreign countries to market Increlex for any indications in those countries. We have not yet submitted a regulatory marketing application in Europe. If we fail to obtain European approval, the geographic market for Increlex would be limited. If such approval is delayed, it would postpone our ability to generate revenues in Europe.

If another party obtains orphan drug and/or pediatric exclusivity for rhIGF-1 for children with Severe Primary IGFD or Primary IGFD, we may be precluded from commercializing Increlex in these indications.

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

In some cases, pediatric exclusivity can provide an additional six months of market exclusivity. Under Section 505a of the Federal Food, Drug, and Cosmetic Act, six months of market exclusivity may be granted in exchange for the voluntary completion of pediatric studies in accordance with an FDA-issued Written Request. The FDA may issue a Written Request for studies on unapproved or approved indications, where it determines that information relating to the use of a drug in a pediatric population, or part of the pediatric population, may produce health benefits in that population. We have not requested or received a Written Request for such pediatric studies, although we may ask the FDA to issue a Written Request for such studies in the future. To receive the six-month pediatric market exclusivity, we would have to receive a Written Request from the FDA, conduct the requested studies, and submit reports of the studies in accordance with a written

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agreement with the FDA or, if there is no written agreement, in accordance with commonly accepted scientific principles. There is no guarantee that FDA will issue a Written Request for such studies or accept the reports of the studies. Although we intend to file for pediatric exclusivity where appropriate, we have not yet sought pediatric exclusivity for any indication.

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

We are aware of a drug being developed by Insmed Incorporated, which we believe is a combination product containing rhIGF-1 that is in development for the treatment of GHIS. Insmed has announced that: it has submitted an NDA for its combination product for the GHIS indication and that the FDA has accepted Insmed s NDA for filing, granted Insmed s NDA filing priority review and subsequently set October 3, 2005 as the FDA s PDUFA date for taking action on Insmed s NDA. Insmed s product has received an orphan drug designation from the FDA, and in Europe, the European Medicines Agency, or EMEA, for the treatment of GHIS. The FDA has notified us that it currently considers Insmed s product to be the same drug as Increlex with respect to orphan drug marketing exclusivity.

If the FDA and EMEA determine that this other product is the same drug as our product or that our product is contained within this other product and is used for the same indication, and Insmed s product is approved first, the approval of Increlex for either Severe Primary IGFD or Primary IGFD could be blocked for up to seven and one-half years in the United States, and ten years in Europe, which could force us to curtail or cease our operations.

Even if our product is approved first, we may not be able to benefit from the orphan drug marketing exclusivity if the FDA determines that the two drugs are not the same with respect to orphan exclusivity or if Insmed s product is determined by the FDA or EMEA to treat a different disease, to be clinically superior or to provide a major contribution to patient care. Products that are clinically superior or provide a major contribution to patient care may be approved for marketing by the FDA and EMEA notwithstanding our initial approval and our initial orphan drug marketing exclusivity.

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 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 of 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.

rhIGF-1 has never been commercialized in the United States or Western Europe for any indication. Even if approved for sale by the appropriate regulatory authorities, physicians may not prescribe Increlex, 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;

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adequate reimbursement by third parties;

relative convenience and ease of administration of Increlex;

prevalence and severity of side effects; and

competitive product approvals.

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 payors, such as private health insurers and health maintenance organizations, reimburse the price patients pay for our product will affect the commercialization of Increlex. We believe that Increlex will be reimbursed to a similar extent that growth hormone therapy is reimbursed. If our assumption regarding reimbursement for Increlex is incorrect, our expected revenues may be substantially reduced. We cannot be sure that reimbursement in the United States or elsewhere will be available for Increlex. If the FDA approves Increlex 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. We have not commenced efforts to have Increlex reimbursed by governments or third-party payors. If reimbursement is not available or is available only to limited levels, we may not be able to commercialize Increlex.

We believe that the price per patient of Increlex therapy for the treatment of Primary IGFD will not be less than approximately $20,000 per year on average. However, we have not yet determined what the actual price per patient will be. 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 Primary IGFD are incorrect, the market opportunity for Increlex therapy for the treatment of Primary IGFD may be substantially reduced.

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

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

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

Until January 2004, all of our clinical trials were conducted using rhIGF-1 manufactured and released by Genentech. In order to obtain FDA approval of Increlex, we submitted a comprehensive assessment program to demonstrate structural and functional comparability between the Genentech-manufactured rhIGF-1 and Increlex as part of our NDA. If the FDA determines that this approach is insufficient to assess whether the manufacturing changes have affected the final product safety, identity, purity or potency of Increlex compared to the rhIGF-1 used in the existing clinical studies, then the FDA could require us to conduct additional clinical trials in order to demonstrate comparability as part of the Increlex approval process. Any additional clinical trial would require us to incur significant expenses and significantly delay or prevent the commercialization of Increlex.

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

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

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

change of some of the raw material suppliers;

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

process changes;

analytical methods changes;

equipment used; and

a solvent used in the purification process.

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

If our contract manufacturers facilities and operations do not achieve a satisfactory cGMP inspection or if our contract manufacturers facilities become unavailable, we may be unable to sell Increlex.

The facilities used by and operations of our contract manufacturers to manufacture Increlex must undergo an inspection by the FDA for compliance with cGMP regulations before Increlex can be approved. Currently, Cambrex Baltimore is our sole provider of bulk rhIGF-1. We have no alternative manufacturing facilities or plans for additional facilities at this time. Cambrex Baltimore has never commercially manufactured rhIGF-1 for any party, including us. We do not know if the Cambrex Baltimore facilities or their operations required for the commercial manufacture of Increlex will receive a satisfactory cGMP inspection. In the event these facilities or operations do not receive a satisfactory cGMP inspection for the manufacture of our product, we may need to fund additional modifications to our manufacturing process, conduct additional validation studies, or find alternative manufacturing facilities, any of which would result in significant cost to us as well as a delay of up to several years in or prevent us from obtaining an approval for Increlex. 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 GMP regulations and similar foreign standards. We do not have direct control over our contract manufacturers compliance with these regulations and standards.

If Cambrex Baltimore s facilities become unavailable to us for any reason, including failure to comply with cGMP regulations, damage from any event, including fire, flood, earthquake, or terrorism or if they fail to perform under our agreement with them, we may be delayed or unable to complete validation of Increlex or manufacture Increlex. This could delay or prevent the approval of our NDA and our clinical trials, or delay or otherwise adversely affect revenues. If the damage to any of these facilities is extensive, or, for any reason, they do not operate in compliance with cGMP or are unable or refuse to perform under our agreements, we will need to find alternative facilities. The number of contract manufacturers with the expertise and facilities to manufacture rhIGF-1 bulk drug substance on a commercial scale in accordance with 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 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.

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

Delays in performing testing and characterization work on Increlex may delay or prevent our NDA approval.

We have contracted with AAI Development Services, a division of aaiPharma Inc., or AAI, to perform some of the testing and characterization work on Increlex. AAI has publicly disclosed that it is operating under Chapter 11 bankruptcy protection. If there are business interruptions at AAI resulting from its uncertain financial condition, or for any other reason, we may need to reassign all or a portion of AAI s work to an alternative contractor, and our NDA approval may be delayed or prevented.

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

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

Since Increlex is under development, we cannot predict the relative competitive position of Increlex if it is approved for use. However, we expect that the following factors will determine our ability to compete effectively:

safety and efficacy;

product price;

ease of administration; and

marketing and sales capability.

We believe that many of our competitors spend significantly more on research and development-related activities than we do. Our competitors may discover new treatments, drugs or therapies or develop existing technologies to compete with 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.

Growth hormone will likely compete with Increlex for the treatment of patients with Primary IGFD. The major suppliers of commercially available growth hormone in the United States are Genentech, Eli Lilly and Company, Novo Nordisk A/S, Pfizer Inc. and Serono S.A. Investigators from a Novo Nordisk clinical trial recently 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, which will also cause growth hormone to be competitive with Increlex. Eli Lilly and Company and Genentech have received FDA approval for their respective growth hormone products for the treatment of children with ISS.

Insmed s combination product will likely compete for the treatment of patients with Primary IGFD if it is approved by the FDA along with Increlex. 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.

In addition, 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.

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

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

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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.

We may 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. Either or both of those actions could require a substantial diversion of financial and personnel resources in support of such actions and 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

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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.

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

We have licensed intellectual property rights and technology from Genentech, under our U.S. and International License and Collaboration agreements with Genentech. Under each agreement, Genentech has the right to terminate our license if we are in material breach of our obligations under that agreement and fail to cure that breach. Under the terms of the agreements, we are obligated, among other things, to use

reasonable business efforts to meet specified milestones, including filing for regulatory approval in the United States for an IGFD indication by December 31, 2005, which we have accomplished, and for either a diabetes indication or a substitute indication by December 31, 2006. Additionally, we are obligated to file for regulatory approval in either the European Union or Japan for an IGFD indication by December 31, 2007. 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 and commercialize 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.

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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 (e.g., in one of 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 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 will be unable to obtain required approvals and will be unable to commercialize Increlex on a timely basis, if at all.

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

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

We may need others to market and commercialize Increlex in Europe.

We may need others to market and commercialize Increlex in Europe. If we decide to sell Increlex in Europe through a third party, we will need to enter into marketing arrangements with them. We may not be able to enter into marketing arrangements with 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 commercialize 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 preclinical laboratory research. Our strategy is to in-license products or product candidates and further develop them for commercialization. The market for acquiring and in-licensing patent rights, products and product candidates is intensely competitive. If we are not successful in identifying and in-licensing other patent rights, products or product candidates, we may be unable to grow our revenues with sales from new products. If the FDA approves Increlex for Severe Primary IGFD only, only prescriptions for that indication may be reimbursable. In this event, we would need to invest significant resources to obtain new product candidates.

In addition, we may need additional intellectual property from other third parties to commercialize Increlex for indications other than 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.

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 cash, cash equivalents and short-term investments as of June 30, 2005 of $83.5 million and proceeds available under our senior credit facility will be sufficient to meet our projected operating and capital expenditure requirements through at least the end of 2006 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:

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

our ability to market and sell sufficient quantities of rhIGF-1;

the commercial readiness of our rhIGF-1 manufacturing operations at Cambrex Baltimore, including the success of our cGMP production activities;

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

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

the pace of expansion of administrative expenses; and

the status of competing products.

We have no committed sources of capital and do not know whether additional financing will be available when needed, or, if available, that the terms will be favorable. If additional funds are not available, we may be forced to curtail or cease operations.

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

Our ability to implement our business plan requires an effective planning and management process. As of June 30, 2005, we had 66 full-time employees, and we may need 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 expect that our anticipated future growth will place a significant strain on our management, systems and resources. In particular, to fulfill our strategy to commercialize Increlex in the United States, we may need to hire a significant number of additional employees. To manage the anticipated growth of our operations, we will need to increase management resources and implement new financial and management controls, reporting systems and procedures. If we are unable to manage our growth, we could be unable to execute our business strategy.

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 results from the treatment of 76 children with Severe Primary IGFD with rhIGF-1 replacement therapy for an average of 4.2 years, with some patients being treated for over 10 years. None of the 76 children discontinued rhIGF-1 treatment due to safety concerns. However, some patients experienced hypoglycemia, or low blood glucose levels. Hearing deficits and enlargement of the tonsils were also noted in some patients.

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 and commercialize rhIGF-1 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 an emerging company with limited resources, and because research and development is an expensive process, we must regularly assess the most efficient allocation of our research and development resources. Accordingly, we may choose to delay or abandon our research and development efforts for the treatment of a particular indication or project to allocate those resources to another indication or project, which could cause us to fall behind our initial timetables for development. As a result, we may not be able to fully realize the value of some of our product candidates in a timely manner, since they will be delayed in reaching the market, or may not reach the market at all.

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 recently have been upgrading our finance and accounting systems, procedures and controls and will need to continue to implement additional finance and accounting systems, procedures and controls as we grow our business and organization and to satisfy new reporting requirements. Compliance with Section 404 will apply in 2005, and 404 reporting will first occur in our Form 10-K for our fiscal year ending December 31, 2005. 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 controls over financial reporting as of December 31, 2005, investors could lose confidence in the reliability of our internal controls over financial reporting, which could adversely affect our stock price.

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If we are unable to attract and retain additional qualified personnel, our ability to commercialize 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; Dr. Ross G. Clark, our Chief Technical Officer; Susan Wong, our acting Chief Financial Officer; Dr. Thorsten von Stein, our Chief Medical Officer; Stephen N. Rosenfield, our General Counsel and Secretary; and Chris Rivera, our Senior Vice President of Commercial Operations, 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 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 June 30, 2005, our directors, executive officers and principal stockholders and their affiliates beneficially owned approximately 67.1% of our common stock. Our greater than five percent beneficial owners include entities affiliated with MPM Capital, which beneficially owned 22.4%; entities affiliated with Prospect Management Co. II, LLC, which beneficially owned 12.1%; MedImmune, Inc., which beneficially owned 9.5%; and entities affiliated with Rho Ventures, which beneficially owned 9.5%. 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.

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:

estimates of our business potential and earnings prospects;

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

if Insmed s combination product receives orphan drug exclusivity, thereby excluding Increlex from the market;

deviations from analysts projections regarding business potential and earnings prospects;

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an assessment of our management;

quarterly variations in our operating results;

significant developments in the businesses of biotechnology companies;

changes in financial estimates by securities analysts;

changes in market valuations or financial results of biotechnology companies;

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.

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 are not providing any forecasts of the amount and timing of our future revenues and earnings until after we have commenced our sales and marketing efforts. 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 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 Risks Related to Our Business. 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.

We are at risk of securities class action litigation.

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

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

If our stockholders sell substantial amounts of our common stock, including shares issued upon the exercise of outstanding options, the market price of our common stock may decline. These sales also might make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem appropriate. We are unable to predict the effect that sales may have on the prevailing market price of our common stock. As of June 30, 2005, we had 31,571,003 outstanding shares of common stock. Of these shares, the 13,225,000 shares sold in our public offerings that were outstanding as of June 30, 2005 were freely tradable without restriction or further registration, other than shares purchased by our officers, directors or other affiliates within the meaning of Rule 144 under the Securities Act of 1933. The remaining 18,346,003 shares outstanding as of June 30, 2005 are now freely tradable, subject to volume limitations, certain restrictions on sales by affiliates and vesting in the case of early exercised options.

We have filed a registration statement covering shares of common stock issuable upon exercise of options and other grants pursuant to our stock plans. The holders of 17,285,928 shares of our common stock outstanding as of June 30, 2005 are entitled to registration rights.

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ITEM 3. QUALITATIVE AND QUANTITATIVE 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, 2004, have not changed significantly.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures

Based on their evaluation as of June 30, 2005, our Chief Executive Officer and Acting 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 June 30, 2005 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 Acting Chief Financial Officer reasonable assurances that our disclosure controls and procedures will achieve their objectives. However, company management, including our Chief Executive Officer and Acting 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.

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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 litigations because we believe that Insmed and Avecia are infringing 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, 2004, filed with the SEC on March 24, 2005, and our disclosures under Part II, Item 1 of our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2005, filed with the SEC on May 16, 2005, for more information regarding our litigation against Avecia and Insmed in the United Kingdom and our litigation against Insmed in the United States. Developments in our litigation against Insmed in the United States during the second quarter of 2005 were as follows:

On April 22, 2005, we and Genentech filed a Second Amended Complaint against Insmed and Celtrix Pharmaceuticals, Inc. in U.S. District Court. The Second Amended Complaint reiterated our claims alleging that the activities of Insmed will infringe U.S. Pat. Nos. 5,187,151; 6,331,414; and 5,258,287; introduced new claims alleging that the activities of Celtrix, a predecessor of Insmed, infringed U.S. Pat. Nos. 5,187,151 and 5,258,287 and alleged that Insmed bears liability for such infringing activities of Celtrix.

On May 6, 2005, Insmed and Celtrix filed a Motion to Dismiss the claims in the Second Amended Complaint relating to infringement of U.S. Pat. No. 5,258,287, and on June 29, 2005, the U.S. District Court issued an Order denying Insmed s and Celtrix s Motion to Dismiss.

On June 16, 2005, we and Genentech filed in the U.S. District Court a Notice of Withdrawal of our and Genentech s Motion for Preliminary Injunction that we filed on May 27, 2005.

On June 17, 2005, the U.S. District Court issued a Supplemental Case Management Order setting November 6, 2006 for the commencement of a jury trial.

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 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 it is likely that Insmed will challenge the validity of U.S. Patent Nos. 5,187,151, 6,331,414 and/or 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

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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.

Insmed and Avecia filed Applications for Summary Judgment in the proceeding for patent infringement and the proceeding for revocation of European Patent No. 0 571 417 on March 3 and March 10, 2005, respectively, in the High Courts of Justice (Chancery Division Patents Court) in the United Kingdom. At a hearing held by the Court on May 10, 11 and 12, 2005, the parties submitted oral argument on both Applications for Summary Judgment. On May 20, 2005, the Court issued a Judgment dismissing both Applications for Summary Judgment.

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

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 $9.00 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 or 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.

Unregistered Sales of Equity Securities

On May 2, 2005, we issued 37,500 shares of our common stock to Venture Lending & Leasing IV, LLC, an entity affiliated with Venture Lending & Leasing IV, Inc., as consideration for the extension of the loan commitment period under our loan agreement with Venture Lending & Leasing IV, Inc. We did not receive any cash consideration in connection with the issuance of these shares. The shares of common stock were issued to Venture Lending & Leasing IV, LLC in a private transaction exempt from registration in reliance upon Section 4(2) of the Securities Act of 1933, as amended (the Securities Act), and Regulation D of the Securities Act.

Issuer Purchases of Equity Securities

The following table sets forth information regarding our repurchases of common stock during the quarter ended June 30, 2005:

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Programs	Maximum Number of Shares that May Yet Be Purchased Under the Programs
April 1 through April 30, 2005		$		
May 1 through May 31, 2005				
June 1 through June 30, 2005	108,582	0.94		
	108,582	0.94		

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The repurchase of shares of common stock indicated in the table above was not made pursuant to a publicly announced program. The shares were repurchased from the purchaser upon termination of the purchaser s employment with us pursuant to our right to repurchase shares that had not yet vested as of the termination date. The repurchase price was equivalent to the purchase price paid by the purchaser for the shares.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS.

Two matters were voted upon at our 2005 Annual Meeting of Stockholders, which was held on June 1, 2005. A description of each matter and a tabulation of the votes for both of the matters are as follows:

1. To elect three directors to hold office until the 2008 Annual Meeting of Stockholders or until their successors are duly elected and have qualified:

	Votes	
Nominee	**For**	**Withheld**
Ross G. Clark, Ph.D.	27,103,566	2,200
Olle Isaakson, M.D., Ph.D.	27,102,930	2,836
David L. Mahoney	27,102,430	3,336

Our Class II directors, Alexander Barkas, Ph.D., Dennis Henner, Ph.D. and Mark Leschly, will each continue to serve on our Board of Directors until our 2006 Annual Meeting of Stockholders and until his successor is elected and has qualified, or until his earlier death, resignation or removal. Our Class III directors, John A. Scarlett, M.D., Karin Eastham, and Thomas G. Wiggans, will each continue to serve on our Board of Directors until our 2007 Annual Meeting of Stockholders and until his or her successor is elected and has qualified, or until his or her earlier death, resignation or removal.

2. To ratify Ernst & Young LLP as our independent registered public accounting firm for the fiscal year ending December 31, 2005:

For	**Votes Against**	**Abstain**
27,019,266	86,400	100

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ITEM 6. EXHIBITS.

3.1	Certificate of Incorporation (1)
3.2	By-laws (2)
4.1	Form of Specimen Stock Certificate (2)
10.7D	Second Amendment to the License and Collaboration Agreement, between Genentech, Inc. and the Registrant, dated as of November 25, 2003.
10.9U	Separation Agreement and Release, dated May 13, 2005, between Thomas H. Silberg and Tercica, Inc.
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 Acting 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 Acting 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.

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SIGNATURE

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

Dated: August 4, 2005

TERCICA, INC.

(Registrant)

/s/ Susan Wong

Susan Wong

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