

TERCICA INC  
Form 10-Q  
August 02, 2007  
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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

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**FORM 10-Q**

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(Mark One)

**Quarterly report pursuant to Section 13 or 15(d) of the Securities and Exchange Act of 1934**  
For the quarterly period ended June 30, 2007

OR

**Transition report pursuant to Section 13 or 15(d) of the Securities and Exchange Act of 1934**  
Commission File Number 000-50461

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**TERCICA, INC.**

(Exact name of Registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

2000 Sierra Point Parkway, Suite 400

Brisbane, CA 94005

(650) 624-4900

**26-0042539**  
(I.R.S. Employer

Identification Number)

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

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

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

Large accelerated filer  Accelerated filer  Non-accelerated filer

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

As of July 31, 2007, there were 51,441,367 shares of the Registrant's Common Stock outstanding.

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**TERCICA, INC.**

**FORM 10-Q FOR THE QUARTER ENDED JUNE 30, 2007**

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**Table of Contents****PART I FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS.****TERCICA, INC.****CONDENSED BALANCE SHEETS****(In thousands)****(Unaudited)**

	<b>June 30,</b>	<b>December 31,</b>
	<b>2007</b>	<b>2006</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 26,204	\$ 40,339
Short-term investments	71,803	85,236
Accounts receivable, net	782	335
Inventories	11,100	5,092
Prepaid expenses and other current assets	2,472	1,948
Total current assets	112,361	132,950
Property and equipment, net	3,413	3,861
Restricted cash	340	340
Other assets	511	536
Total assets	\$ 116,625	\$ 137,687
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 3,036	\$ 2,457
Accrued expenses	6,471	6,214
Liability for early exercise of stock options	8	32
Other current liabilities	297	290
Deferred revenue, less long-term portion	776	776
Total current liabilities	10,588	9,769
Long-term convertible note	25,486	25,172
Deferred rent	1,206	1,363
Deferred revenue, long-term portion	11,063	11,452
Commitments and contingencies		
Stockholders' equity:		
Common stock	50	50
Additional paid-in capital	342,169	338,608
Accumulated other comprehensive income	2	11
Accumulated deficit	(273,939)	(248,738)
Total stockholders' equity	68,282	89,931

Total liabilities and stockholders' equity	\$ 116,625	\$ 137,687
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*See accompanying notes.*

**Table of Contents****TERCICA, INC.****CONDENSED STATEMENTS OF OPERATIONS****(In thousands, except per share data)****(Unaudited)**

	<b>Three Months Ended</b>		<b>Six Months Ended</b>	
	<b>June 30,</b>	<b>June 30,</b>	<b>June 30,</b>	<b>June 30,</b>
	<b>2007</b>	<b>2006</b>	<b>2007</b>	<b>2006</b>
Net revenues				
Net product sales	\$ 2,048	\$ 166	\$ 3,139	\$ 251
Licenses revenue	194		388	
Total net revenues	2,242	166	3,527	251
Costs and expenses:				
Cost of product sales	1,599	557	2,152	640
Research and development*	4,101	4,596	9,013	9,226
Selling, general and administrative*	10,556	10,586	20,153	21,090
Total costs and expenses	(16,256)	(15,739)	(31,318)	(30,956)
Loss from operations	(14,014)	(15,573)	(27,791)	(30,705)
Interest expense	190		378	
Interest and other income, net	1,397	889	2,968	1,752
Net loss	\$ (12,807)	\$ (14,684)	\$ (25,201)	\$ (28,953)
Basic and diluted net loss per share	\$ (0.26)	\$ (0.39)	\$ (0.50)	\$ (0.79)
Shares used to compute basic and diluted net loss per share	50,178	37,508	50,161	36,579

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

Research and development	\$ 525	\$ 548	\$ 1,049	\$ 977
Selling, general and administrative	1,110	1,099	2,087	1,787
Total	\$ 1,635	\$ 1,647	\$ 3,136	\$ 2,764

*See accompanying notes.*

**Table of Contents****TERCICA, INC.****CONDENSED STATEMENTS OF CASH FLOWS****(In thousands)****(Unaudited)**

	<b>Six months ended June 30,</b>	
	<b>2007</b>	<b>2006</b>
<b>Cash flows from operating activities:</b>		
Net cash used in operating activities	\$ (28,034)	\$ (26,523)
<b>Cash flows from investing activities:</b>		
Purchases of property and equipment	(340)	(745)
Purchases of available-for-sale securities	(57,536)	(32,050)
Proceeds from sales and maturities of available-for-sale securities	71,559	30,782
Net cash provided by (used in) investing activities	13,683	(2,013)
<b>Cash flows from financing activities:</b>		
Net proceeds from issuance of common stock	216	34,494
Net cash provided by financing activities	216	34,494
Net increase/(decrease) in cash and cash equivalents	(14,135)	5,958
Cash and cash equivalents, beginning of period	40,339	14,817
Cash and cash equivalents, end of period	\$ 26,204	\$ 20,775
<b>Supplemental schedule of noncash activities:</b>		
Reversal of deferred stock compensation upon adoption of SFAS No. 123R	\$	\$ (2,591)
Other, net	25	62

*See accompanying notes.*

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**TERCICA, INC.**

**NOTES TO THE CONDENSED FINANCIAL STATEMENTS**

**(Unaudited)**

**1. Company and Basis of Presentation**

***Company***

Tercica, Inc. (the "Company") is a biopharmaceutical company developing and marketing a portfolio of endocrine products. The Company's predecessor, Tercica Limited, a New Zealand company, was formed in October 2000. Tercica Medica, Inc. was incorporated in Delaware in December 2001, and subsequently changed its name to Tercica, Inc.

***Basis of Presentation***

The accompanying unaudited condensed financial statements have been prepared in accordance with the requirements of the U.S. Securities and Exchange Commission ("SEC") for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by U.S. generally accepted accounting principles ("GAAP") can be condensed or omitted. In the opinion of management, the financial statements include all normal and recurring adjustments that are considered necessary for the fair presentation of the Company's financial position and operating results. The condensed balance sheet at December 31, 2006 has been derived from the audited financial statements at that date.

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 or any future periods. 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, 2006, included in the Company's Annual Report on Form 10-K for the year ended December 31, 2006, filed with the SEC on March 9, 2007.

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

**Significant Accounting Policies**

On January 1, 2007, we adopted a new policy related to income taxes, as described more fully below. Other than this change, there have been no significant changes in our significant accounting policies during the six months ended June 30, 2007 as compared to the significant accounting policies described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2006.

***Accounting for Income Taxes***

The Company adopted FASB Interpretation 48, *Accounting for Uncertainty in Income Taxes* ("FIN 48"), on January 1, 2007. As a result of the implementation of FIN 48, the Company did not recognize any adjustment to the liability for uncertain tax positions and therefore did not record any adjustment to the beginning balance of retained earnings on the balance sheet. The Company's continuing practice is to recognize interest and/or penalties related to income tax matters in income tax expense, although there have been no such interest or penalties charged to the Company with the adoption of FIN 48. The Company had no unrecognized tax benefits as of June 30, 2007 and expects no significant changes in unrecognized tax benefits in the next 12 months.

**Recent Accounting Pronouncements**

In September 2006, the FASB issued Statement of Financial Accounting Standards No. 157, *Fair Value Measurements* ("SFAS No. 157"). SFAS No. 157 defines fair value, establishes a framework for measuring fair value in GAAP, and expands disclosures about fair value measurements. SFAS No. 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. The Company is currently evaluating the impact of adopting SFAS No. 157 on its financial position or results of operations.



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In June 2007, the EITF ratified the consensus on EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* ( EITF 07-3 ). EITF 07-3 concludes that nonrefundable advance payments for future research and development activities should be deferred and capitalized and recognized as expense as the related goods are delivered or the related services are performed. EITF 07-3 is effective for fiscal years beginning after December 15, 2007, including interim periods within those fiscal years. Adoption of 07-3 will not have an impact on the Company's financial position or results of operations.

**Table of Contents****2. Balance Sheet Information**

	June 30, 2007	December 31, 2006
	(in thousands)	
<i>Accounts receivable, net:</i>		
Receivables	\$ 798	\$ 343
Less: allowance for doubtful accounts	(16)	(8)
	\$ 782	\$ 335
<i>Inventories</i>		
Raw materials	\$ 1,902	\$ 1,477
Work-in-process	7,976	3,280
Finished goods	1,222	335
	\$ 11,100	\$ 5,092
<i>Property and equipment, net:</i>		
Office equipment	\$ 316	\$ 316
Furniture and fixtures	635	635
Computer equipment and software	2,689	2,291
Manufacturing equipment	1,305	1,240
Leasehold improvements	1,301	1,302
Construction in progress		216
	6,246	6,000
Less: accumulated depreciation and amortization	(2,833)	(2,139)
	\$ 3,413	\$ 3,861
<i>Accrued expenses:</i>		
Accrued compensation and related liabilities	\$ 2,751	\$ 2,938
Accrued professional fees	699	1,691
Accrued contract manufacturing expenses	1,397	629
Clinical trial costs	269	335
Other accrued liabilities	1,355	621
	\$ 6,471	\$ 6,214

**3. 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, net of tax:

	Six Months Ended			
	Three Months Ended		June 30,	
	June 30, 2007	2006	2007	2006
Net loss, as reported	\$ (12,807)	\$ (14,684)	\$ (25,201)	\$ (28,953)

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Change in unrealized losses on marketable securities	(7)	(5)	(8)	(13)
Comprehensive loss	\$ (12,814)	\$ (14,689)	\$ (25,209)	\$ (28,966)

### 4. Long-Term Debt

In October 2006, the Company issued to Ipsen a convertible note in the principal amount of \$25,037,000 (the First Convertible Note). The First Convertible Note accrues interest at a rate of 2.5% per year, compounded quarterly, and is convertible into the Company's common stock at an initial conversion price of \$7.41 per share, subject to adjustment, which represents 3,439,340 shares at June 30, 2007. The conversion price of the First Convertible Note is subject to certain weighted-average price-based antidilution adjustments, that, if triggered, would result in an increase of the number of shares

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of common stock issuable upon conversion of the First Convertible Note. The entire principal balance and accrued interest under the First Convertible Note is due and payable on the later to occur of October 13, 2011 or the second anniversary of the date on which Ipsen (or a subsequent holder of the First Convertible Note) notifies the Company that it will not convert the First Convertible Note in full. Notwithstanding the foregoing, Ipsen (or a subsequent holder of the First Convertible Note) is entitled to declare all amounts outstanding under the First Convertible Note immediately due and payable: (i) if an event of default occurs (as set forth in the First Convertible Note); (ii) for so long as Ipsen's approval rights as set forth in the affiliation agreement the Company entered into pursuant to its collaboration with Ipsen remain in effect, if any other person or group acquires beneficial ownership of greater than 9.9% of the Company's common stock (or if such person or group that already has beneficial ownership of greater than 9.9% of the Company's common stock increases its beneficial ownership); or (iii) in the event that the Company's approval rights as set forth in the affiliation agreement with Ipsen cease to remain effective, if any other person or group acquires beneficial ownership of greater than 50% of the Company's common stock.

As of June 30, 2007, the Company accrued \$449,000 of cumulative interest expense on the First Convertible Note, of which \$158,000 and \$313,000 were recorded as interest expense in the three months and six months ended June 30, 2007, respectively. If not earlier converted or repaid, the amount payable under the First Convertible Note on October 13, 2011 would be \$28,362,000, would include cumulative interest of \$3,325,000.

**5. Equity*****Warrant Issued to Ipsen***

Concurrently with the issue of the First Convertible Note, the Company issued a warrant to Ipsen, which is exercisable for such number of shares of the Company's common stock equal to the greater of (i) 4,948,795 shares of the Company's common stock (the Baseline Amount) or (ii) the Baseline Amount plus a variable amount of shares of the Company's common stock, which variable amount will fluctuate throughout the term of the warrant. The number of shares of the Company's common stock issuable upon exercise of the warrant as of October 13, 2006, the date of issue, was 5,026,712, with a fair value of \$13,622,000, estimated using the Black-Scholes-Merton valuation model, which was recorded to additional paid-in capital. The number of shares of the Company's common stock issuable upon exercise of the warrant as of June 30, 2007 was 4,966,184. The exercise term of the warrant is five years beginning on October 13, 2006, and the warrant is exercisable, in full or in part, at an initial exercise price of \$7.41 per share, subject to adjustment, including certain weighted-average price-based antidilution adjustments.

***Committed Equity Financing Facility***

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

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

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During the six months ended June 30, 2007, the Company did not draw down any funds under the CEFF and had not issued any shares pursuant to the CEFF as of June 30, 2007. Under the terms of an affiliation agreement the Company entered into pursuant to its collaboration with Ipsen, the Company has only a limited ability to raise capital through the sale of its equity securities, including pursuant to the CEFF, without first obtaining Ipsen's approval.

**6. Stock-Based Compensation**

Stock-based compensation expense is measured at the grant date, based on the fair value of the award, and is recognized as expense over the remaining requisite service period. Total stock-based compensation expense of \$1,635,000 and \$1,647,000 was recorded during the three months ended June 30, 2007 and 2006, respectively, and \$3,136,000 and \$2,764,000 was recorded during the six months ended June 30, 2007 and 2006, respectively.

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

	Six months ended			
	Three months ended		June 30,	
	2007	2006	2007	2006
Expected volatility	61.0%	69.0%	63.0%	76.0%
Expected term (years)	6.0	5.9	6.2	6.2
Risk-free interest rate	5.0%	5.7%	4.6%	5.2%
Dividend yield				

The Company's computation of expected volatility is based on an average of the historical volatility of the Company's stock and the historical volatility of a peer-group of similar companies. The Company's computation of expected term utilizes the simplified method in accordance with SAB 107. The risk-free interest rate for periods within the contractual life of the option is based on treasury constant maturities rates in effect at the time of grant. The Company recognizes stock-based compensation expense for the fair values of these awards on a straight-line basis over the requisite service period of each of these awards.

As of June 30, 2007, unrecognized stock-based compensation expense related to stock options of \$14,321,000 was expected to be recognized over a weighted-average period of 2.46 years.

**7. Net Loss Per Share**

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

	Six Months Ended			
	Three Months Ended		June 30,	
	2007	2006	2007	2006
	(In thousands, except per share data)			
<b>Historical</b>				
Numerator:				
Net loss	\$ (12,807)	\$ (14,684)	\$ (25,201)	\$ (28,953)
Denominator:				
Weighted-average common shares outstanding	50,178	37,508	50,161	36,580
Less: Weighted-average unvested common shares subject to repurchase				(1)

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Denominator for basic and diluted net loss per share	50,178	37,508	50,161	36,579
Basic and diluted net loss per share	\$ (0.26)	\$ (0.39)	\$ (0.50)	\$ (0.79)

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	June 30,	
	2007	2006
	(In thousands)	
<b>Historical outstanding dilutive securities not included in diluted net loss per share</b>		
Options to purchase common stock	5,405	4,125
Convertible note	3,439	
Warrants	5,226	260
	14,070	4,385

**8. Commitments and Contingencies**

The Company presently leases approximately 34,400 square feet of office space in Brisbane, California. The lease expires in October 2011 with an option to renew for five years. This lease agreement includes scheduled rent increases over the lease term and rent abatement for the first 15 months. 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 reimbursement. In September 2005, the Company received a \$1,046,000 reimbursement from the landlord for facility improvements, which was recorded as deferred rent and is being amortized to offset rent expense over the remaining life of the lease. Under the lease agreement, the Company has provided the landlord with irrevocable letter of credit in the amount of \$340,000. The irrevocable letter of credit is 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. In July 2007, the Company entered into an amendment to its amended lease agreement that provides for the expansion of the leased premises by approximately 2,700 square feet, and for a period coterminous with the original lease, as amended.

At June 30, 2007, future minimum lease commitments under operating leases were as follows (in thousands):

Year ending December 31,	
2007	\$ 490
2008	999
2009	1,026
2010	1,065
2011	809
Thereafter	
	\$ 4,389

Rent expense was \$109,300 and \$206,600 for the three-months and six-months ended June 30, 2007, respectively. Rent expense for the three-months and six-months ended June 30, 2006 was \$97,300 and 194,500, respectively. Rent expense includes the impact of the allowance for leasehold improvements of \$43,000 and \$86,000 for the three-months and six-months ended June 30, 2007, respectively, and \$43,000 and \$86,000 for the three-months and six-months ended June 30, 2006, respectively.

**Manufacturing Services Agreement**

In December 2002, the Company entered into a development and commercial supply agreement (the *Manufacturing Agreement*) with Cambrex Bio Science Baltimore, Inc. ( *Cambrex Baltimore* ). At that time, the Company began to transfer its manufacturing technology to Cambrex Baltimore in order for them to establish the process for rhIGF-1 fermentation and purification. Under the terms of the *Manufacturing Agreement*, Cambrex Baltimore was obligated to annually provide the Company with certain minimum quantities of bulk rhIGF-1. In February 2007, Cambrex Baltimore was purchased by Lonza Group AG ( *Lonza Baltimore* ).

In May 2007, the Company amended the *Manufacturing Agreement* with Lonza Baltimore to increase the Company's purchase obligation for certain additional quantities of bulk rhIGF-1. Under this amendment, the Company has a non-cancelable obligation to pay Lonza Baltimore on a time and materials and per batch basis in connection with the commercial production of bulk rhIGF-1. The Company estimates that its total purchase commitment to Lonza Baltimore is approximately \$17.5 million through March 31, 2008.

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In May 2007, the Company entered into a development and commercial supply agreement with Lonza Hopkinton (the Hopkinton Manufacturing Agreement ). The Company has begun to transfer its manufacturing technology to Lonza Hopkinton in order for them to establish the process for rhIGF-1 fermentation and purification at Lonza Hopkinton. Pursuant



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to the Hopkinton Manufacturing Agreement, the Company has a non-cancelable obligation to pay Lonza Hopkinton a capacity reservation fee related to the technology transfer of manufacturing facilities in the amount of \$5.0 million, of which the Company paid \$1.3 million in May 2007 and the remaining \$3.7 million will be paid on or before January 4, 2008. The total cost of the technology transfer of \$5.0 million is being recognized straight-line over the technology transfer period which the Company expects to conclude in June 2008. In connection with the initiation of construction and purchasing of equipment and other site development activities, Lonza Hopkinton will bear upfront costs of \$6.6 million which the Company would have to reimburse a portion of in the event we do not fulfill our commitment to purchase a certain number of commercial drug substance batches. Further, the Company has an obligation to pay Lonza Hopkinton approximately \$1.2 million during 2008 for the production of bulk rhIGF-1 conformance lots, exclusive of required materials. As the Company reaches certain future milestones, it may be committed to commercial production of Increlex<sup>®</sup> on a time and materials basis and per batch basis.

In November 2006, the Company entered into a development and commercial supply agreement with a third-party fill and finish agent. At that time, the Company began to transfer its manufacturing technology to this agent in order for the agent to establish the process for drug product fill and finish. Further, under the terms of this agreement, the agent is obligated to annually provide the Company with certain minimum quantities of finished rhIGF-1 drug product. The Company has a non-cancelable obligation to reimburse the agent on a milestone basis in connection with the preparation for commercial production of Increlex<sup>®</sup>. The Company estimates that its total purchase commitment to this agent to validate the fill and finish processes, which must then be approved by the FDA is approximately \$342,000 through December 31, 2007.

### **Guarantees and Indemnifications**

The Company, as permitted under Delaware law and in accordance with its Bylaws, indemnifies its officers and directors for certain events or occurrences, subject to certain limits, while the officer or director is or was serving at the Company's request in such capacity. The term of the indemnification period is for the officer's or director's lifetime. The Company may terminate the indemnification agreements with its officers and directors upon 90 days written notice, but termination will not affect claims for indemnification relating to events occurring prior to the effective date of termination. The maximum amount of potential future indemnification is unlimited; however, the Company has a director and officer liability insurance policy that mitigates its exposure and may enable it to recover a portion of any future amounts paid. The Company believes the fair value of these indemnification agreements is minimal. Accordingly, the Company had not recorded any liabilities for these agreements as of June 30, 2007.

### **9. 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 in the U.S. District Court for the Northern District of California. On June 12, 2006, we filed a complaint against Insmed for False Advertising, Unfair Competition and Intentional Interference with Prospective Business Relations, Case No. 3:06cv403, in the U.S. District Court for the Eastern District of Virginia.

On March 6, 2007, we publicly announced agreements that settled all the ongoing litigation among the companies. We also disclosed the settlement in our Form 10-K filed with the SEC on March 9, 2007 and disclosed details of the settlement in our Form 8-K filed with the SEC on March 7, 2007.

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

### **10. Subsequent Events**

#### **Combination Product Development and Commercialization Agreement**

Effective as of July 6, 2007, the Company and Genentech, Inc. ( Genentech ) entered into a Combination Product Development and Commercialization Agreement (the Combination Product Agreement ), that governs the worldwide development and commercialization of two combination products containing IGF-1 and human growth hormone for the treatment of all indications except those of the central nervous system. The Combination Product Agreement became effective on July 9, 2007, the date of the satisfaction of all conditions to its effectiveness. Under the terms of the Combination Product Agreement, the parties contemplate the development of two combination products for the following indications: one product formulation for certain defined short stature indications ( Short Stature Indications ) and another



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separately formulated combination product for adult growth hormone deficiency ( AGHD ) and any potential other indications (the Other Indications ). Initially, the Company will be responsible for the development and commercialization of all combination products under the Combination Product Agreement and agreed to pay Genentech a royalty on net sales of combination products covered by Genentech s (or the parties joint) patents, subject to Genentech s right to opt in, as described below.

Under the Combination Product Agreement, Genentech has a right to opt into the Company s development and commercialization of such combination products for the Short Stature Indications, AGHD and the Other Indications following the FDA s acceptance of the Company s Investigational New drug Application for the first Phase II clinical trial for such indication(s) (the First Option ). If Genentech does not exercise the First Option, it would then have the right to acquire a second right to opt in (a Second Option ) after the Company obtains Phase II clinical trial data that is pivotal study-enabling for the Short Stature Indication at issue, or for AGHD or the Other Indications. If Genentech opts in, it would then become the lead party with respect to the development and commercialization of combination products for Other Indications, and it may also choose to become the lead party in development and commercialization for AGHD. Upon opt-in, Genentech may also choose to exercise a commercial option to become the lead party for commercialization in Short Stature Indications. The lead commercialization party would determine the commercialization plan for such combination products for such indications, and the non-lead party would have the right to co-promote such combination products.

Upon opting in, Genentech would become obligated to reimburse the Company for a portion of the development costs incurred since July 9, 2007 and a milestone payment if Genentech chooses to become the lead commercial party for short stature, and thereafter the parties would share future costs and all operating profits and losses. Genentech would receive such profit share in lieu of its royalty payment. If Genentech opts in, it would have the right to subsequently elect to opt out of such development and commercialization of combination products, but only for all indications. In addition, following an opt in by Genentech, the Company would have the right to subsequently elect to opt out of the joint development and commercialization of the combination products for AGHD and the Other Indications only, but not for the Short Stature Indications. If a party elects to opt out, the other party would have a limited period of time in which it could also elect to opt out, in which case the parties would wind down development and commercialization of the applicable products. After opting out, a party would remain responsible for its share of operating profits and losses for a transition period only, after which time such party would be entitled to a royalty payment from the continuing party on net sales of such combination product. If Genentech opts in and neither party elects to opt out before a combination product receives regulatory approval for any Other Indication (such receipt of regulatory approval, the Milestone ), Genentech would owe the Company a cash Milestone payment. Under the Combination Product Agreement, the parties have granted each other sublicenseable licenses under their respective technology. The parties will share manufacturing responsibilities and costs depending on which opt-in or opt-out rights have been exercised, but in general the parties contemplate that the Company will supply IGF-1 needed for the combination products, and Genentech will supply human growth hormone for such products.

### **Genentech Purchase Agreement**

Effective as of July 6, 2007, the Company and Genentech entered into a Common Stock Purchase Agreement (the Genentech Purchase Agreement ), pursuant to which the Company agreed to sell, and Genentech agreed to purchase, up to a maximum of 2,603,328 shares of the Company s common stock (the Genentech Shares ) in three separate closings. On July 30, 2007, the Company and Genentech consummated the first closing under the Genentech Purchase Agreement pursuant to which the Company issued 708,591 shares of common stock (the First Closing Shares ) at price per share of \$5.645, resulting in gross cash proceeds of approximately \$4,000,000.

In the event that Genentech acquires a Second Option, Genentech would, subject to customary closing conditions, purchase up to 842,105 shares of the Company s common stock (the Second Option Shares ) in a subsequent closing (the Second Option Closing ) at a price per share equal to the average of the closing prices of the Company s common stock for the 20 trading days ending on the trading date immediately prior to the expiration of the First Option (the Second Option Price ), provided that Genentech may purchase no more than \$4,000,000 of the Company s common stock in the Second Option Closing. If the Second Option Price is below \$4.75, however, the purchase of the Second Option Shares in the Second Option Closing would be at the Company s option. In the event that the Second Option Price is below \$4.75 and the Company does not elect to have Genentech purchase the Second Option Shares, Genentech may acquire the Second Option without purchasing the Second Option Shares.

In the event that Genentech opts in, neither party elects to opt out and the Milestone occurs, upon the Company s request, Genentech would, subject to customary closing conditions, purchase up to 1,052,632 shares of the Company s common stock in a subsequent closing (the Milestone Closing ) at a price per share equal to the average of the closing prices of the Company s common stock for the 20 trading days ending on the trading date immediately prior to the effective date of regulatory approval of a combination product for any Other Indication (the Milestone Price ), provided that Genentech may purchase no more than \$5,000,000 of the Company s common stock in such closing.



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In the event that the Combination Product Agreement is terminated, the Genentech Purchase Agreement would terminate in its entirety.

**Ipsen Purchase Agreement**

On July 30, 2007, the Company issued 519,101 shares of common stock to Ipsen, S.A. ( Ipsen ) at price per share of \$5.63 pursuant to a Common Stock Purchase Agreement (the Ipsen Purchase Agreement ), dated July 9, 2007, by and among the Company, Ipsen and Suraypharm (an affiliate of Ipsen), resulting in gross cash proceeds of approximately \$2,923,000. The shares of common stock issued to Ipsen under the Ipsen Purchase Agreement were acquired by Ipsen in exercise of certain pro rata purchase rights in connection with the issuance of the First Closing Shares to Genentech. Under the terms of an Affiliation Agreement the Company entered into with Ipsen in October 2006, Ipsen has a right of first offer to purchase up to its pro rata portion of new equity securities offered by the Company (subject to certain exceptions).

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Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of

Tercica, Inc.

We have reviewed the condensed balance sheet of Tercica, Inc. as of June 30, 2007, and the related condensed statements of operations for the three and six-month periods ended June 30, 2007 and 2006, and the condensed statements of cash flows for the six-month periods ended June 30, 2007 and 2006. These financial statements are the responsibility of the Company's management.

We conducted our review in accordance with the standards of the Public Company Accounting Oversight Board (United States). A review of interim financial information consists principally of applying analytical procedures and making inquiries of persons responsible for financial and accounting matters. It is substantially less in scope than an audit conducted in accordance with the standards of the Public Company Accounting Oversight Board, the objective of which is the expression of an opinion regarding the financial statements taken as a whole. Accordingly, we do not express such an opinion.

Based on our review, we are not aware of any material modifications that should be made to the condensed financial statements referred to above for them to be in conformity with U.S. generally accepted accounting principles.

We have previously audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheet of Tercica, Inc. as of December 31, 2006, and the related statements of operations, stockholders' equity, and cash flows for the year then ended not presented herein and in our report dated March 5, 2007, we expressed an unqualified opinion on those financial statements and included an explanatory paragraph for the Company's change in its method of accounting for stock-based compensation in accordance with guidance provided in Statement of Financial Accounting Standards No. 123R, "Share-Based Payment". In our opinion, the information set forth in the accompanying condensed balance sheet as of December 31, 2006, is fairly stated, in all material respects, in relation to the balance sheet from which it has been derived.

/s/ ERNST & YOUNG LLP

Palo Alto, California

August 1, 2007

**Table of Contents****ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.**

*This report includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities and Exchange Act of 1934, as amended. All statements other than statements of historical facts are forward-looking statements for purposes of these provisions, including any projections of earnings, revenues or other financial items, any statement of the plans and objectives of management for future operations, any statements concerning proposed new products or licensing or collaborative arrangements, any statements regarding future economic conditions or performance, and any statement of assumptions underlying any of the foregoing. In some cases, forward-looking statements can be identified by the use of terminology such as may, will, expects, plans, anticipates, estimates, potential, or continue or the negative thereof or other comparable terminology. Although we believe that the expectations reflected in the forward-looking statements contained herein are reasonable, there can be no assurance that such expectations or any of the forward-looking statements will prove to be correct, and actual results could differ materially from those projected or assumed in the forward-looking statements. Our future financial condition and results of operations, as well as any forward-looking statements, are subject to inherent risks and uncertainties, including but not limited to the Risk Factors set forth under Part II, Item 1A below, and for the reasons described elsewhere in this report. All forward-looking statements and reasons why results may differ included in this report are made as of the date hereof, and we assume no obligation to update these forward-looking statements or reasons why actual results might differ.*

**Overview**

We are a biopharmaceutical company developing and marketing a portfolio of endocrine products. We currently have the following products in our commercialization and development portfolio:

Increlex<sup>®</sup>, which we began commercializing in the United States in January 2006;

Somatuline<sup>®</sup> Autogel<sup>®</sup>, which was approved for marketing in July 2006 by Health Canada for the treatment of acromegaly and for which a New Drug Application, or NDA, was accepted in December 2006 by the U.S. Food and Drug Administration, or FDA. The Prescription Drug User Fee Act, or PDUFA, date for Somatuline<sup>®</sup> Autogel<sup>®</sup> for the treatment of acromegaly is August 30, 2007; and

Two product candidates containing different combinations of recombinant human growth hormone, or rhGH, and recombinant human insulin-like growth factor-1, or rh-IGF-1 (i.e., Increlex<sup>®</sup>), for which we expect to initiate clinical trials in 2008.

*Increlex<sup>®</sup>*. We market Increlex<sup>®</sup> as a long-term replacement therapy for the treatment of short stature in children with severe primary insulin-like growth factor-1 deficiency, or severe Primary IGFD, and for children with growth hormone gene deletion who have developed neutralizing antibodies to growth hormone. We obtained approval for the long-term treatment of severe Primary IGFD from the FDA, in August 2005. We are currently conducting a Phase IIIb clinical trial for the use of Increlex<sup>®</sup> for the treatment short stature in children with Primary IGFD. In January 2006, we launched Increlex<sup>®</sup> in the United States. Increlex<sup>®</sup> generated net revenues of \$3.1 million in the six-months ended June 30, 2007.

In May 2007, the Committee for Medicinal Products for Human Use, or CHMP, of the European Medicines Agency, or EMEA, adopted a positive opinion recommending marketing authorization for Increlex<sup>®</sup> in the European Union. The indication recommended is for the long-term treatment of growth failure in children and adolescents with severe Primary IGFD. Based on an acceptance of the CHMP positive opinion by the European Commission, we expect a European marketing authorization in the third quarter of 2007, and because Increlex<sup>®</sup> previously received Orphan Drug Designation in the European Union, we expect to obtain ten years of marketing exclusivity for the treatment of severe Primary IGFD. Pursuant to our worldwide strategic collaboration with Ipsen that was completed in October 2006, we granted to Ipsen and its affiliates the exclusive right under our patents and know-how to develop and commercialize Increlex<sup>®</sup> in all countries of the world except the United States, Japan, Canada, and for a certain period of time, Taiwan and certain countries of the Middle East and North Africa for all indications, other than treatment of central nervous system and diabetes indications.

*Somatuline<sup>®</sup> Autogel<sup>®</sup>*. Pursuant to our worldwide strategic collaboration with Ipsen, we have the exclusive right under Ipsen's patents and know-how to develop and commercialize Somatuline<sup>®</sup> Autogel<sup>®</sup> in the United States and Canada for all indications other than ophthalmic indications. In July 2006, Somatuline<sup>®</sup> Autogel<sup>®</sup> was approved for marketing by Health Canada for the treatment of acromegaly and is currently in the reimbursement review process. Acromegaly is a hormonal disorder that results when a tumor in the pituitary gland produces excess growth hormone, resulting in overproduction of insulin-like growth factor-1 (IGF-1). In October 2006, Ipsen submitted an NDA to the FDA for the use of Somatuline<sup>®</sup> Autogel<sup>®</sup> for the treatment of acromegaly. The FDA accepted the NDA on December 30, 2006, and the Prescription Drug User Fee Act, or PDUFA, date for Somatuline<sup>®</sup> Autogel<sup>®</sup> for the treatment of acromegaly is August 30, 2007.





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Somatuline® Autogel® is an injectable sustained-release formulation containing lanreotide, a somatostatin analogue. The Somatuline® Autogel® formulation requires no excipient other than water and is generally injected monthly. The product is contained in a pre-filled syringe, and can be administered as a deep subcutaneous injection. In contrast, Sandostatin LAR® Depot, the only currently available, long-acting somatostatin analogue, which is marketed by Novartis, must be reconstituted from a powdered form and drawn up into a syringe, and must be then be given as a deep intramuscular injection. Like Sandostatin LAR® Depot, Somatuline® Autogel® is used primarily when circulating levels of growth hormone remain high despite surgery or radiotherapy in patients with acromegaly. Through its inhibitory effects, Somatuline® Autogel® lowers growth hormone and IGF-1 levels, thus controlling disease progression and relieving the symptoms associated with active disease.

*Growth hormone/IGF-1 Combination Product Candidates.* In July 2007, we entered into a combination product development and commercialization agreement with Genentech, Inc. which governs the development, manufacture and worldwide commercialization of two product candidates containing Genentech's rhGH, Nutropin AQ®, and our rhIGF-1, Increlex®, for the treatment of all indications except those of the central nervous system. Nutropin AQ® and Increlex® were originally designed and formulated so that the therapies could be combined and potentially given as a single, daily injection. We believe that treatment with a combination of both rhGH and rhIGF-1 may be superior to monotherapy of either component alone, particularly for certain patients with short stature and adult growth hormone deficiency, or AGHD, and potentially other metabolic disorders.

Pending FDA guidance and a timely acceptance of an investigational new drug application, we plan to initiate Phase II clinical development in 2008 of one combination product candidate for patients with low IGF-1 levels and short stature not associated with growth hormone deficiency, and a second combination product candidate for patients with AGHD. After review of clinical data in AGHD, we and Genentech will evaluate the attractiveness of this combination product candidate in treating other metabolic disorders associated with abnormal body composition, including metabolic syndrome, obesity and/or type 2 diabetes.

As of June 30, 2007, we had approximately \$98.0 million in cash, cash equivalents and short-term investments. We have funded our operations since inception through the private placement of equity securities and public offerings of our common stock. In October 2006, we also received net cash proceeds of \$100.0 million in connection with our strategic collaboration with Ipsen. In addition, in July 2007, we received gross cash proceeds of \$6.9 million as a result of the issuance of shares of our common stock to Genentech and Ipsen as described under "Liquidity and Capital Resources - Genentech Combination Product Collaboration" below.

### **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. On January 1, 2007, we adopted a new policy related to income taxes, as described more fully below. Other than this change, there have been no significant changes in our significant accounting policies during the six-months ended June 30, 2007 as compared to the significant accounting policies described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2006.

### ***Accounting for Income Taxes***

We adopted FASB Interpretation 48, *Accounting for Uncertainty in Income Taxes*, or FIN 48, on January 1, 2007. As a result of the implementation of FIN 48, we did not recognize any adjustment to the liability for uncertain tax positions and therefore did not record any adjustment to the beginning balance of retained earnings on the balance sheet. Our continuing practice is to recognize interest and/or penalties related to income tax matters in income tax expense, although there have been no such interest or penalties charged to us with the adoption of FIN 48. We had no unrecognized tax benefits as of June 30, 2007 and expect no significant changes in unrecognized tax benefits in the next 12 months.

**Table of Contents****Results of Operations****Comparison of Three Months and Six Months Ended June 30, 2006 and 2007**

	Three months		Six months	
	ended June 30, 2006	ended June 30, 2007	ended June 30, 2006	ended June 30, 2007
	(in thousands)			
Net product sales	\$ 166	\$ 2,048	\$ 251	\$ 3,139
Period over period increase		1,882		2,888
Percentage increase		N/A(1)		N/A(1)
License revenue		194		388
Period over period increase		194		388
Percentage increase		N/A(1)		N/A(1)
Cost of sales	557	1,599	640	2,152
Period over period increase		1,042		1,512
Percentage increase		N/A(1)		N/A(1)
Research and development expenses	4,596	4,101	9,226	9,013
Period over period (decrease)		(495)		(213)
Percentage (decrease)		(11)%		(2)%
Selling, general and administrative expenses	10,586	10,556	21,090	20,153
Period over period (decrease)		(30)		(937)
Percentage (decrease)		(0.3)%		(4)%
Interest expense		190		378
Period over period increase		190		378
Percentage increase		N/A(1)		N/A(1)
Interest and other income, net	889	1,397	1,752	2,968
Period over period increase		508		1,216
Percentage increase		57%		69%

(1) Comparable data for prior period or comparison to period is not meaningful.

**Net Revenues**

Net revenues consist of net product sales and amortized license revenue associated with our Increlex<sup>®</sup> license and collaboration agreement with Ipsen. Net revenues for the three and six-month periods ended June 30, 2007 were comprised of net product sales of \$2.0 million and \$3.1 million, respectively and amortized license revenues of \$0.2 million and \$0.4 million, respectively. Net revenues for the three and six-month periods ended June 30, 2006 were comprised of net product sales of \$0.17 million and \$0.25 million, respectively. There were no license revenues recorded during the three and six-months ended June 30, 2006.

Net product sales consist of gross Increlex<sup>®</sup> sales less provisions for discounts to customers, rebates to government agencies, product returns and other adjustments. The increase in net product sales in the quarter and six months ended June 30, 2007 compared to the same periods ended June 30, 2006 was primarily due to growth in Increlex<sup>®</sup> product sales in the U.S. The Increlex<sup>®</sup> product sales increase was driven by a continued increase in adoption of our product, including as a result of patients switching to Increlex<sup>®</sup> from IPLEX, a product that was marketed by Insmid, Inc., or Insmid. In March 2007, we announced agreements that settled all prior litigation against Insmid. One of the key terms in the settlement agreement stipulated that Insmid will no longer provide IPLEX to patients with severe Primary IGFD and other short stature indications. Following the settlement agreement with Insmid, a number of patients receiving IPLEX have switched to treatment with Increlex<sup>®</sup>. We expect Increlex<sup>®</sup> revenues to increase over the next several quarters; however, we do not expect net Increlex<sup>®</sup> product sales to increase at the same rate on a quarter-to-quarter basis for the remainder of 2007. As Increlex<sup>®</sup> is generally ordered by our distributors against specific prescriptions, we believe that our distributors carry minimal levels of inventory.

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In the three and six months ended June 30, 2007, we recorded \$0.2 million and \$0.4 million, respectively, of amortized revenue in connection with our Increlex<sup>®</sup> license and collaboration agreement with Ipsen. We are amortizing the upfront payment, received in October 2006 of 10.0 million, or \$12.4 million, over a period of approximately 16 years based on the expected term of the license under this agreement.

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**Table of Contents*****Cost of Sales***

Our cost of sales represents the supply cost and cost of production, shipping, distribution and handling costs, royalties owed to our licensor, inventory write-downs/write-offs based on our review of obsolete, excess, expired and failed inventory lots, and other costs related to production activities, including technology transfer and validation cost associated with manufacturing site changes. Prior to regulatory approval of Increlex<sup>®</sup> in August 2005, drug supply production costs were charged to research and development. Beginning in the fourth quarter of 2005, with the marketing approval of Increlex<sup>®</sup> by the FDA, we began capitalizing these production costs to inventory and began to charge cost of sales in the first quarter of 2006 as units of Increlex<sup>®</sup> were sold. In addition to these capitalized drug supply production costs, there are also certain variable and fixed shipping, distribution and handling costs charged to cost of sales.

Cost of sales for the three and six months ended June 30, 2007 increased over the same period in 2006, as more units were sold and product revenue increased. Further, we incurred costs related to transfer our manufacturing operations to alternate manufacturing sites that totaled \$0.5 million. We anticipate that these transfer activities will continue through the end of 2008 and expect the manufacturing costs to increase during this transfer period. The total remaining cost of the technology transfer to be recorded in cost of sales is estimated to be \$4.2 million, which we expect to incur over the next eight quarters.

***Research and Development Expenses***

Research and development expenses consisted primarily of costs associated with clinical, regulatory, manufacturing development activities and acquired rights to technology or products in development. Clinical and regulatory activities included the preparation, implementation, and management of our clinical trials and clinical assay development, as well as regulatory compliance, data management and biostatistics. Manufacturing development activities included pre-regulatory approval activities associated with technology transfer, process development and validation, quality control and assurance, analytical services, as well as preparations for current good manufacturing practices (cGMP) and regulatory inspections. In addition to these manufacturing development and clinical activities, license payments for patents and know-how to develop and commercialize products, are also recorded as research and development expense.

During the three and six months ended June 30, 2007, research and development expenses decreased as compared to the three and six months ended June 30, 2006 primarily due to a decrease in project costs and other departmental costs. The decrease in project costs was due primarily to reduced activities associated with our marketing authorization application, or MAA, in the three and six months ended June 30, 2007 as compared to the same period in 2006.

The \$4.1 million in research and development expense for the three months ended June 30, 2007 was comprised primarily of personnel and related costs of \$2.7 million, external project costs related to our clinical activities for Primary IGFD and severe Primary IGFD of \$0.9 million and clinical activities for Somatuline<sup>®</sup> Autogel<sup>®</sup> activities in acromegaly of \$0.2 million. The \$9.0 million in research and development expense for the six-months ended June 30, 2007 was comprised primarily of personnel and related costs of \$5.5 million, external project costs related to our clinical activities for Primary IGFD and severe Primary IGFD of \$1.9 million, clinical activities for Somatuline<sup>®</sup> Autogel<sup>®</sup> activities in acromegaly of \$0.5 million, Increlex<sup>®</sup> activities in support of our MAA of \$0.4 million and other clinical activities associated with short stature research of \$0.3 million.

***Selling, General and Administrative Expenses***

Selling, general and administrative expenses consisted primarily of payroll and related costs associated with sales and marketing personnel, executive management, corporate administration, legal fees, commercial activities including cost of free drug, medical education, facility costs, insurance, information technology and accounting services.

Selling, general and administrative expenses for the quarter ended June 30, 2007 were flat as compared to the three months ended June 30, 2006 primarily due to an increase in sales and marketing costs of \$0.9 million along with an increase in payroll and related costs of \$0.6 million, partially offset by decreased expenses associated with litigation of \$1.2 million.

Selling, general and administrative expenses decreased \$0.9 million for the six months ended June 30, 2007 as compared to the six months ended June 30, 2006. This decrease is primarily due to a decrease in legal expenses associated with litigation of \$3.1 million. This decrease was partially offset by an increase in payroll and related costs of \$1.7 million along with an increase in non-employee sales and marketing costs of \$1.0 million.



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**Table of Contents*****Interest Expense***

Interest expense for the three and six months ended June 30, 2007 was due to interest on the convertible note in the principal amount of \$25.0 million and amortization of related prepaid financing costs issued in October 2006 in connection with our strategic collaboration with Ipsen. There was no interest expense for the three and six months ended June 30, 2006.

***Interest and Other Income, net***

Interest and other income, net for the three and six month periods ended June 30, 2007 increased as compared to the three and six month periods ended June 30, 2006 primarily due to interest income on higher average cash, cash equivalents and short-term investment balances as a result of \$100.0 million in net cash proceeds in connection with our Ipsen collaboration in October 2006.

**Liquidity and Capital Resources*****Sources of Liquidity***

As of June 30, 2007, we had an accumulated deficit of \$273.9 million, which was primarily comprised of \$230.9 million of accumulated net losses and \$44.1 million of a non-cash deemed dividend related to the beneficial conversion feature of convertible preferred stock. We have funded our operations and growth from inception through June 30, 2007 with net cash proceeds of \$66.0 million in private equity financings and \$135.3 million from our public offerings of common stock and \$100.0 million, net of issuance costs, from the issuance of common stock and a convertible note to Ipsen.

***Ipsen Collaboration***

On October 13, 2006, we completed the initial closing of the transactions contemplated by the stock purchase and master transaction agreement we entered into with Ipsen in July 2006. At the closing, we issued 12,527,245 shares of our common stock to an affiliate of Ipsen for an aggregate purchase price of \$77.3 million and issued to Ipsen a convertible note in the principal amount of \$25.0 million and a warrant to purchase a minimum of 4,948,795 shares of our common stock, which warrant is exercisable at any time during the five-year period after the initial closing and carries an initial exercise price equal to \$7.41 per share. The stock purchase and master transaction agreement we entered into with Ipsen also provides for the issuance by us of a second convertible note and a third convertible note to Ipsen in connection with our Somatuline® Autogel® license and collaboration agreement as described below. Each of the convertible notes that we issued or that we may issue to Ipsen mature five years from issuance of the first note or two years from the date of notification of non-convert and carry a coupon of 2.5% per annum from the date of issuance, compounded quarterly, and are convertible into shares of our common stock at an initial conversion price per share equal to \$7.41 per share ( 5.92 per share with respect to the second convertible note). Together with the shares issued at the initial closing, the conversion of all three convertible notes and the exercise of the warrant in full would enable Ipsen to acquire an ownership interest in us of approximately 40% on a fully diluted basis.

Pursuant to the licensing agreements we entered into with Ipsen (and/or affiliates thereof) in connection with the initial closing under the stock purchase and master transaction agreement, we granted to Ipsen and its affiliates exclusive rights to develop and commercialize Increlex® in all countries of the world except the United States, Japan, Canada, and for a certain period of time, Taiwan and certain countries of the Middle East and North Africa, and Ipsen granted to us exclusive rights to develop and commercialize Somatuline® Autogel® in the United States and Canada. Further, we and Ipsen granted to each other product development rights and agreed to share the costs for improvements to, or new indications for, Somatuline® Autogel® and Increlex®. In addition, we and Ipsen agreed to rights of first negotiation for our respective endocrine pipelines. Under the license and collaboration agreement with respect to Increlex®, Ipsen made an upfront cash payment to us of 9.5 million after tax withholding in October 2006, and will pay us an additional milestone of 15.0 million (or approximately \$20.2 million at June 30, 2007) upon approval of the Increlex® MAA in the European Union for the targeted product label. On May 25, 2007, we announced that the CHMP of the EMEA adopted a positive opinion recommending marketing authorization for Increlex®. Based on an acceptance of the CHMP positive opinion by the European Commission, we expect a European marketing authorization in the third quarter of 2007, and because Increlex® previously received Orphan Drug Designation in the European Union, we expect to obtain ten years of marketing exclusivity for the treatment of severe Primary IGF1D. Ipsen is our marketing partner for Increlex® in the European Union. If Increlex® is launched in Ipsen's territory, Ipsen would pay royalties to us on a sliding scale from 15% to 25% of net sales, in addition to a supply price of 20% of net sales of Increlex®.

Under the license and collaboration agreement with respect to Somatuline® Autogel®, we made an upfront payment of \$25.0 million to Ipsen in October 2006, which was financed through the issuance by us of the first convertible note to Ipsen at the initial closing under the stock purchase and master transaction agreement. When Somatuline® Autogel® is approved in the United States for the targeted product label (and the second closing under the under the stock purchase and master



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transaction agreement is consummated), we would make a milestone payment of 30.0 million (or approximately \$40.4 million at June 30, 2007) to Ipsen, which would be financed through the issuance by us of the second convertible note to Ipsen at the second closing. If the second closing is consummated, we would also issue the third convertible note to Ipsen and Ipsen would deliver \$15.0 million to us, which would be used by us for working capital. Once Somatuline® Autogel® is launched in our territory, we would pay royalties to Ipsen, on a sliding scale from 15% to 25% of net sales, in addition to a supply price of 20% of net sales of Somatuline® Autogel®.

There can be no assurance that we will receive all or any remaining portion of the anticipated proceeds from our collaboration with Ipsen, nor can there be an assurance that we would achieve the anticipated benefits of our collaboration Ipsen. Further, we would be required to pay to Ipsen the principal amounts, including accrued interest, under all three convertible notes that we issued or that we may issue to Ipsen if Ipsen elects not to convert these notes into shares of our common stock. For more information on these and other risks and uncertainties related to our collaboration with Ipsen, see the sections entitled Risks Related to Our Business and Risks Related to Our Common Stock under Part II, Item 1A below.

### ***Genentech Combination Product Collaboration***

Effective as of July 6, 2007, we and Genentech entered into a combination product development and commercialization agreement which governs the worldwide development and commercialization of two combination products containing Genentech's rhGH, Nutropin A® and our rhIGF-1, Increlex®, for the treatment of all indications except those of the central nervous system. Initially, we will be responsible for the development and commercialization of all combination products under the combination product agreement and have agreed to pay Genentech a royalty on net sales of combination products covered by Genentech's (or the parties' joint) patents, subject to certain opt in rights granted to Genentech as described under Note 9 Subsequent Events in the notes to our condensed financial statements. Upon opting in, Genentech would become obligated to reimburse us for a portion of the development costs incurred since July 9, 2007, and thereafter we and Genentech would share future costs and all operating profits and losses and no royalties shall be owed to Genentech. Genentech would receive such profit share in lieu of its royalty payment. As described in more detail under Note 9 Subsequent Events in the notes to our condensed financial statements, we may receive a cash milestone payment under certain circumstances and may be entitled to royalties on net sales of certain combination products. In connection with the entering into of the combination product agreement, we issued 708,591 shares of common stock to Genentech at price per share of \$5.645 pursuant to a stock purchase agreement we entered into with Genentech, resulting in gross cash proceeds of approximately \$4.0 million, and we may issue up to an additional 1,894,737 shares of common stock (or up to a maximum of \$9.0 million of shares of common stock) to Genentech pursuant to the stock purchase agreement. However, there can be no assurance that we will receive all or any remaining portion of the anticipated proceeds, including the reimbursement of development costs, the cash milestone payment and additional proceeds from the sale of shares of our common stock to Genentech, nor can there be an assurance that we would achieve the anticipated benefits of our combination product agreement with Genentech. Further, we must first obtain Ipsen's approval to issue shares of common stock to Genentech under the stock purchase agreement at a price per share less than \$4.75 and if we do issue shares to Genentech under the stock purchase agreement at a price per share less than \$4.75, such issuance would trigger certain weighted-average price-based antidilution adjustments to the convertible notes and warrant that we may issue to Ipsen. In addition, although Ipsen purchased additional shares of common stock from us in exercise of certain pro rata purchase rights granted to Ipsen under the terms of an affiliation agreement we entered into pursuant to our collaboration with Ipsen, we cannot assure that Ipsen will exercise such rights if we issue additional shares of common stock to Genentech pursuant to the stock purchase agreement. Please refer to Note 9 Subsequent Events in the notes to our condensed financial statements for more detail on the terms of the combination product agreement and stock purchase agreement.

### ***Committed Equity Financing Facility***

Under the terms of the CEFF, Kingsbridge committed to purchase a maximum of approximately 6,000,000 newly issued shares of our common stock over a three-year period beginning in October 2005, for cash up to an aggregate of \$75.0 million, subject to certain conditions. We may draw down under the CEFF in tranches of up to the lesser of \$7.0 million or 2% of our market capitalization at the time of the draw down of such tranche, subject to certain conditions. The common stock to be issued for each draw down will be issued and priced over an eight-day pricing period at discounts ranging from 6% to 10% from the volume weighted average price of our common stock during the pricing period. During the term of the CEFF, Kingsbridge may not short our stock, nor may it enter into any derivative transaction directly related to our stock. The minimum acceptable purchase price, prior to the application of the appropriate discount for any shares to be sold to Kingsbridge during the eight-day pricing period, is determined by the greater of \$3.00 or 90% of our closing share price on the trading day immediately prior to the commencement of each draw down. In connection with the CEFF, we issued a warrant to Kingsbridge to purchase up to 260,000 shares of our common stock at an exercise price of \$13.12 per share. We intend to exercise our right to draw down amounts under the CEFF, if and to the extent available, at such times as we have a



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need for additional capital and when we believe that sales of our common stock under the CEFF provide an appropriate means of raising capital. However, we are not obligated to sell any of the \$75.0 million of common stock available under the CEFF, and there are no minimum commitments or minimum use penalties. Under the terms of an affiliation agreement we entered into pursuant to our collaboration with Ipsen, we have only a limited ability to raise capital through the sale of our equity securities, including pursuant to the CEFF, without first obtaining Ipsen's approval.

**Cash Flow**

	Six months ended June 30,	
	2007	2006
	(In thousands)	
Net cash provided by (used for):		
Operating activities	\$ (28,034)	\$ (26,523)
Investing activities	13,683	(2,013)
Financing activities	216	34,494
<b>Net change in cash and cash equivalents</b>	<b>\$ (14,135)</b>	<b>\$ 5,958</b>

Cash, cash equivalents and short-term investments totaled \$98.0 million at June 30, 2007, compared to \$125.6 million at December 31, 2006. Cash and cash equivalents totaled \$26.2 million at June 30, 2007, compared to \$40.3 million at December 31, 2006. The decrease was primarily due to cash used in operating activities of \$28.0 million. The uses of cash in operations, during the first quarter of 2007 were primarily related to the manufacture of Increlex<sup>®</sup> inventories, sales, marketing and related support personnel and activities associated with severe Primary IGFD, clinical and regulatory activities related to severe Primary IGFD and Primary IGFD. The increase in cash used in operations during the quarter ended June 30, 2007 compared to the same period in 2006 of \$1.5 million, was due primarily to increases in activities related to manufacturing of Increlex<sup>®</sup>, sales and marketing activities and transfer of our manufacturing operations to an alternate manufacturing sites. We expect an increase in net cash used in operations for the remainder of 2007, primarily to support the commercial activities in preparation with the Somatuline<sup>®</sup> Autogel<sup>®</sup> launch in the United States and Canada, and clinical, regulatory, new product development activities including activities for our combination products, the transfer of manufacturing operations to an alternative manufacturing sites and the manufacturing of inventories.

Net cash provided from investing activities totaled \$13.7 million in the six-months ended June 30, 2007, compared to net cash used of \$2.0 million in the same period in 2006. Net cash provided from investing activities represented purchases, sales and maturities of investments offset by purchases of property and equipment. Net proceeds from the sales and maturities of short-term investments were \$14.0 million in the six-months ended June 30, 2007, compared to net purchases of 1.3 million for the same period in 2006. The increase of \$15.3 million in net proceeds from the sales and maturities of short-term investments in the six-months ended June 30, 2007, compared to the same period in 2006, was primarily due to the timing of maturities, sales and purchases of short-term investments, as well as the increased cash in-flow from our collaboration agreement with Ipsen which provided \$100.0 million in funding net of issuance costs, resulting in higher net purchases of short-term investments.

There were no financing activities for the six-months ended June 30, 2007 other than employee purchases of company stock of \$216,000. Net cash provided by financing activities for the six-months ended June 30, 2006 was \$34.5 million which primarily related to net proceeds received from our public offerings of common stock which totaled \$34.2 million in the six-months ended June 30, 2006.

We expect capital outlays and operating expenditures to increase over the next several years as we expand our operations. We believe that our cash, cash equivalents and short-term investments as of June 30, 2007, together with the funds that we would potentially receive from our collaboration with Ipsen will be sufficient to meet our projected operating and capital expenditure requirements through at least the middle of 2008 based on our current business plan. However, our future capital needs and the adequacy of our available funds will depend on many factors, including:

changes to our business plan;

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our ability to market and sell sufficient quantities of Increlex<sup>®</sup> and Somatuline<sup>®</sup> Autogel<sup>®</sup> at the anticipated level;

the commercial status of the Increlex<sup>®</sup> bulk drug manufacturing operations at Lonza Baltimore and Lonza Hopkinton including the success of our cGMP production activities;

the success of Increlex<sup>®</sup> final drug product manufacturing;

the costs, timing and scope of additional regulatory approvals for Increlex<sup>®</sup>;

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Ipsen's ability to supply Somatulin® Autogel® to us in sufficient quantities;

the costs, timing and scope of additional regulatory approvals for Somatulin® Autogel®;

Ipsen's ability to market and sell sufficient quantities of Increlex® in the licensed territories at the anticipated level;

any required repayment of the convertible notes we issued or that we may issue to Ipsen;

the status of competing products;

the rate of progress and cost of our future clinical trials and other research and development activities, including research and development activities and clinical trial costs in connection with our growth hormone/IGF-1 combination product candidates; and

the pace of expansion of administrative expenses.

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

We expect that we will require and will attempt to raise additional funds through equity or debt financings, collaborative arrangements with corporate partners or from other sources, and including potentially the CEFF. However, there can be no assurance that additional financing will be available when needed, or, if available, that the terms will be favorable. In addition, under the terms of an affiliation agreement we entered into pursuant to our collaboration with Ipsen, we have only a limited ability to raise capital through the sale of our equity without first obtaining Ipsen's approval. Although we have entered into a stock purchase agreement with Genentech pursuant to which we may issue up to an additional 1,894,737 shares of common stock (or up to a maximum of \$9.0 million of shares of common stock) to Genentech, such issuances are subject to various conditions, including a Genentech opt in and the achievement of a regulatory approval milestone, and there can be no assurance that we will receive additional funds from Genentech pursuant to the stock purchase agreement. If additional funds are not available, we may be forced to curtail or cease operations.

***Contractual Obligations and Commercial Commitments***

During the six months ended June 30, 2007, the material changes to our contractual obligation and commercial commitment disclosures as set forth under the caption, "Contractual Obligations and Commercial Commitments" in Part II, Item 7, *Management's Discussion and Analysis of Financial Condition and Results of Operations*, of our Annual Report on Form 10-K for the year ended December 31, 2006 were: (i) an extension to our manufacturing agreement with Lonza Baltimore, Inc., or Lonza Baltimore; (ii) the entry into a manufacturing agreement with Lonza Hopkinton, Inc., or Lonza Hopkinton, and (iii) an amendment to the operating lease for our office facility.

In May 2007, we amended our Manufacturing Agreement with Lonza Baltimore to increase our purchase obligation for certain additional quantities of bulk rhIGF-1. Under the agreement with Lonza Baltimore we have a non-cancelable obligation to pay Lonza Baltimore on a time and materials and per batch basis in connection with the commercial production of bulk rhIGF-1. We estimate that its total purchase commitment to Lonza Baltimore is approximately \$17.5 million through March 31, 2008.

In May 2007, we entered into a development and commercial supply agreement or the Hopkinton Manufacturing Agreement, with Lonza Hopkinton. We have begun to transfer our manufacturing technology to Lonza Hopkinton to establish the process for rhIGF-1 fermentation and purification at Lonza Hopkinton. Pursuant to the Hopkinton Manufacturing Agreement, we have a non-cancelable obligation to pay Lonza Hopkinton a capacity reservation fee related to the technology transfer of manufacturing facilities in the amount of \$5.0 million, of which we paid \$1.3 million in May 2007 and the remaining \$3.7 million will be paid on or before January 4, 2008. The total cost of the technology transfer

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of \$5.0 million is being recognized straight-line over the technology transfer period which we expect to conclude in June 2008. In connection with the initiation of construction and purchasing of equipment and other site development activities, Lonza Hopkinton will bear upfront costs of \$6.6 million which we would have to reimburse a portion of in the event we do not fulfill our commitment to purchase a certain number of commercial drug substance batches. Further, we have an obligation to pay Lonza Hopkinton approximately \$1.2 million during 2008 for the production of bulk rhIGF-1 conformance lots, exclusive of required materials. As the Company reaches certain future milestones, it may be committed to commercial production of Increlex<sup>®</sup> on a time and materials basis and per batch basis.

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We presently lease approximately 34,400 square feet of office space in Brisbane, California. In July 2007, we entered into an amendment to our amended lease agreement that provides for the expansion of the leased premises by approximately 2,700 square feet for a period coterminous with the original amended lease. The lease expires in October 2011 and includes an option to renew for five years. Please refer to Note 8 Commitments and Contingencies in the notes to our condensed financial statements for further discussion regarding our future operating lease commitment.

### **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

During the six months ended June 30, 2007, there were no material changes to our market risk disclosures as set forth in Part II, Item 7A, *Quantitative and Qualitative Disclosures About Market Risk*, of our Annual Report on Form 10-K for the year ended December 31, 2006.

### **ITEM 4. CONTROLS AND PROCEDURES.**

#### *Evaluation of Disclosure Controls and Procedures*

Based on their evaluation as of June 30, 2007, our Chief Executive Officer and Chief Financial Officer, with the participation of our management, have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934) were effective.

#### *Changes in Internal Control over Financial Reporting*

There were no changes in our internal control over financial reporting during the six-months ended June 30, 2007 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

#### *Limitations on the Effectiveness of Controls*

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

## **PART II OTHER INFORMATION**

### **ITEM 1. LEGAL PROCEEDINGS.**

None.

### **ITEM 1A. RISK FACTORS.**

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

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*decline due to any of these risks, and investors may lose all or part of their investment.*

*We have marked with an asterisk (\*) those risks described below that reflect substantive changes from the risks described under Item 1A. Risk Factors included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 9, 2007.*

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### **Risks Related to Our Business**

*We have a limited operating history and may not be able to successfully market and sell products, generate significant revenues or attain profitability.\**

We are primarily focused on developing and marketing a portfolio of endocrine products. We had an accumulated deficit of \$273.9 million at June 30, 2007. We had net revenues of \$3.5 million and incurred a net loss of \$25.2 million during the six-months ended June 30, 2007. We may not be able to generate significant revenues from operations and may not be able to attain profitability. We expect to incur substantial net losses, in the aggregate and on a per share basis, for the foreseeable future as we attempt to develop, market and sell Increlex<sup>®</sup> for severe Primary IGFD and Primary IGFD and Somatuline<sup>®</sup> Autogel<sup>®</sup> for acromegaly, and as we develop growth hormone/IGF-1 combination product candidates under our combination product agreement with Genentech. 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 dependent on the successful commercialization by us and Ipsen of Increlex<sup>®</sup> for the treatment of severe Primary IGFD and Primary IGFD, as well as on the successful commercialization by us of Somatuline<sup>®</sup> Autogel<sup>®</sup> for acromegaly in the United States and Canada. There is no assurance that we will be able to obtain or maintain governmental regulatory approvals to market our products in the United States or rest of the world for these or any other indications. If we are unable to generate significant revenue from Increlex<sup>®</sup> or Somatuline<sup>®</sup> Autogel<sup>®</sup>, or attain profitability, we will not be able to sustain our operations.

*If there are fewer children with severe Primary IGFD or Primary IGFD than we estimate, our ability to generate revenues sufficient to fund our development and commercialization efforts may be curtailed, or we may not be able to complete our clinical trials for Increlex<sup>®</sup>.*

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

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

Prior to our January 2006 commercial launch of Increlex<sup>®</sup> in the United States for the treatment of severe Primary IGFD, rhIGF-1 had never been commercialized in the United States or Europe for any indication. Even though the FDA has approved Increlex<sup>®</sup> for sale in the United States, Somatuline<sup>®</sup> Autogel<sup>®</sup> has received marketing approval in Canada and may receive marketing approval in the United States, physicians may choose not to prescribe these products, and third-party payers may choose not to pay for them, in which event we may be unable to generate significant revenue or become profitable.

Acceptance of our products will depend on a number of factors including:

acceptance of our products by physicians and patients as a safe and effective treatment;

reimbursement adoption;

product price;

the effectiveness of our sales and marketing efforts;

storage requirements and ease of administration;

dosing regimen;

safety and efficacy;



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prevalence and severity of side effects; and

competitive products.

***If we do not receive additional regulatory marketing approvals for Increlex® in Primary IGFD and Somatuline® Autogel® for our target label, our business will be harmed. \****

We are currently developing Increlex® for the treatment of Primary IGFD. The FDA has substantial discretion in the approval process and may decide that the data from our clinical trial is insufficient to allow approval of Increlex® for Primary IGFD. If we do not receive regulatory marketing approval in the United States for Primary IGFD, our business will be harmed. We will also need to file applications with regulatory authorities in foreign countries to market Increlex® for Primary IGFD. Although we have received a positive opinion from the Committee for Medicinal Products for Human Use, or CHMP, in Europe for severe Primary IGFD, there is no assurance that we will receive marketing approval in Europe for either severe Primary IGFD or Primary IGFD. In addition, if we fail to obtain European marketing approval for Increlex® for the target label as defined under our license and collaboration agreement with Ipsen (or for a label which provides access to an agreed upon number of patients), we would not receive the European Medicines Agency, or EMEA, approval-related milestone payment provided for under our agreement with Ipsen. Further, even if European marketing authorization for Increlex® is obtained but the target label or access to the agreed upon patient population is not approved within three years from the date of obtaining such initial marketing authorization, we would not be owed the EMEA approval-related milestone payment provided for under our agreement with Ipsen. Further, if EMEA approvals are delayed, it would postpone our ability to receive royalties from the commercialization of Increlex® in Europe.

In addition, if the FDA does not approve Somatuline® Autogel® for the treatment of acromegaly, or the approval is significantly delayed, or we do not receive the target label that we anticipate, our ability to generate revenues would be adversely affected, and our business would be harmed. We may also elect not to, or we may be unable to develop or obtain FDA approval of Somatuline® Autogel® for indications other than acromegaly, such as neuroendocrine tumors.

***We may not realize the anticipated benefits from our collaboration with Ipsen.***

Somatuline® Autogel® may not receive U.S. regulatory approval in a timely manner, for the label that we anticipate, or at all. Even if Somatuline® Autogel® receives U.S. regulatory approval, the approval may not be maintained. Further, Ipsen may be unable to maintain the supply of the product. In addition, revenues from sales of Somatuline® Autogel® in the United States and Canada may not meet our expectations, including as a result of competing products or unavailable or limited reimbursement by third-party payers. Under the license and collaboration agreement with respect to Somatuline® Autogel®, Ipsen may terminate the agreement in a particular country if we fail to meet certain minimum sales and promotional requirements with respect to that country. It is also possible that Ipsen will not be successful in marketing and selling Increlex® in the licensed territories, or may be delayed in doing so, in which case we would not receive royalties on the timeframe and to the extent that we currently anticipate. We also may not be able to successfully develop additional products or improvements to, or new indications for, Somatuline® Autogel® and/or Increlex® or share the costs of such developments in a manner that is commercially feasible for us. In addition to cross-licensing agreements for Somatuline® Autogel® and Increlex®, we and Ipsen have granted to each other a right of first negotiation for products in our respective endocrine pipelines and have agreed on a framework for joint clinical development and subsequent commercialization of endocrine products on a worldwide basis. However, the development of Ipsen's endocrine pipeline may not advance at the rate we currently expect, or at all, and in any event, we cannot assure you that we will be able to reach an agreement with Ipsen on reasonable terms, or at all, for any of these endocrine pipeline products. The license and collaboration agreements would also be terminable by Ipsen under certain circumstances, including certain change of control transactions. In any such or similar events, we may not realize the anticipated benefits from our collaboration with Ipsen.

There can be no assurance that we will receive all or any remaining portion of the anticipated proceeds from our collaboration with Ipsen, nor can there be an assurance that we would achieve the anticipated benefits of our collaboration with Ipsen. Further, we would be required to pay to Ipsen the principal amounts, including accrued interest, under all three convertible notes that we issued or that we may issue to Ipsen if Ipsen elects not to convert these notes into shares of our common stock.

***We may not realize the anticipated benefits from our growth hormone/IGF-1 combination product candidates or from the related agreement with Genentech.\****

Our two growth hormone/IGF-1 combination product candidates may not enter clinical trials or receive U.S. or other countries' regulatory approval, in a timely manner, for the labels that we anticipate, or at all. The FDA and other countries' regulatory authorities have substantial discretion in the approval process. They may decide that our pre-clinical and clinical data are insufficient to warrant timely, or any, entry into Phase I, Phase II or Phase III clinical trials, and/or that the data from



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our Phase III clinical trials are insufficient to allow marketing approval of our growth hormone/IGF-1 combination product candidates for their target labels. If we do not receive regulatory marketing approvals for the target labels, our business will be harmed.

Even if our combination product candidates were to receive such regulatory marketing approvals, the approvals may not be maintained. In addition, revenues from worldwide sales of these two product candidates may not meet our expectations, including, as a result of competing products or unavailable or limited reimbursement by third-party payers. We also may not be able to successfully develop improvements to, or new indications for, our combination product candidates or receive financial consideration from sub-licensees in a manner that is commercially feasible for us. In connection with our agreement with Genentech for our combination product candidates, Genentech may opt into the programs and obtain a share of the financial benefit going forward. In any such or similar events, we may not realize the anticipated benefits from our combination product candidates or from the related agreement with Genentech. There can be no assurance that we will receive all or any remaining portion of the anticipated proceeds from such agreement with Genentech, nor can there be an assurance that we would achieve the anticipated benefits from such agreement with Genentech.

***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. For example, we are seeking to develop our growth hormone/IGF-1 combination product candidates for short stature, AGHD, and potentially other metabolic disorders but we may determine that such trials are prohibitively expensive and ultimately may not proceed with such 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 pre-clinical testing or in 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.

***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 an investigational new drug application, or IND, a clinical trial protocol or place a clinical trial on clinical hold;

patients do not enroll in clinical trials at the rate we expect or they withdraw at a greater rate than 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 our products.

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***Reimbursement for our products may be slow, not available at the levels we expect, or not available at all, resulting in our expected revenues being delayed or substantially reduced. \****

Market acceptance, our sales of Increlex<sup>®</sup> and Somatuline<sup>®</sup> Autogel<sup>®</sup>, and our profitability will depend on reimbursement policies and health care reform measures. The levels at which government authorities and third-party payers, such as private health insurers and health maintenance organizations, reimburse the price patients pay for our products, and the timing of reimbursement decisions by these payers, will affect the commercialization of our products. If our assumptions regarding the timing of reimbursement decisions and level of reimbursement, or regarding the age, dosage or price per patient for Increlex<sup>®</sup> are incorrect, our expected revenues, including potential royalties from our collaboration with Ipsen, may be delayed or substantially reduced. Since Increlex<sup>®</sup> is approved by the FDA for severe Primary IGFD, only prescriptions for that indication may be reimbursable. Also, we cannot be sure that the formulary status that our products ultimately receive by payers will not limit the ability of patients to afford our products and therefore reduce the demand for, or the price of, our products. If reimbursement is not available or is available only to limited levels, we may not be able to market and sell our products and our revenues may be delayed or substantially reduced.

We believe that the annual wholesale acquisition cost of Increlex<sup>®</sup> therapy for the treatment of severe Primary IGFD for a 24 kilogram child at a 120mcg/kg twice daily dose at 100% compliance is approximately \$30,940 per year. The actual cost per year per patient for Increlex<sup>®</sup> will depend on the weight of the child, the treatment dose prescribed and compliance. If our assumptions regarding the revenue per patient of Increlex<sup>®</sup> therapy for the treatment of severe Primary IGFD and Primary IGFD are incorrect, our expected revenues and the market opportunity for Increlex<sup>®</sup> therapy for the treatment of severe Primary IGFD and Primary IGFD may be substantially reduced.

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

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

***We are dependent on our collaboration with Ipsen for the development and commercialization of Increlex<sup>®</sup> outside of the United States, Canada and Japan and for a certain period of time, certain countries of the Middle East and North Africa and Taiwan. We may also be dependent upon additional collaborative arrangements in the future. These collaborative arrangements may place the development and commercialization of our product candidates outside of our control, may require us to relinquish important rights or may otherwise be on terms unfavorable to us.***

Under the terms of our collaboration with Ipsen, we granted Ipsen the exclusive right to develop and commercialize Increlex<sup>®</sup> in all regions of the world except the United States, Japan, and Canada and for a certain period of time, certain countries of the Middle East and North Africa and Taiwan. We may also enter into additional collaborations with third parties to develop and commercialize our product candidates such as the agreement with Genentech for our growth hormone/IGF-1 combination product candidates. Dependence on collaborators for the development and commercialization of our product candidates subjects us to a number of risks, including:

we may not be able to control the amount and timing of resources that our collaborators devote to the development or commercialization of product candidates or to their marketing and distribution, which could adversely affect our ability to obtain milestone and royalty payments;

collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;



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disputes may arise between us and our collaborators that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management's attention and resources;

our collaborators may experience financial difficulties;

collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to expose us to potential litigation, jeopardize or lessen the value of our proprietary information, or weaken or invalidate our intellectual property rights;

business combinations or significant changes in a collaborator's business strategy may also adversely affect a collaborator's willingness or ability to complete its obligations under any arrangement;

a collaborator could independently move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors; and

the collaborations may be terminated or allowed to expire, which would delay product development and commercialization efforts.

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

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

We cannot predict the relative competitive positions of Increlex<sup>®</sup>, Somatuline<sup>®</sup> Autogel<sup>®</sup> and our growth hormone/IGF-1 combination product candidates. However, we expect that the following factors, among others, will determine our ability to compete effectively:

acceptance of our marketed products by physicians and patients as a safe and effective treatment;

reimbursement adoption;

product price;

manufacturing costs;

the effectiveness of our and Ipsen's sales and marketing efforts;

storage requirements and ease of administration;

dosing regimen;

safety and efficacy;

prevalence and severity of side effects; and

competitive products.

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

Growth hormone products compete with Increlex<sup>®</sup> for the treatment of severe Primary IGFD. If Increlex<sup>®</sup> receives regulatory approval for the treatment of patients with Primary IGFD, growth hormone products will also compete with Increlex<sup>®</sup> for the treatment of patients in that indication. The major suppliers of commercially available growth hormone products in the United States are Genentech Inc., Eli Lilly and Company, Teva Pharmaceutical Industries Ltd., Novo Nordisk A/S, Pfizer Inc and Merck Serono S.A. Investigators from a Novo Nordisk clinical trial presented data that demonstrated growth hormone was effective in a population that included children with Primary IGFD.

In addition, children with Primary IGFD may be diagnosed as having idiopathic short stature, or ISS. Eli Lilly and Genentech have received FDA approval for their respective growth hormone products for the treatment of children with ISS in the United States. Moreover, biosimilar growth hormone products, including Omnitrope marketed by Sandoz, a division of Novartis AG, have been or may be approved in the United States and other countries. Accordingly, we expect that several growth hormone products will compete directly with Increlex<sup>®</sup> for the treatment of children with Primary IGFD.



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

We believe that Bristol-Meyers Squibb Company; Genentech; Merck & Co., Inc.; Novo Nordisk and Pfizer 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 Sapphire Therapeutics, Inc. 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. These products work by increasing the levels of rhIGF-1 and, if approved, could potentially compete with Increlex®.

If our growth hormone/IGF-1 combination products are approved for commercial sale, they would compete across all their approved indications with all: then existing, biosimilar and long acting, growth hormone products; growth hormone secretagogue products; IGF-1 products including Increlex®, and other products.

Somatuline® Autogel® is approved in Canada for the treatment of acromegaly and together with Ipsen, we are seeking regulatory approval for the same indication in the United States. In Canada, and in the United States if approved, Somatuline® Autogel® will compete directly with Sandostatin LAR® Depot and Somavert®. Sandostatin LAR® Depot is a somatostatin analogue and has the same mechanism of action as Somatuline® Autogel®. Sandostatin LAR® Depot is indicated for long-term maintenance therapy in patients with acromegaly and in the treatment of symptoms related to carcinoid syndrome and vasoactive intestinal peptide tumors. Somavert®, a growth hormone antagonist, and Sandostatin LAR® Depot are marketed by Pfizer and Novartis, respectively, in the United States and Canada. Moreover, a subset of patients with acromegaly can be treated with radiotherapy and dopaminergic agonists. These therapies are commercially available in the United States and Canada and will also compete with Somatuline® Autogel® for the treatment of patients with acromegaly.

We are aware that Ambrilia Biopharma Inc., QLT Inc., Indevus Pharmaceuticals Inc. and Camurus AB are conducting research and development programs with long acting versions of octreotide for the treatment of acromegaly. Octreotide is the generic name of the active molecule in Sandostatin and Sandostatin LAR® Depot. We are also aware that Novartis is developing pasireotide and that Ipsen is developing dopastatin for the treatment of acromegaly and other hormone secreting tumors. If approved, these therapies would compete with Somatuline® Autogel® in these indications. It is possible that there are other products currently in development or that exist on the market that may compete directly with Increlex® or Somatuline® Autogel®.

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

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

If our contract facilities, contractors or suppliers become unavailable to us for any reason, including as a result of the failure to comply with cGMP regulations, manufacturing problems or other operational failures, such as equipment failures or unplanned facility shutdowns required to comply with cGMP, damage from any event, including fire, flood, earthquake or terrorism, business restructuring or insolvency, or if they fail to perform under our agreements with them, such as failing to deliver commercial quantities of bulk drug substance or finished product on a timely basis and at commercially reasonable prices, we may be delayed in manufacturing Increlex® or may be unable to maintain validation of Increlex®. This could delay or prevent the supply of commercial and clinical product, or delay or otherwise adversely affect revenues. If the damage to any of these facilities is extensive, or, for any reason, they do not operate in compliance with cGMP or are unable or refuse to perform under our licenses and/or agreements, we will need to find alternative facilities. Further, we are responsible for the manufacture and supply of Increlex® to Ipsen (through our contract manufacturer) for Ipsen's clinical development and commercial needs. In the event we fail to meet Ipsen's supply obligations, Ipsen would have the right to exercise its option to manufacture Increlex® on its own or to engage a third-party manufacturer to do so. The number of contract manufacturers with the expertise and facilities to manufacture rhIGF-1 bulk drug substance on a commercial scale in accordance with cGMP regulations is extremely limited, and it would take a significant amount of time and expense to arrange for alternative manufacturers. If we need to change to other commercial manufacturers, these manufacturers' facilities and processes, prior to our use, would likely have to undergo pre-approval and/or cGMP compliance inspections. In addition, we would need to transfer and validate the processes and analytical methods necessary for the production and testing of rhIGF-1 to these new manufacturers.

### ***Our inability to timely transfer to an alternate single-source manufacturer to fill-finish Increlex® could adversely affect our commercial supply and ability to grow revenues.***



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We currently source all of our Increlex<sup>®</sup> fill-finish manufacturing and portions of release testing through a single-source third-party supplier. This supplier is the only FDA-approved manufacturer currently available to us, and could only be replaced by qualification of a new site for the same operations. We have negotiated a short-term commercial agreement with this fill-finish manufacturer and during the term of this agreement, we are attempting to move our process to another fill-finish manufacturer. It will take a significant amount of time and expense to complete the transfer to, and validate an alternative manufacturer. For us to change to this commercial fill-finish manufacturer, the manufacturer's facilities and processes, prior to our use, will need to undergo pre-approval and/or cGMP compliance inspections. In addition, we need to transfer and validate the processes and certain analytical methods necessary for the production and testing of Increlex<sup>®</sup> by this new fill-finish manufacturer. A delay in this transfer may also result in a shortage of Increlex<sup>®</sup> and a loss of revenues.

***Our inability to timely transfer or to complete the transfer at all to an alternate single-source manufacturer for bulk Increlex<sup>®</sup> could significantly adversely affect our commercial supply and ability to grow revenues. \****

We currently source all of our Increlex<sup>®</sup> bulk manufacturing and portions of release testing through a single-source third-party supplier, Lonza Baltimore Inc. This supplier is the only FDA-approved manufacturer currently available to us, and could only be replaced by qualification of a new manufacturing site for the same operations. We have negotiated short-term commercial agreements with Lonza, and during the term of these agreements, we are attempting to move our bulk manufacturing process from Lonza Baltimore to Lonza Hopkinton. It will take a significant amount of time and expense to complete the transfer to and validate the Lonza Hopkinton manufacturing facility. For us to change to this new bulk manufacturing site, Lonza Hopkinton's facilities and processes, prior to our use, will need to undergo pre-approval and/or cGMP compliance inspections. In addition, we need to transfer and validate the processes and certain analytical methods necessary for the production and testing of bulk rhIGF-1 by Lonza Hopkinton. A delay in this transfer could result in a shortage of bulk Increlex<sup>®</sup> and a significant loss of revenues. If we are not able to complete this transfer, our ability to supply Increlex<sup>®</sup> will be impaired and our business will suffer irreparable harm.

***If our contract manufacturers and/or Ipsen's facilities and operations do not maintain satisfactory cGMP compliance, we may be unable to market and sell Increlex<sup>®</sup> and/or Somatuline<sup>®</sup> Autogel<sup>®</sup>.***

The facilities used by and operations of our contract manufacturers to manufacture and test Increlex<sup>®</sup> must undergo continuing inspections by the FDA for compliance with cGMP regulations in order to maintain our Increlex<sup>®</sup> approval for the treatment of severe Primary IGF1D. Similarly, the facilities used by and operations of Ipsen to manufacture Somatuline<sup>®</sup> Autogel<sup>®</sup> must undergo an inspection by the FDA for compliance with cGMP regulations before Somatuline<sup>®</sup> Autogel<sup>®</sup> can be approved. Currently, Lonza Baltimore is our sole provider of bulk rhIGF-1 and Ipsen is our sole provider of Somatuline<sup>®</sup> Autogel<sup>®</sup>. We have no alternative manufacturing facilities or plans for additional facilities at this time. We do not know if the Lonza Baltimore facilities or their operations required for the commercial manufacture of Increlex<sup>®</sup> will continue to receive satisfactory cGMP inspections, and we do not know if Ipsen's facilities or their operations required for the commercial manufacture of Somatuline<sup>®</sup> Autogel<sup>®</sup> will receive a satisfactory cGMP inspection. In the event these facilities or operations do not receive, or continue to receive, satisfactory cGMP inspections for the manufacture of our products, or for the operation of their facilities in general, we may need to invest in significant compliance improvement programs, fund additional modifications to our manufacturing processes, conduct additional validation studies, or find alternative manufacturing facilities, any of which would result in significant cost to us as well as result in a delay or prevention of commercialization, and may result in our failure to obtain or maintain approvals. In addition, Lonza Baltimore and Lonza Hopkinton, and any alternative contract manufacturer we may utilize, will be subject to ongoing periodic inspection by the FDA and corresponding state and foreign agencies for compliance with cGMP regulations and similar foreign standards. We do not have direct control over Ipsen's or our contract manufacturers' compliance with these regulations and standards. Any of these factors could delay or suspend clinical trials, regulatory submissions or regulatory approvals, entail higher costs and result in us being unable to effectively market and sell our products or maintain our products in the marketplace, which would adversely affect our ability to generate revenues.

***We rely in certain cases on single-source and sole-source materials suppliers to manufacture Increlex<sup>®</sup>.***

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



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

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

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

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

***If other companies overcome our U.S. orphan drug marketing exclusivity for Increlex®, or for Somatuline® Autogel® if obtained, or obtain marketing authorization in Europe for the treatment of severe Primary IGFD, they will be able to compete with us, and our revenues will be diminished.***

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States. The company that obtains the first FDA approval for a designated orphan drug for a rare disease receives marketing exclusivity for use of that drug for the designated condition for a period of seven years. Increlex® has received from the FDA orphan drug marketing exclusivity for the long-term treatment of patients with severe Primary IGFD. Ipsen is seeking orphan drug marketing exclusivity for Somatuline® Autogel® for acromegaly in connection with the marketing approval application that Ipsen submitted to the FDA; however, there can be no assurance that the FDA will grant marketing exclusivity to Somatuline® Autogel®.

Although Increlex® has received marketing exclusivity for severe Primary IGFD, the FDA can still approve different drugs for use in treating the same indication or disease covered by our product, which would create a more competitive market for us. Similarly, there may be additional drugs for treating acromegaly that could compete with Somatuline® Autogel® despite its seven-year orphan drug marketing exclusivity, even if granted by the FDA.

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

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

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

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

In the future, rhIGF-1 manufactured by other parties may be approved for use in the United States. For example, we are aware that Novartis has developed a process to manufacture rhIGF-1 using yeast expression and has intellectual property with respect to that process. In the event there are other rhIGF-1 products approved by the FDA to treat indications other than those covered by Increlex<sup>®</sup>, physicians may elect to prescribe a competitor's product containing rhIGF-1 to treat the indications for which Increlex<sup>®</sup> has received and may receive approval. This is commonly referred to as off-label use. While under FDA regulations a competitor is not allowed to promote off-label use of its product, the FDA does not regulate the practice of medicine and as a result cannot direct physicians as to which product containing rhIGF-1 to prescribe to their patients. As a result, we would have limited ability to prevent off-label use of a competitor's product containing rhIGF-1 to treat any diseases for which we have received FDA approval, even if it violates our method of use patents and/or we have orphan drug exclusivity for the use of rhIGF-1 to treat such diseases.

***Competitors could challenge our patents and file an Abbreviated New Drug Application, or ANDA, or a 505(b)(2) new drug application for an IGF-1 or Somatuline<sup>®</sup> Autogel<sup>®</sup> product and adversely affect the competitive position of each.***

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

***We are subject to fraud and abuse and similar laws and regulations, and a failure to comply with such regulations or prevail in any litigation related to noncompliance could harm our business.***

Upon approval of Increlex<sup>®</sup> by the FDA, we became subject to various health care fraud and abuse laws, such as the Federal False Claims Act, the federal anti-kickback statute and other state and federal laws and regulations. Pharmaceutical companies have faced lawsuits and investigations pertaining to violations of these laws and regulations. We cannot guarantee that measures that we have taken to prevent such violations, including our corporate compliance program, will protect us from future violations, lawsuits or investigations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

***If we fail or are unable to protect or defend our intellectual property rights, competitors may develop competing products, and our business will suffer.\****

If 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, our growth hormone/IGF-1 combination product candidates, and Somatuline<sup>®</sup> Autogel<sup>®</sup> technologies from Genentech and Ipsen, respectively. 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 meaningful revenues.



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We do not have composition of matter patent 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 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 U.S. and foreign courts use to interpret patents, are not the same and are not always applied predictably or uniformly and can change, particularly as new technologies develop. As such, the degree of patent protection obtained in the 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 U.S. Patent No. 6,331,414 B1 licensed from Genentech is directed to methods for bacterial expression of rhIGF-1 and expires in 2018. We have no equivalent European patent. The European Patent Office has determined that the claims of Genentech's corresponding European patent application are not patentable under European patent law in view of public disclosures made before the application was filed.

We do not have composition of matter patent coverage on the lanreotide molecule (the active pharmaceutical ingredient of Somatuline® Autogel®) alone. We have licensed from Ipsen its rights to formulation and method of use patents for Somatuline® Autogel® that expire between 2015 and 2019, and Ipsen intends to seek seven-year orphan drug marketing exclusivity in connection with any marketing authorization for Somatuline® Autogel® for the treatment of acromegaly in the United States. However, there can be no assurance that we have patent rights sufficient to prevent others from competing with us, nor can there be any assurance that Somatuline® Autogel® will be granted any orphan drug marketing exclusivity to block a competitor from marketing the same drug for the treatment of acromegaly.

We do not have composition of matter patent coverage on either the growth hormone or the IGF-1 component of our growth hormone/IGF-1 combination product candidates. Our U.S. Patent No. 5,374,620 and our equivalent European Patent No. 0 536 226 B1, both of which are licensed from Genentech, are composition of matter patents covering combinations of growth hormone and IGF-1 and expire in 2009 and 2011, respectively. Therefore, it is likely that these patents will expire before we are able to launch any growth hormone/IGF-1 combination product in the U.S. or in European markets. We have also licensed from Genentech certain method of use patents for our growth hormone/IGF-1 combination product candidates that expire between 2009 and 2014. Our U.S. Patent No. 6,331,414 B1 licensed from Genentech will provide protection in the United States for our process of manufacturing IGF-1 for our growth hormone/IGF-1 combination product candidates until it expires in 2018. We have no equivalent patent protection for our process of manufacturing IGF-1 in Europe.

If we attempt to enforce against a competitor the patent rights we have licensed from Ipsen or the patent rights we have licensed from Genentech, and if such patents are challenged in court by defenses the competitor may raise, such as invalidity, unenforceability or possession of a valid license, we may fail to stop the competitor and we may lose the ability to assert the affected patents against other competitors as well. If we assert the patents we licensed from Ipsen or the patents we licensed from Genentech in an infringement proceeding against a competitor, and if the court were to find in favor of any defense of invalidity or unenforceability raised by the competitor against the asserted patents, we would be unable to use the affected patents to exclude others from competing with Somatuline® Autogel® or Increlex®. 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 technology similar to our Increlex®, or any growth hormone/IGF-1 combination product or Somatuline® Autogel® technologies.

In addition to the patented technology licensed from Genentech and Ipsen, 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.***

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





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always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our products or methods of use do not infringe the patent claims of the relevant patent and/or that the patent claims are invalid, and we may not be able to do so. Proving invalidity, in particular, is difficult since it requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents.

We are aware of a U.S. patent of Novartis 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<sup>®</sup>, we cannot predict whether our activities relating to the development and commercialization of Increlex<sup>®</sup> in the United States will be found to infringe Novartis' s patent in the event Novartis brings patent infringement proceedings against us. We may not be able to obtain a license to Novartis' s patent under commercially reasonable terms, if at all. If we are unable to obtain a license to Novartis' s patent, and if in any patent infringement proceeding Novartis brings against us the court decides that our activities relating to the development and commercialization of Increlex<sup>®</sup> in the United States infringe Novartis' s patent, the court may award damages and/or injunctive relief to Novartis. Any such damages, injunctive relief and/or other remedies the court may award could render any further development and commercialization of Increlex<sup>®</sup> commercially infeasible for us or otherwise curtail or cease any further development and commercialization of Increlex<sup>®</sup>.

We cannot be certain that others have not filed patent applications for technology covered by the issued patents of any of our licensors, or by our pending applications or by the pending applications of any of our licensors, or that we or any of 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 U.S. 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.

***Ipsen may seek to influence our business in a manner that is contrary to our goals or strategies or to the interests of our other stockholders.***

Based on its significant ownership position through certain protective provisions, Ipsen has the ability to significantly influence the outcome of certain actions by our Board of Directors and those requiring the approval of our stockholders. Our other stockholders may be unable to prevent actions taken by Ipsen. Together with the 12,527,245 shares of our common stock that we issued in connection with the initial closing of our collaboration with Ipsen, and held at June 30, 2007, the conversion of the convertible notes that we issued or that we may issue to Ipsen and the exercise of the warrant that we issued to Ipsen would enable Ipsen to acquire an ownership interest in us of approximately 40% on a fully diluted basis, with the opportunity to increase its ownership position to 60% or greater through market purchases upon the expiration of a one-year standstill period. Ipsen was also granted a preemptive right to purchase its *pro rata* portion of new securities that we may offer in the future to maintain its percentage ownership interest. In addition, under the terms of our affiliation agreement with Ipsen, so long as Ipsen holds at least 15% of the outstanding shares of our common stock, Ipsen would be entitled to nominate two out of the nine directors on our Board of Directors. In the event that Ipsen holds at least 10% of the outstanding shares of our common stock, but less than 15%, it would be entitled to nominate one director to our Board of Directors. Our affiliation agreement with Ipsen also provides that in the event Ipsen holds at least 60% of the outstanding shares of our common stock, Ipsen is entitled to nominate an unlimited number of directors to our Board of Directors. For so long as Ipsen holds at least 15% of the outstanding shares of our common stock, Ipsen is also entitled to nominate additional independent director

nominees, who must be independent of Ipsen, starting in 2008. Our certificate of incorporation was also amended in

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connection with our collaboration with Ipsen to waive the corporate opportunity provisions under Delaware law and the corporate opportunity doctrine with respect to opportunities of which Ipsen and Ipsen's designees to our Board of Directors may become aware as a result of their affiliation with us. Additionally, our certificate of incorporation provides that any person purchasing or acquiring an interest in shares of our common stock shall be deemed to have consented to these provisions of our certificate of incorporation. This deemed consent might restrict the ability to challenge transactions carried out in compliance with these provisions. We make no assurances that Ipsen will not seek to influence our business in a manner that is contrary to our goals or strategies or the interests of other stockholders. Moreover, persons who are directors and/or officers of Ipsen and who also serve on our Board of Directors may decline to take action in a manner that might be favorable to us but adverse to Ipsen. Currently, two of our directors, Jean-Luc Bélingard and Christophe Jean, also serve as the Chief Executive Officer and Chief Operating Officer, respectively, of Ipsen.

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

We have licensed intellectual property rights and technology from Genentech and from Ipsen. Under our license and collaboration agreements with Genentech and Ipsen, each of Genentech and Ipsen have the right to terminate our licenses if we are in material breach of our obligations under our agreements with them 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. If any of these agreements are terminated, then we would lose our rights to utilize the technology and intellectual property covered by that agreement to develop, manufacture, market and sell Increlex<sup>®</sup> for any indication; to develop, market and sell Somatuline<sup>®</sup> Autogel<sup>®</sup>; and to develop, manufacture, market and sell our growth hormone/IGF-1 combination product candidates. This may prevent us from continuing our business.

***We are subject to Genentech's option rights with respect to the commercialization of Increlex<sup>®</sup> for all diabetes and non-orphan indications in the United States; Ipsen's right of first negotiation to develop and commercialize other endocrine products subsequently acquired or owned by us; and Genentech's option rights with respect to our growth hormone/IGF-1 combination product candidates.\****

Under our U.S. license and collaboration agreement with Genentech for Increlex<sup>®</sup>, 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 the development and commercialization of such indications. Our ability to sublicense the development and commercialization of such products requires the consent of Genentech. Further, if we do not initiate development of IGF-1 for the treatment of diabetes before Genentech elects to initiate such development, subject to terms to be agreed upon, Genentech may develop IGF-1 for the treatment of diabetes. Further, if we were to agree, Genentech would have the right to substitute a new indication for diabetes.

Under our license and collaboration agreement with Ipsen with respect to Increlex<sup>®</sup>, Ipsen has a right of first negotiation to develop and commercialize, in Ipsen's territory, other products subsequently acquired or owned by us in the field of endocrinology. Accordingly, we may not receive a reasonable return on our investment if we develop new endocrinology products. In its territory, Ipsen also has the exclusive right to sublicense our growth hormone/IGF-1 combination product candidates. Accordingly, we have limited ability to sublicense these candidates to other parties.

Under our development and commercialization agreement with Genentech with respect to our growth hormone/IGF-1 combination product candidates, Genentech has a right to opt into our development and commercialization for short stature indications, AGHD and certain other indications. If Genentech opts in, it would still have the right to subsequently elect to opt out of such development and commercialization of such combination product candidates and products, but only for all indications.

Following an opt in by Genentech, Genentech would control the joint development and commercialization of the combination product candidates and products for certain other indications and could assume control of the joint development and/or commercialization of products for the treatment of AGHD and short stature. Because of Genentech's ability to control the timing and extent of such joint development and commercialization activities and our obligation to co-fund such activities, Genentech may induce us to bear an excessive financial burden in support of or to opt out of the joint development and commercialization of our combination product candidates and/or products for AGHD and certain other indications. In addition, our ability to sublicense the development and commercialization of our growth hormone/IGF-1 combination product candidates requires the consent of Genentech.

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Accordingly, because of these various option, limits on sublicensing, and right of first negotiation rights, we may not receive a reasonable return on our investment for developing and/or commercializing Increlex or our growth hormone/IGF-1 combination product candidates.

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

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

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

We do not conduct any discovery research. Our strategy is to in-license products or product candidates and further develop them for commercialization. The market for acquiring and in-licensing patent rights, products and product candidates is intensely competitive. If we are not successful in identifying and in-licensing other patent rights, products or product candidates, we may be unable to grow our revenues with sales from additional products. Further, under the terms of our collaboration with Ipsen, Ipsen has certain approval rights with respect to our entering into material contracts or transactions, making capital expenditures or acquiring certain assets. Accordingly, Ipsen may prevent us from in-licensing products or product candidates. In addition, under the terms of our collaboration, Ipsen has a right of first negotiation to develop and commercialize, in Ipsen's territory, products subsequently acquired or owned by us in the field of endocrinology. Under our combination product agreement with Genentech, Genentech has certain opt-in rights with respect to our development and commercialization of combination products and, with respect to certain combination products, to become the lead party for the planning, development and/or commercialization of such combination products.

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

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

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

a minimum price for our common stock;

the accuracy of representations and warranties made to Kingsbridge;

compliance with laws;

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

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

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

The terms of the CEFF require us to pay certain liquidated damages in the event that the registration statement filed by us with the SEC is not available for the resale of securities purchased by Kingsbridge under the CEFF or upon exercise of the warrant we issued to Kingsbridge. Except for certain periods of ineffectiveness permitted under the CEFF, we are obligated to pay to Kingsbridge an amount equal to the number of shares purchased under the CEFF and held by Kingsbridge at the

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date the registration statement becomes unavailable, multiplied by any positive difference in price between the volume weighted average price on the trading day prior to such period of unavailability and the volume weighted average price on the first trading day after the period of unavailability. In addition, we are entitled in certain circumstances to deliver a blackout notice to Kingsbridge to suspend the use of the registration statement and prohibit Kingsbridge from selling shares under the registration statement. If we deliver a blackout notice in the 15 trading days following a settlement of a draw down, then we must make a blackout payment to Kingsbridge as liquidated damages, or issue Kingsbridge additional shares in lieu of this payment, calculated by means of a varying percentage of an amount based on the number of shares purchased and held by Kingsbridge and the change in the market price of our common stock during the period in which the use of the registration statement is suspended. If the trading price of our common stock declines during a suspension of the registration statement, the blackout payment could be significant and could adversely affect our liquidity and our ability to raise capital. In addition, under the terms of an affiliation agreement we entered into pursuant to our collaboration with Ipsen, we have only a limited ability to raise capital through the sale of our equity securities, including pursuant to the CEFF, without first obtaining Ipsen's approval.

***We may not have the ability to raise the funds necessary to finance the repayment of the convertible notes we issued or that we may issue to Ipsen, which could adversely affect our cash position and harm our business.***

Under the terms of our collaboration with Ipsen, we issued Ipsen a convertible note in the principal amount of \$25.0 million, and may issue up to two additional convertible notes to Ipsen in the principal amounts of \$30.0 million and \$15.0 million, respectively. All of these notes mature five years from the date of issuance of the first note or two years from the date of notification of non-convert, and carry a 2.5% coupon per annum from the date of issuance, compounded quarterly. If Ipsen chooses not to convert these notes, we would be required to pay to Ipsen the principal amount of the notes plus accrued interest at maturity. We will also be subject to currency risk on the \$30.0 million convertible note that we may issue to Ipsen, which, if the note is not converted, may result in the need to raise a greater amount of U.S. dollars to repay this note at maturity than would be required based on a conversion of this note to U.S. dollars at the time we entered into the stock purchase and master transaction agreement with Ipsen in July 2006 or issuance of the note. If we are required to pay the notes in cash, we will likely need to raise such amounts from the capital markets or through a strategic transaction. There is no assurance that we would be able to do so in a timely manner or on reasonable terms. If we are unable to do so, we may be required to delay or curtail our development and commercialization efforts, which would harm our business.

Our indebtedness to Ipsen could have significant additional negative consequences, including, but not limited to:

increasing our vulnerability to general adverse economic and industry conditions;

limiting our ability to obtain additional financing;

limiting our flexibility in planning for, or reacting to, changes in our business and the industry in which we compete; and

placing us at a possible competitive disadvantage to less leveraged competitors and competitors that have better access to capital resources.

***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, 2007, together with the funds that we would potentially receive from our collaboration with Ipsen, will be sufficient to meet our projected operating and capital expenditure requirements through at least the middle of 2008 based on our current business plan. However, our future capital needs and the adequacy of our available funds will depend on many factors, including:

changes to our business plan;

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our ability to market and sell sufficient quantities of Increlex<sup>®</sup> and Somatuline<sup>®</sup> Autogel<sup>®</sup> at the anticipated level;

the commercial status of the Increlex<sup>®</sup> bulk drug manufacturing operations at Lonza Baltimore and Lonza Hopkinton, including the success of our cGMP production activities;

the success of Increlex<sup>®</sup> final drug product manufacturing;

the costs, timing and scope of additional regulatory approvals for Increlex<sup>®</sup>;

Ipsen's ability to supply Somatuline<sup>®</sup> Autogel<sup>®</sup> to us in sufficient quantities;

the costs, timing and scope of additional regulatory approvals for Somatuline<sup>®</sup> Autogel<sup>®</sup>;

Ipsen's ability to market and sell sufficient quantities of Increlex<sup>®</sup> in the licensed territories at the anticipated level;

any required repayment of the convertible notes we issued or that we may issue to Ipsen;



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the status of competing products;

the rate of progress and cost of our future clinical trials and other research and development activities, including research and development activities and clinical trial costs in connection with our combination product agreement with Genentech; and

the pace of expansion of administrative and legal expenses.

We expect capital outlays and operating expenditures to increase over the next several years as we expand our operations. We expect that we may require and attempt to raise additional funds through equity or debt financings, collaborative arrangements with corporate partners or from other sources, including potentially the CEFF. However, there can be no assurance that additional financing will be available when needed, or, if available, that the terms will be favorable. In addition, under the terms of an affiliation agreement we entered into pursuant to our collaboration with Ipsen, we have only a limited ability to raise capital through the sale of our equity without first obtaining Ipsen's approval. If additional funds are not available, we may be forced to curtail or cease operations. Although we have entered into a stock purchase agreement with Genentech pursuant to which we may issue up to an additional 1,894,737 shares of common stock (or up to a maximum of \$9.0 million of shares of common stock) to Genentech, such issuances are subject to various conditions, including a Genentech opt in and the achievement of a regulatory approval milestone, and there can be no assurance that we will receive additional funds from Genentech pursuant to the stock purchase agreement. Further, we must first obtain Ipsen's approval to issue shares of common stock to Genentech under the stock purchase agreement with Genentech at a price per share less than \$4.75, which we may not be able to obtain. If additional funds are not available, we may be forced to curtail or cease operations.

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

Our ability to implement our business plan requires an effective planning and management process. As of June 30, 2007, we had 114 full-time employees, and we expect to hire additional employees in the near term. Our offices are located in the San Francisco Bay area where competition for personnel with biopharmaceutical skills is intense. If we fail to identify, attract, retain and motivate these highly skilled personnel, we may be unable to continue our development and commercialization activities.

We believe that our anticipated future growth may strain our management, systems and resources. To manage the anticipated growth of our operations, we may need to increase management resources and implement additional financial and management controls, reporting systems and procedures. If we are unable to manage our growth, we may be unable to execute our business strategy.

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

One potential risk of using growth factors like rhIGF-1 is that it may increase the likelihood of developing cancer or, if patients already have cancer, that the cancer may develop more rapidly. Increlex<sup>®</sup> 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. In our Phase III clinical trials for severe Primary IGF1D, the data of which we submitted to the FDA in our NDA, some patients experienced hypoglycemia, or low blood glucose levels. Other side effects noted in some patients include hearing deficits, enlargement of the tonsils and intracranial hypertension.

Somatuline<sup>®</sup> Autogel<sup>®</sup> is a member of a class of products known as somatostatin analogs, which have the potential to cause gallstones and other disorders associated with obstruction of the biliary tract, including pancreatitis. These products also alter the balance between the counter-regulatory hormones insulin, glucagon and growth hormone, which may result in hypoglycemia or hyperglycemia, and suppress secretion of thyroid stimulating hormone, which may result in hypothyroidism. Cardiac conduction abnormalities have also occurred during treatment with this class of drugs.

There may also be other adverse events associated with the use of Increlex<sup>®</sup> or Somatuline<sup>®</sup> Autogel<sup>®</sup>, and adverse events may arise that are related to our growth hormone/IGF-1 combination product candidates, which may result in product liability suits being brought against us. While we have licensed the rights to develop, market and sell Increlex<sup>®</sup>, Somatuline<sup>®</sup> Autogel<sup>®</sup> and our growth hormone/IGF-1 combination product candidates in certain indications, we are not indemnified by any third party, including our contract manufacturers, for any liabilities arising out of our development or use of any of these products or product candidates.

Whether or not we are ultimately successful in defending product liability litigation, such litigation would consume substantial amounts of our financial and managerial resources, and might result in adverse publicity or reduced acceptance of our products in the market, or product candidates in development, 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.

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

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

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

***If we are unable to attract and retain additional qualified personnel, our ability to market and sell our products and develop other product candidates will be harmed.***

Our success depends on our continued ability to attract and retain highly qualified management and scientific personnel and on our ability to develop relationships with leading academic scientists and clinicians. We are highly dependent on our current management and key medical, scientific and technical personnel, including: Dr. John A. Scarlett, our President and Chief Executive Officer and Dr. Ross G. Clark, our Founder and Chief Technical Officer, whose knowledge of our industry and technical expertise would be extremely difficult to replace. We have at will employment contracts with all of our executive officers. They may terminate their employment without cause or good reason and without notice to us.

### **Risks Related to Our Common Stock**

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

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

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

As of June 30, 2007, our directors, executive officers and principal stockholders and their affiliates beneficially owned approximately 74.8% of our common stock. Our greater than five percent beneficial owners include Ipsen and its affiliates, which beneficially owned 35.7% (not including shares subject to limited voting agreements with certain of our stockholders); entities affiliated with MPM BioVentures III LLC, which beneficially owned 13.8%; entities affiliated with Prospect Management Co. II, LLC, which beneficially owned 6.1%; MedImmune, Inc., which beneficially owned 6.0%; and entities affiliated with Rho Capital Partners, which beneficially owned 6.0%. 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.

***Our collaboration with Ipsen limits our ability to enter into transactions and to pursue opportunities in conflict with Ipsen, which could cause the price of our common stock to decline.***

Under the terms of an affiliation agreement we entered into pursuant to our collaboration with Ipsen, the approval of Ipsen is required for us to take certain actions, including, but not limited to:

entering into most material transactions or agreements;

merging or consolidating with other entities;

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establishing or approving an operating budget with anticipated research and development spending in excess of \$25.0 million per year, plus potential additional amounts for new Ipsen projects under the license and collaboration agreement we entered into with respect to Somatuline® Autogel®;

subject to limited exceptions, incurring any indebtedness other than certain permitted indebtedness (provided that our total permitted indebtedness may not exceed \$2.5 million if our ratio of net indebtedness to EBITDA exceeds 1:1);

incurring capital expenditures of more than \$2.0 million in any given year;

making any investment, other than certain permitted investments;

entering into any transaction that results in competition with Ipsen;

declaring or paying any cash dividends;

taking any action with respect to takeover defense measures, including with respect to our stockholder rights plan; and

issuing or selling shares of our capital stock, other than issuances or sales after the second anniversary of the initial closing of our collaboration with Ipsen that may not exceed \$25.0 million in any three-year period, and other limited exceptions.

These provisions could continue indefinitely and may limit our ability to enter into transactions otherwise viewed as beneficial to us, which could cause the price of our common stock to decline.

***Our stockholder rights plan and anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult.***

Provisions of our amended and restated certificate of incorporation and amended and restated 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

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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.

We have adopted a rights agreement under which certain stockholders have the right to purchase shares of a new series of preferred stock at an exercise price of \$40.00 per one one-hundredth of a share of such preferred stock if a person or group of persons acquires more than a certain percentage of our common stock. The rights plan could make it more difficult for a person to acquire a majority of our outstanding voting stock. The rights plan could also reduce the price that investors might be willing to pay for shares of our common stock and result in the market price being lower than it would be without the rights plan. In addition, the existence of the rights plan itself may deter a potential acquirer from acquiring us. As a result, either by operation of the rights plan or by its potential deterrent effect, mergers or other business combinations that our stockholders may consider in their best interests may not occur.

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

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

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

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

announcements by us, Ipsen, Genentech, our suppliers and key third-party vendors, or our competitors of regulatory developments, product development agreements, clinical trial results, clinical trial enrollment, regulatory filings, new products and product launches, significant acquisitions, strategic partnerships or joint ventures;

estimates of our business potential and earnings prospects;

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

developments with respect to our collaboration with Ipsen;

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, including potential sales of a substantial number of shares by Ipsen and its affiliates, or the perception that such sales are likely to occur;

general economic, industry and market conditions; and

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



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

### ***We are at risk of securities class action litigation.***

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

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

If our stockholders sell substantial amounts of our common stock, including shares issued upon the exercise of outstanding options or pursuant to the CEFF, and the shares issued or issuable to Ipsen and its affiliates, the market price of our common stock may decline. In addition, the perceived risk of dilution from sales or issuances of our common stock to or by Kingsbridge or Ipsen may cause holders of our common stock to sell their shares, or it may encourage short selling by market participants, which could contribute to a decline in our stock price. These sales also might make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem appropriate. We are unable to predict the effect that sales may have on the prevailing market price of our common stock.

As of June 30, 2007, we had 50,213,508 outstanding shares of common stock. Of these shares, the 18,975,000 shares sold in our public offerings were freely tradable without restriction or further registration unless purchased by our affiliates. Of the remaining 31,238,508 shares outstanding as of June 30, 2007, substantially all of these shares, other than the 12,527,245 shares we issued to an affiliate of Ipsen, were eligible for sale in the public market (subject to certain restrictions)

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on sales by affiliates and vesting in the case of early exercised options). The 12,527,245 shares we issued to an affiliate of Ipsen will become eligible for sale in the public market under Rule 144 in October 2007, subject to compliance with the volume, manner of sale and other limitations under Rule 144. As of June 30, 2007, we had 5,404,960 shares subject to outstanding options granted under our equity compensation plans. In addition, as of June 30, 2007, 8,405,524 shares were issuable upon the exercise of the warrant and conversion of convertible note we issued to Ipsen in connection with the initial closing of our collaboration. Further, the terms of the warrant we issued to Ipsen provide that the number of shares of our common stock subject to the warrant may increase in the event of certain issuances of equity securities by us that dilute Ipsen's percentage ownership interest in us. Moreover, the initial exercise price of the warrant, and the conversion price of convertible notes we issued or that we may issue to Ipsen, are subject to certain weighted-average price-based antidilution adjustments. These terms of the warrant and convertible notes may entitle Ipsen to acquire a greater number of shares of our common stock than we currently anticipate.

We have filed a registration statement covering shares of common stock issuable upon exercise of options and other grants pursuant to our stock plans. In September 2005, we filed a shelf registration statement pursuant to which we may, from time-to-time, sell shares of our common stock and preferred stock, various series of debt securities and/or warrants to purchase any of such securities, either individually or in units, in one or more offerings. In November 2005, we also filed a registration statement for the resale of the shares of common stock issuable in connection with the CEFF and the shares of common stock underlying the warrant we issued to Kingsbridge in connection with our entering into the CEFF. Moreover, we have agreed that, upon Ipsen's request after October 13, 2007, we would file one or more registration statements in order to permit Ipsen and its affiliates to offer and sell a substantial number of shares of our common stock, including the 12,527,245 shares we issued to an affiliate of Ipsen and the shares issuable upon exercise of the warrant and conversion of the convertible notes we issued or that we may issue to Ipsen. In addition, certain holders of shares of our common stock that are parties to our amended and restated investors' rights agreement are entitled to registration rights.

**Table of Contents****ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.**

None.

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

On May 24, 2007, our 2007 Annual Meeting of Stockholders was held at our corporate offices located at 2000 Sierra Point Parkway, Brisbane, California. During this meeting, our stockholders voted on the following three proposals:

(a) Proposal to elect three directors to hold office until the 2010 Annual Meeting of Stockholders:

Nominee	Votes	
	For	Withheld
John A. Scarlett, M.D.	42,683,568	151,225
Karin Eastham	42,687,513	147,280
Christophe Jean	42,683,468	151,325

Our Class I directors, Jean-Luc Bélingard, Ross G. Clark, Ph.D. and David L. Mahoney, will each continue to serve on our Board of Directors until our 2008 Annual Meeting of Stockholders and until his successor is elected and has qualified, or until his earlier death, resignation or removal. 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 2009 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.

(b) Proposal to ratify the selection by the Audit Committee of our Board of Directors of Ernst & Young LLP as our independent registered public accounting firm for the fiscal year ending December 31, 2007:

For	Votes Against	Abstain
42,801,138	24,755	8,900

(c) Proposal to approve the amendments to our amended and restated certificate of incorporation and our amended and restated bylaws to eliminate our classified board of directors and certain other anti-takeover protections:

For	Votes Against	Abstain
42,668,045	154,999	11,749

**ITEM 6. EXHIBITS.**

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation(1)
3.2	Amended and Restated Bylaws, as amended(2)
3.3	Certificate of Designation of Series A Junior Participating Preferred Stock(3)
3.4	Certificate of Amendment of Amended and Restated Certificate of Incorporation(3)
3.5	Certificate of Amendment of Amended and Restated Certificate of Incorporation(2)
4.1	Form of Specimen Stock Certificate(4)

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- 4.2 Reference is made to Exhibits 3.1, 3.2, 3.3, 3.4 and 3.5
- 4.3 Warrant issued to Kingsbridge Capital Limited, dated October 14, 2005(5)
- 4.4 Warrant issued to Ipsen, S.A., dated October 13, 2006(4)
- 4.5 First Senior Convertible Promissory Note issued to Ipsen, S.A., dated October 13, 2006(4)
- 4.6A Rights Agreement, dated as of October 13, 2006, between the Registrant and Computershare Trust Company, N.A., as Rights Agent(4)
- 4.6B Form of Right Certificate(4)

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<b>Number</b>	<b>Description</b>
10.6H	Second Amendment to Lease Agreement dated January 4, 2007 between 2000 Sierra Point Parkway LLC and the Registrant.
10.6I	Third Amendment to Lease Agreement dated July 6, 2007 between 2000 Sierra Point Parkway LLC and the Registrant.
10.7E	Combination Product Development and Commercialization Agreement, dated as of July 6, 2007, between Genentech, Inc. and the Registrant.
10.7F	Letter Agreement, dated as of July 6, 2007, between Genentech, Inc. and the Registrant.
10.7G	Common Stock Purchase Agreement, dated as of July 6, 2007, between Genentech, Inc. and the Registrant.
10.8C	Addendum to Manufacturing Services Agreement, effective as of May 11, 2007, between the Registrant and Lonza Baltimore, Inc. (as successor in interest to Cambrex Bio Science Baltimore, Inc.)
10.8D	Agreement, dated as of May 14, 2007, between the Registrant and Lonza Hopkinton, Inc.
10.9Z	Amendment to Employment Letter for Richard A. King, dated August 1, 2007.
10.10	Second Amended and Restated Investors Rights Agreement, dated July 30, 2007.
10.14E	Common Stock Purchase Agreement, dated as of July 9, 2007, between the Registrant, Suraypharm and Ipsen, S.A.
10.14F	Amendment No. 1 to Registration Rights Agreement, dated as of July 30, 2007, between the Registrant, Suraypharm and Ipsen, S.A.
15.1	Letter regarding Unaudited Interim Financial Information.
31.1	Certification of Chief Executive Officer of Tercica, Inc., as required by Rule 13a-14(a) or Rule 15d-14(a).
31.2	Certification of Chief Financial Officer of Tercica, Inc., as required by Rule 13a-14(a) or Rule 15d-14(a).
32.1	Certification by the Chief Executive Officer, as required by Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350).
32.2	Certification by the Chief Financial Officer, as required by Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350).

Confidential treatment has been requested with respect to certain portions of this exhibit. This exhibit omits the information subject to this confidentiality request. Omitted portions have been filed separately with the SEC.

- (1) Incorporated by reference to the similarly described exhibit included with the Registrant's quarterly report on Form 10-Q (File No. 000-50461) filed on May 13, 2004.
- (2) Incorporated by reference to the similarly described exhibit included with the Registrant's Current Report on Form 8-K (File No. 000-50461) filed on May 25, 2007.
- (3) Incorporated by reference to the similarly described exhibit included with the Registrant's Current Report on Form 8-K (File No. 000-50461) filed on October 18, 2006.
- (4) Incorporated by reference to the similarly described exhibit included with the Registrant's quarterly report on Form 10-Q (File No. 000-50461) filed on November 3, 2006.
- (5) Incorporated by reference to the similarly described exhibit included with the Registrant's quarterly report on Form 10-Q (File No. 000-50461) filed on November 4, 2005.

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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 2, 2007

TERCICA, INC.  
(Registrant)

/s/ Ajay Bansal  
Ajay Bansal

Chief Financial Officer  
(Authorized Officer and Principal Financial Officer)