TERCICA INC
Form 10-Q
November 01, 2007
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

x Quarterly report pursuant to Section 13 or 15(d) of the Securities and Exchange Act of 1934
For the quarterly period ended September 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

TERCICA, INC.

(Exact name of Registrant as specified in its charter)

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

2000 Sierra Point Parkway, Suite 400

Brisbane, CA 94005

(650) 624-4900

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

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

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

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

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

As of October 31, 2007, there were 51,447,870 shares of the Registrant s Common Stock outstanding.

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TERCICA, INC.

FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2007

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PART I FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS.

TERCICA, INC.

CONDENSED BALANCE SHEETS

(In thousands)

(Unaudited)

	September 30, 2007	December 31, 2006
Assets		
Current assets:		
Cash and cash equivalents	$ 69,614	$ 40,339
Short-term investments	58,135	85,236
Accounts receivable, net	1,302	335
Inventories	11,695	5,092
Prepaid expenses and other current assets	2,208	1,948
Total current assets	142,954	132,950
Property and equipment, net	3,160	3,861
Intangible assets	42,140	
Restricted cash	340	340
Other assets	478	536
Total assets	$ 189,072	$ 137,687
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 4,208	$ 2,457
Accrued expenses	8,046	6,214
Liability for early exercise of stock options		32
Other current liabilities	299	290
Deferred revenue, less long-term portion	973	776
Fair value of derivative financial instruments	12,930	
Total current liabilities	26,456	9,769
Long-term convertible notes, net	70,447	25,172
Deferred rent	1,146	1,363
Deferred revenue, long-term portion	10,869	11,452
Commitments and contingencies		
Stockholders equity:		
Common stock	51	50
Additional paid-in capital	350,615	338,608
Accumulated other comprehensive income	5	11
Accumulated deficit	(270,517)	(248,738)
Total stockholders equity	80,154	89,931

Total liabilities and stockholders equity	$ 189,072	$ 137,687

See accompanying notes.

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TERCICA, INC.

CONDENSED STATEMENTS OF OPERATIONS

(In thousands, except per share data)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Net revenues				
Net product sales	$ 2,851	$ 316	$ 5,990	$ 567
License revenue	20,537		20,925	
Total net revenues	23,388	316	26,915	567
Costs and expenses:				
Cost of product sales	2,096	516	4,248	1,156
Research and development*	5,588	3,513	14,601	12,739
Selling, general and administrative*	11,409	10,162	31,562	31,252
Total costs and expenses	(19,093)	(14,191)	(50,411)	(45,147)
Income (loss) from operations	4,295	(13,875)	(23,496)	(44,580)
Interest expense	334		712	
Other expense	951		951	
Interest and other income, net	1,429	812	4,397	2,564
Pretax income (loss)	4,439	(13,063)	(20,762)	(42,016)
Provision for income taxes	1,017		1,017	
Net income (loss)	$ 3,422	$ (13,063)	$ (21,779)	$ (42,016)
Basic net income (loss) per share	$ 0.07	$ (0.35)	$ (0. 43)	$ (1.14)
Shares used to compute basic net loss per share	51,041	37,550	50,458	36,906
Diluted net income (loss) per share	$ 0.07	$ (0.35)	$ (0. 43)	$ (1.14)
Shares used to compute diluted net loss per share	51,345	37,550	50,458	36,906

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

Research and development	$ 405	$ 525	$ 1,454	$ 1,502
Selling, general and administrative	1,086	1,027	3,173	2,814
Total	$ 1,491	$ 1,552	$ 4,627	$ 4,316

See accompanying notes.

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TERCICA, INC.

CONDENSED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Nine Months Ended September 30,	
	2007	**2006**
Cash flows from operating activities:		
Net cash used in operating activities	$ (19,672)	$ (38,331)
Cash flows from investing activities:		
Purchases of property and equipment	(573)	(900)
Milestone payments to partners	(42,140)	
Purchases of available-for-sale securities	(83,144)	(38,254)
Proceeds from sales and maturities of available-for-sale securities	111,072	41,128
Net cash provided by (used in) investing activities	(14,785)	1,974
Cash flows from financing activities:		
Net proceeds from issuance of common stock	241	34,534
Net proceeds from sale of common stock	6,851	
Proceeds from issuance of convertible debt	56,640	
Net cash provided by financing activities	63,732	34,534
Net increase/(decrease) in cash and cash equivalents	29,275	(1,823)
Cash and cash equivalents, beginning of period	40,339	14,817
Cash and cash equivalents, end of period	$ 69,614	$ 12,994

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

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

Revenue Recognition

The Company recognizes revenue from the sale of its products and license and collaboration agreements pursuant to Staff Accounting Bulletin No. 104, *Revenue Recognition*, and Emerging Issues Task Force (EITF) Issue 00-21 *Revenue Arrangements with Multiple Deliverables*. Multiple element agreements entered into are evaluated under the provision of EITF 00-21. The Company evaluates whether there is stand-alone value for the delivered elements and objective and reliable evidence of fair value to allocate revenue to each element in multiple element agreements. When the delivered element does not have stand-alone value or there is insufficient evidence of fair value for the undelivered element(s), the Company recognizes the consideration for the combined unit of accounting in the same manner as the revenue is recognized for the final deliverable, which is generally ratably over the longest period of involvement.

Product revenues. The Company recognizes revenue from product sales when there is persuasive evidence that an arrangement exists, title passes, the price is fixed or determinable and collectibility is reasonably assured. The Company records provisions for discounts to customers and rebates to government agencies and international distributors, which are based on contractual terms and regulatory requirements. To date, these provisions have been de minimis. The Company s product returns policy only allows for the return of product damaged in transit, product shipped in error by the Company, or discontinued, withdrawn or recalled merchandise. To date, product returns have been de minimis and based on the Company s historical experience as well as the specialized nature of our product, the Company historically has not provided a reserve for

product returns. The Company will continue to monitor returns in the future and will reassess the need to estimate a product returns reserve if the returns experience increases.

License revenues. License revenue generally includes upfront and continuing licensing fees and milestone payments. Nonrefundable upfront fees that require the Company s continuing involvement in the manufacturing or other commercialization efforts by the Company are recognized as revenue ratably over the contractual term. Fees associated with substantive milestones, which are contingent upon future events for which there is reasonable uncertainty as to their achievement at the time the agreement was entered into, are recognized as revenue when these milestones, as defined in the contract, are achieved.

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Inventories

Inventories are stated at the lower of cost or market. Cost is determined using the first-in, first-out basis. The valuation of inventory requires the Company to estimate obsolete or excess inventory based on analysis of future demand for our products. Due to the nature of the Company s business and our target market, levels of inventory in the distribution channel, changes in demand due to price changes from competitors and introduction of new products are not significant factors when estimating the Company s excess or obsolete inventory. If inventory costs exceed expected market value due to obsolescence or lack of demand, inventory write-downs may be recorded as deemed necessary by management for the difference between the cost and the market value in the period that impairment is first recognized.

In general, the process for evaluating whether there exists excess or obsolete inventory is not a complex process and does not require significant management judgment. The primarily factors considered in evaluating whether there exists excess or obsolete inventory are:

- the Company s forecast of future demand, which is updated on a quarterly basis; and
- the expiration date for each lot manufactured.

In May of 2007, the Company began to transfer its manufacturing process to new facilities and as such, there will be period of time where the Company will need to cease production of Increlex® until the new manufacturing facilities are fully validated, approved by the FDA, and operational. The Company is increasing its inventory levels to ensure that the Company has adequate supplies to meet future demand and therefore our long-term sales forecast will become more critical in management s evaluation of excess inventories over the next few quarters. Once the transfer of manufacturing facilities is complete, the Company will have more flexibility in the manufacturing schedule to ensure inventory supply is in line with a shorter forward demand forecast for Increlex®.

See Manufacturing Services Agreement in Note 9 Commitments and Contingencies, for further discussion regarding inventory purchase commitments.

Intangible Assets

The Company capitalizes fees paid to the Company s collaboration partners related to license agreements for approved products or technology that has alternative future uses, as intangible assets in accordance with Statement of Financial Accounting Standards No. 142, *Goodwill and Other Intangible Assets* (SFAS 142), when the Company has obtained rights to develop and commercialize licensed products. The Company amortizes these intangible assets with definite lives on a straight-line basis over their estimated useful lives, and reviews for impairment when events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable.

Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset and its eventual disposition. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the assets, the assets are written down to their estimated fair values.

Valuation of Derivative Instruments

The Company issued a convertible note in September 2007 and valued certain features embedded therein as derivative liabilities under SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*. The Company estimates the fair value of its derivative liabilities each quarter using the Black-Scholes-Merton valuation model. This model is complex and requires significant judgments in the estimation of fair values based on certain assumptions. Factors affecting the amount of these liabilities include changes in the Company s stock price and other assumptions. Changes in value are recorded as non-cash valuation adjustments within other expense in the Company s condensed statement of operations. These changes in the carrying value of derivatives can have a material impact on the Company s financial statements. The derivative liabilities may be reclassified into stockholders equity upon conversion, payment or expiration of the convertible notes, the timing of which is outside the Company s control.

The embedded derivative liability does not qualify for hedge accounting under SFAS 133 and therefore, subsequent changes in fair value are recorded as non-cash valuation adjustments within other expense in the condensed statement of operations.

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 policy is to recognize interest and/or penalties related to income tax matters in income tax expense. To date there have been no such interest or penalties charged to the Company. The Company had no unrecognized tax benefits as of September 30, 2007 and expects no significant changes in unrecognized tax benefits in the next 12 months.

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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 potential impact of adopting SFAS No. 157 on its financial position and results of operations.

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. The Company does not expect that the adoption of 07-3 will have a material impact on its financial position or results of operations.

2. Balance Sheet Information

	September 30, 2007	December 31, 2006
	(in thousands)	
Accounts receivable, net:		
Receivables	$ 1,329	$ 343
Less: allowance for discounts	(27)	(8)
	$ 1,302	$ 335
Inventories		
Raw materials	$ 2,968	$ 1,477
Work-in-process	7,553	3,280
Finished goods	1,174	335
	$ 11,695	$ 5,092
Property and equipment, net:		
Office equipment	$ 359	$ 316
Furniture and fixtures	635	635
Computer equipment and software	2,843	2,291
Manufacturing equipment	1,305	1,240
Leasehold improvements	1,336	1,302
Construction in progress		216
	6,478	6,000
Less: accumulated depreciation and amortization	(3,318)	(2,139)
	$ 3,160	$ 3,861
Accrued expenses:		
Accrued compensation and related liabilities	$ 3,801	$ 2,938
Accrued professional fees	1,563	1,691
Accrued contract manufacturing expenses	1,008	629
Clinical trial costs	322	335
Other accrued liabilities	1,352	621
	$ 8,046	$ 6,214

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3. Intangible Assets

	Gross Carrying Amount	September 30, 2007 Accumulated Amortization	Net Carrying Amount
Milestone payment	$ 42,140	$	$ 42,140
Total	$ 42,140	$	$ 42,140

The Company made milestone payments of $42.1 million to Ipsen and Genentech in connection with approval of our licensed products which were recorded as intangible assets. The intangible assets will be amortized over 15 years based on the estimated useful life of the assets, and the Company will begin amortization upon first commercial sale of the licensed products which is expected in November 2007. Amortization expense will be recognized on a straight-line basis at approximately $2.8 million per year and will be recorded to cost of goods sold.

The Company will review this intangible asset for impairment when events or changes in circumstance indicate that the carrying amount of such assets may not be recoverable.

The expected future annual amortization expense of our intangible assets is as follows (in thousands):

Year ending December 31,	
2007	$ 468
2008	2,809
2009	2,809
2010	2,809
2011	2,809
Thereafter	30,436
Total expected future annual amortization	$ 42,140

4. Comprehensive Income (Loss)

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Net income (loss), as reported	$ 3,422	$ (13,063)	$ (21,779)	$ (42,016)
Change in unrealized income (losses) on marketable securities	3	15	(6)	2
Comprehensive income (loss)	$ 3,425	$ (13,048)	$ (21,785)	$ (42,014)

5. Long-Term Debt

In October 2006, the Company issued to Ipsen, S.A. (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 3,461,013 shares at September 30, 2007.

In September 2007, the Company issued to Ipsen two convertible notes in the principal amounts of 30,000,000, or $41,640,000 at September 17, 2007 (the Second Convertible Note), and $15,000,000 (the Third Convertible Note). The Second and Third Convertible Notes each accrue interest at a rate of 2.5% per year, compounded quarterly, and are convertible into the Company s common stock at an initial conversion price of 5.92 per share for the Second Convertible Note and $7.41 per share for the Third Convertible Note, subject to adjustment, which represents 5,072,080 and 2,026,094 shares, respectively, at September 30, 2007.

The conversion price of all the Convertible Notes is subject to certain weighted-average price-based antidilution adjustments, which, if triggered, would result in an increase of the number of shares of common stock issuable upon conversion of the Convertible Notes. The entire principal balance and accrued interest under all the Convertible Notes is due and payable on the later to occur of October 13, 2011 or the second anniversary of the date on which Ipsen (or subsequent holders of the Convertible Notes) notifies the Company that it will not convert the Convertible Notes in full. Notwithstanding the foregoing, Ipsen (or subsequent holders of the

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Convertible Notes) is entitled to declare all amounts outstanding under the Convertible Notes immediately due and payable: (i) if an event of default occurs (as set forth in the Convertible Notes); (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 Ipsen s approval rights as set forth in the affiliation agreement cease to remain effective, if any other person or group acquires beneficial ownership of greater than 50% of the Company s common stock.

Because the Second Convertible Note has a conversion price stated in a foreign currency, the conversion feature constitutes a derivative liability. The Company initially valued the derivative liability associated with the Second Convertible Note at 9.2 million (or approximately $13.1 million at September 30, 2007). This amount was accounted for as a reduction in the initial carrying value of the Second Convertible Note and an increase to current liabilities. This discount to the Second Convertible Note, as a result of this bifurcation, is being accreted over four years using the effective interest method. The carrying value which approximates the fair value on the date of issuance of the Second Convertible Note is 20.9 million (or approximately $29.8 million at September 30, 2007) which is net of the discount plus accretion and accrued interest.

As of September 30, 2007, the Company accrued $609,000 of cumulative interest expense on the First Convertible Note, of which $161,000 and $474,000 were recorded as interest expense in the three and nine months ended September 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, including cumulative interest of $3,325,000.

As of September 30, 2007, the Company recorded valuation adjustment expense of $133,000 representing an increase in value of the derivative liability associated with the Second Convertible Note. The Company accrued $37,000 of cumulative interest expense in the three and nine months ended September 30, 2007, and $89,000 of non-cash accretion charges for the three and nine months ended September 30, 2007. If not earlier converted or repaid, the amount payable under the Second Convertible Note on October 13, 2011 would be 33,206,000, including cumulative interest of 3,206,000.

As of September 30, 2007, the Company accrued $13,000 of cumulative interest expense on the Third Convertible Note, of which $13,000 was recorded as interest expense in the three and nine months ended September 30, 2007. If not earlier converted or repaid, the amount payable under the Third Convertible Note on October 13, 2011 would be $16,603,000, including cumulative interest of $1,603,000.

Valuation of Second Convertible Note and Related Derivative

The derivative related to the Second Convertible Note has been valued using the Black-Scholes-Merton valuation model. The Company completed the valuation of the conversion option in connection with issuance of the Second Convertible Note. The valuations are based on the information pertinent as of the respective valuation dates.

The inputs for valuation analysis include the market value of the Company s common stock, exercise price of the conversion option, volatility of the Company s common stock, the expected life and the risk-free interest rate.

The key inputs for the valuation analysis were as follows:

	September 17, 2007	September 30, 2007
Market value of Company s common stock	$ 6.04	$ 6.20
Volatility	59.7%	59.4%
Risk free interest rate	4.35%	4.3%
Exercise price of the conversion option	5.92	5.92
Expected life	4.1 years	4.0 years

6. 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), which Baseline Amount is subject to certain weighted-average price-based anti-dilution adjustments, 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

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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 September 30, 2007 was 4,948,795. 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 anti-dilution 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 to 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. Through September 30, 2007, the Company has not drawn down any funds under the CEFF and has not issued any shares pursuant to the CEFF as of September 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.

7. 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 $1,491,000 and $1,552,000 was recorded during the three months ended September 30, 2007 and 2006, respectively, and $4,627,000 and $4,316,000 was recorded during the nine months ended September 30, 2007 and 2006, respectively.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Expected volatility	61.0%	72.0%	63.0%	76.0%
Expected term (years)	6.3	6.3	6.2	6.2
Risk-free interest rate	4.6%	5.0%	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 September 30, 2007, unrecognized stock-based compensation expense related to stock options of $12,793,000 was expected to be recognized over a weighted-average period of 2.46 years.

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8. Net Income (Loss) Per Share

Basic net income (loss) per share is calculated by dividing the net income (loss) by the weighted-average number of common shares outstanding during the period, without consideration for common stock equivalents. Diluted net income per share is computed by dividing the net income by the weighted-average number of common shares outstanding as well as common share equivalents outstanding for the period determined using the treasury-stock method for stock options and warrants and the if-converted method for convertible notes. For purposes of this calculation, common stock subject to repurchase by the Company, options, and warrants and convertible notes are considered to be common stock equivalents and are only included in the calculation of diluted net income per share when their effect is dilutive.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
	(In thousands, except per share data)			
Numerator:				
Net income (loss)	$ 3,422	$ (13,063)	$ (21,779)	$ (42,016)
Denominator:				
Weighted-average common shares outstanding used to compute basic income (loss) per share	51,041	37,550	50,458	36,906
Plus: Options to purchase common stock	304			
Weighted average shares outstanding and dilutive securities used to compute diluted net income (loss) per share	51,345	37,550	50,458	36,906
Diluted net income (loss) per share	$ 0.07	$ (0.35)	$ (0.43)	$ (1.14)

	September 30,	
	2007	2006
	(In thousands)	
Outstanding dilutive securities not included in diluted net loss per share		
Options to purchase common stock	5,209	3,982
Convertible notes	10,559	
Warrants	5,209	260
	20,977	4,242

9. 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, which was subsequently amended, 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 6,100 square feet, and for a period coterminous with the original lease, as amended.

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

Year ending December 31,	
2007	$ 245
2008	999
2009	1,026
2010	1,065
2011	809
Thereafter	
	$ 4,144

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Rent expense was $162,500 and $369,000 for the three and nine months ended September 30, 2007, respectively. Rent expense for the three and nine months ended September 30, 2006 was $97,300 and $291,800, respectively. Rent expense includes the impact of the allowance for leasehold improvements of $43,000 and $129,000 for the three and nine months ended September 30, 2007, respectively, and $43,000 and $129,000 for the three and nine months ended September 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 Cambrex Baltimore 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 aquired by Lonza Group AG (Lonza).

In May 2007, the Company amended the Manufacturing Agreement with Lonza Baltimore, Inc., a subsidiary of Lonza (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. At September 30, 2007, the Company estimates that its total purchase commitment to Lonza Baltimore was approximately $16.6 million through July 31, 2008.

In May 2007, the Company entered into a development and commercial supply agreement with Lonza Hopkinton, Inc., a subsidiary of Lonza, (Lonza Hopkinton). The Company has begun to transfer its manufacturing technology to Lonza Hopkinton in order for Lonza Hopkinton to establish the process for rhIGF-1 fermentation and purification at the Lonza Hopkinton facilities. Pursuant to the development and commercial supply agreement with Lonza Hopkinton, 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 that the Company does not fulfill its commitment to purchase a certain number of commercial drug substance batches. Further, the Company has an obligation to pay Lonza Hopkinton approximately $2.0 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® on a time and materials basis and per batch basis.

In November 2006, the Company entered into a development and supply agreement with Hospira Worldwide, Inc. (Hospira), a third-party fill and finish agent. At that time, the Company began to transfer its manufacturing technology to Hospira in order for Hospira to establish the process for Increlex® fill and finish. Following approval by the FDA of the fill and finish process, Hospira is obligated to annually provide the Company with certain minimum quantities of Increlex®. 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® . At September 30, 2007, the Company estimates that its total purchase commitment to Hospira to validate the fill and finish processes, which must then be approved by the FDA was approximately $562,000 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 September 30, 2007.

10. Litigation

On December 20, 2004, the Company initiated patent infringement proceedings against Avecia Limited and Insmed Incorporated as co-defendants in the High Court of Justice (Chancery Division Patents Court) in the United Kingdom. On December 23, 2004, the Company, with Genentech, initiated patent infringement proceedings against Insmed in the U.S. District Court for the Northern District of California. On

June 12, 2006, the Company 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

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for the Eastern District of Virginia. On March 6, 2007, the Company publicly announced agreements that settled all the ongoing litigation among the companies. The Company also disclosed the settlement in its Form 10-K filed with the SEC on March 9, 2007 and disclosed details of the settlement in its 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 matters that may have a material adverse affect on the financial position, results of operations or cash flows of the Company.

11. 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 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 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

In conjunction with the Combination Product Agreement, and 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

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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.

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

Ipsen Purchase Agreement

In conjunction with the Combination Product Agreement, effective 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).

12. License and Collaboration Agreements and Related Party Transactions

Ipsen Collaboration

In August 2007, Ipsen received notice of approval from the FDA for marketing Somatuline® Depot in the United States. In connection with the notice of marketing approval from the FDA, under conditions set forth in the Company s Somatuline license and collaboration agreement with Ipsen, the Company made a milestone payment of 30.0 million (or approximately $41.6 million at September 30, 2007) to Ipsen, which was financed through the issuance by the Company of the Second Convertible Note to Ipsen at the second closing (convertible into Tercica common stock at a conversion price of 5.92) under the stock purchase and master transaction agreement with Ipsen. At the second closing, the Company also issued the Third Convertible Note to Ipsen and Ipsen delivered $15.0 million to the Company, which will be used by the Company for working capital. Somatuline® Depot is expected to be commercially available in the Company s territory in November 2007, for which the Company will pay royalties to Ipsen, on a sliding scale from 15% to 25% of net sales, in addition to a supply price of 20% of the average net sales price of Somatuline® Depot.

The milestone payment of $41.6 million was recorded as an intangible asset and capitalized under intangible assets as presented on the condensed balance sheet at September 30, 2007. The intangible asset will be amortized over 15 years, based on the estimated useful life of the asset, and the Company will begin amortization upon first commercial sale in the United States expected in November 2007. Amortization expense will be recognized on a straight-line basis at approximately $2.8 million per year and will be recorded to cost of goods sold.

In August 2007, the European Commission granted marketing authorization for Increlex® in the European Union for the long-term treatment of growth failure in children and adolescents with severe Primary IGFD. The European Medicines Agency designated Increlex® as an orphan drug for the treatment of severe Primary IGFD, providing a ten year period of marketing exclusivity for the approved indication. Under the license and collaboration agreement with respect to Increlex®, Ipsen paid the Company a milestone of approximately $20.3 million for receiving marketing authorization of Increlex® in the European Union for the targeted product label set forth in the Increlex® license and collaboration agreement. Ipsen is the Company s marketing partner for Increlex® in the European Union. When Increlex® is launched in Ipsen s territory, Ipsen will pay royalties to the Company on a sliding scale from 15% to 25% of net sales, in addition to a supply price of 20% of the average net sales price of Increlex®. The milestone payment of $20.3 million was recognized as license revenue in September 2007 since all obligations were satisfied as presented in the condensed statements of operations as of September 30, 2007.

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Related Party Transactions

We enter into transactions with Ipsen and other Ipsen affiliates under existing agreements in the ordinary course of business. The accounting policies we apply to our transactions with our related parties are no more favorable to the Company than with independent third-parties.

Genentech Collaboration

In connection with the grant of marketing authorization for Increlex® in the European Union, the Company paid Genentech a milestone payment of $0.5 million in September 2007 under the terms of the Company s international license and collaboration agreement with Genentech. The milestone payment was recorded as an intangible asset and capitalized under intangible assets as presented on the condensed balance sheet at September 30, 2007. The intangible asset will be amortized over 15 years, based on the estimated useful life of the asset, and the Company will begin amortization upon the first commercial sale which is expected in November 2007. Amortization expense will be recognized on a straight-line basis at approximately $33,000 per year and will be recorded to cost of goods sold.

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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 September 30, 2007, and the related condensed statements of operations for the three and nine month periods ended September 30, 2007 and 2006, and the condensed statements of cash flows for the nine month periods ended September 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

October 31, 2007

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ITEM 2. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

This report includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities and Exchange Act of 1934, as amended. All statements other than statements of historical facts are forward-looking statements for purposes of these provisions, including any projections of earnings, revenues or other financial items, any statement of the plans and objectives of management for future operations, any statements concerning proposed new products or licensing or collaborative arrangements, any statements regarding product development, commercialization and/or regulatory approvals, 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 t 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®, which is approved for marketing in both the United States and the European Union;
- Somatuline® Depot, which is approved for marketing in both the United States and Canada; and
- Two product candidates containing different combinations of recombinant human growth hormone, or rhGH, and recombinant human insulin-like growth factor-1, or rhIGF-1 (i.e., Increlex®), for which we expect to initiate clinical trials in 2008.

Increlex®. We market Increlex® 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. The FDA has granted Increlex® orphan drug exclusivity in the United States providing seven years of marketing exclusivity for the approved indication. We are currently conducting a Phase IIIb clinical trial for the use of Increlex® for the treatment of short stature in children with Primary IGFD, a less severe and more prevalent form of IGFD. In January 2006, we launched Increlex® in the United States. Increlex® generated net revenues of $6.0 million in the nine months ended September 30, 2007. Patient enrollment for these trials were completed in July 2007.

In August 2007, the European Commission granted marketing authorization for Increlex® in the European Union for the long-term treatment of growth failure in children and adolescents with severe Primary IGFD. The European Medicines Agency, or EMEA, granted Increlex® orphan drug exclusivity for the treatment of severe Primary IGFD, providing a ten year period of marketing exclusivity for the approved indication. 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® 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® Depot. 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® Depot in the United States and in Canada where it is known as Somatuline® Autogel®, for all indications other than opthalmic indications. On August 30, 2007, Ipsen received notice of approval from the FDA for marketing Somatuline® Depot in the United States for the long-term treatment of acromegaly in patients who have had an inadequate response to surgery and/or radiotherapy, or for whom surgery and/or radiotherapy is not an option. Acromegaly is a hormonal disorder that results when a tumor in the pituitary gland produces excess growth hormone, resulting in overproduction of IGF-1. The FDA has also granted Somatuline® Depot orphan drug exclusivity for the treatment of acromegaly, providing a seven-year period of marketing exclusivity. In July 2006, Somatuline® Autogel® was approved for marketing by Health Canada for the same indication and is currently in the reimbursement approval process. In the third quarter, Somatuline® Autogel® received a recommendation for formulary listing from the Canadian Expert Drug Advisory Committee or CEDAC, through the Common Drug Review process. CEDAC recommended that Somatuline® Autogel® be listed with restrictions in a similar manner that drug plans currently list long-acting octreotide acetate (Sandostatin LAR) for the treatment of acromegaly. We received provincial reimbursement approval in the province of Quebec early in the fourth quarter of 2007 and we also expect approvals for additional major provinces in the fourth quarter of 2007.

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Somatuline® Depot is an injectable sustained-release formulation containing lanreotide, a somatostatin analogue. The Somatuline® Depot formulation contains 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 given as a deep intramuscular injection. Like Sandostatin LAR® Depot, Somatuline® Depot is used primarily when circulating levels of growth hormone remain high despite surgery or radiotherapy in patients with acromegaly. Through its inhibitory effects, Somatuline® Depot 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 recombinant human growth hormone (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 September 30, 2007, we had approximately $127.7 million in cash, cash equivalents and short-term investments. We have funded our operations since inception primarily through the private placement of equity securities and public offerings of our common stock, as well as through our collaboration with Ipsen. We have generated only limited revenues from product sales to date and we expect to incur substantial net losses for the foreseeable future as we attempt to develop, market and sell Increlex® and Somatuline® Depot, and as we attempt to develop growth hormone/IGF-1 combination products under our combination product collaboration with Genentech.

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. During 2007, we adopted a new policy related to the accounting for income taxes. Other than these changes, there have been no significant changes in our significant accounting policies during the nine months ended September 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.

Revenue Recognition

We recognize revenue from the sale of our products and license and collaboration agreements pursuant to Staff Accounting Bulletin No. 104, *Revenue Recognition*, and Emerging Issues Task Force (EITF) Issue 00-21 *Revenue Arrangements with Multiple Deliverables*. Multiple element agreements entered into are evaluated under the provision of EITF 00-21. We evaluate whether there is stand-alone value for the delivered elements and objective and reliable evidence of fair value to allocate revenue to each element in multiple element agreements. When the delivered element does not have stand-alone value or there is insufficient evidence of fair value for the undelivered element(s), we recognize the consideration for the combined unit of accounting in the same manner as the revenue is recognized for the final deliverable, which is generally ratably over the longest period of involvement.

We recognize revenue from product sales when there is persuasive evidence that an arrangement exists, title passes, the price is fixed or determinable and collectibility is reasonably assured. We record provisions for discounts to customers and rebates to government agencies and international distributors, which are based on contractual terms and regulatory requirements. To date, these provisions have been de minimis. Our product returns policy only allows for the return of product damaged in transit, product shipped in error by us, or discontinued, withdrawn or recalled merchandise. To date, product returns have been de minimis and based on our historical experience as well as the specialized nature of our product, we historically have not provided a reserve for product returns. We will continue to monitor returns in the future and will reassess the need to estimate a product returns reserve if returns policy changes or the returns experience increases.

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License revenue generally includes upfront and continuing licensing fees and milestone payments. Nonrefundable upfront fees that require our continuing involvement in the manufacturing or other commercialization efforts by us are recognized as revenue ratably over the contractual term. Fees associated with substantive milestones, which are contingent upon future events for which there is reasonable uncertainty as to their achievement at the time the agreement was entered into, are recognized as revenue when these milestones, as defined in the contract, are achieved.

Inventories

Inventories are stated at the lower of cost or market. Cost is determined using the first-in, first-out basis. The valuation of inventory requires the Company to estimate obsolete or excess inventory based on analysis of future demand for our products. Due to the nature of our business and our target market, levels of inventory in the distribution channel, changes in demand due to price changes from competitors and introduction of new products are not significant factors when estimating our excess or obsolete inventory. If inventory costs exceed expected market value due to obsolescence or lack of demand, inventory write-downs may be recorded as deemed necessary by management for the difference between the cost and the market value in the period that impairment is first recognized.

These inventory write-downs are determined based on estimates by management based on the following factors:

- our forecast of future demand, which is updated on a quarterly basis; and
- the expiration date for each lot manufactured.

In May of 2007, we began to transfer our manufacturing process to new facilities and as such, there will be a period of time where we will need to cease production of Increlex® until the new manufacturing facilities are fully validated, approved by the FDA, and operational. We are increasing inventory levels to ensure that we have adequate supplies to meet future demand and therefore our long-term sales forecast will become more critical in our evaluation of excess inventories over the next few quarters. Once our transfer of manufacturing facilities is complete, we will have more flexibility in our manufacturing schedule to ensure inventory supply is in line with a shorter forward demand forecast for Increlex®.

See Manufacturing Services Agreement in Note 9 Commitments and Contingencies, for further discussion regarding inventory purchase commitments.

Intangible Assets

We capitalize fees paid to the Company s collaboration partners related to license agreements for approved products or technology that has alternative future uses, as intangible assets in accordance with Statement of Financial Accounting Standards No. 142, *Goodwill and Other Intangible Assets* (SFAS 142), when we have obtained rights to develop and commercialize licensed products. We amortize these intangible assets with definite lives on a straight-line basis over their estimated useful lives, and review for impairment when events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable.

Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset and its eventual disposition. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the assets, the assets are written down to their estimated fair values.

Valuation of Derivative Instruments

We issued a convertible note in September 2007 and valued certain features embedded therein as derivative liabilities under SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*. We estimate the fair value of its derivative liabilities each quarter using the Black-Scholes-Merton valuation model. This model is complex and requires significant judgments in the estimation of fair values based on certain assumptions. Factors affecting the amount of these liabilities include changes in our stock price and other assumptions. Changes in value are recorded as non-cash valuation adjustments within other expense in our condensed statement of operations. These changes in the carrying value of derivatives can have a material impact on our financial statements. The derivative liabilities may be reclassified into stockholders equity upon conversion, payment or expiration of the convertible notes, the timing of which is outside of our control.

The embedded derivative liability does not qualify for hedge accounting under SFAS 133 and therefore, subsequent changes in fair value are recorded as non-cash valuation adjustments within other expense in the condensed statement of operations. A change in the market value of our common stock could have a significant impact on the results of our operations; however, there would not be any impact on our cash flows (see Item 3 Qualitative and Quantitative Disclosures about Market Risk). The fair value adjustment recorded for the embedded derivative for the three and nine months ended September 30, 2007 was $133,000.

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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 policy is to recognize interest and/or penalties related to income tax matters in income tax expense. To date there have been no such interest or penalties charged to us. We had no unrecognized tax benefits as of September 30, 2007 and expect no significant changes in unrecognized tax benefits for the next 12 months.

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Results of Operations

Comparison of Three Months and Nine Months Ended September 30, 2006 and 2007

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2007	2006	2007
	(in thousands)			
Net product sales	$ 316	$ 2,851	$ 567	$ 5,990
Period over period increase		2,535		5,423
Percentage increase		N/A(1)		N/A(1)
License revenue		20,537		20,925
Period over period increase		20,537		20,925
Percentage increase		N/A(1)		N/A(1)
Cost of sales	516	2,096	1,156	4,248
Period over period increase		1,580		3,092
Percentage increase		N/A(1)		N/A(1)
Research and development expenses	3,513	5,588	12,739	14,601
Period over period increase		2,075		1,862
Percentage increase		59.1%		14.6%
Selling, general and administrative expenses	10,162	11,409	31,252	31,562
Period over period increase		1,247		310
Percentage increase		12.3%		0.1%
Interest expense		334		712
Period over period increase		334		712
Percentage increase		N/A(1)		N/A(1)
Interest and other income, net	812	1,429	2,564	4,397
Period over period increase		617		1,833
Percentage increase		76.0%		71.5%
Other expense		951		951
Period over period increase		951		951
Percentage increase		N/A(1)		N/A(1)
Provision for income taxes		1,017		1,017
Period over period increase		1,017		1,017
Percentage increase		N/A(1)		N/A(1)

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

Net Revenues

Net revenues consisted of net product sales, a milestone payment from Ipsen and amortized license revenue associated with our Increlex® License and Collaboration Agreement with Ipsen. Net revenues for the three and nine month periods ended September 30, 2007 were comprised of net product sales of $2.9 million and $6.0 million, respectively and license revenues of $20.5 million and $20.9 million, respectively. Net revenues for the three and nine month periods ended September 30, 2006 were comprised of net product sales of $0.3 million and $0.6 million, respectively. There were no license revenues recorded during the three and nine months ended September 30, 2006.

Net product sales consisted of gross Increlex® sales less provisions for discounts to customers, rebates to government agencies, product returns and other adjustments. The increase in net product sales in the three and nine months ended September 30, 2007 compared to the same periods ended September 30, 2006 was primarily due to growth in Increlex® product sales in the United States. The Increlex® product sales increase was driven by a continued increase in adoption of Increlex®. In March 2007, we announced agreements that settled all prior litigation against Insmed.

One of the key terms in the settlement agreement stipulated that Insmed will no longer provide IPLEX to patients with severe Primary IGFD and other short stature indications. Following the settlement agreement with Insmed, a number of patients receiving IPLEX , a product marketed by Insmed, switched to treatment with Increlex®, which resulted in a higher than normal increase to our net product revenues in the quarter ended June 2007. We expect

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Increlex® revenues to increase over the next several quarters; however, we do not expect net Increlex® product sales to increase at the same rate on a quarter-to-quarter basis as we experienced over the last two quarters. As Increlex® is generally ordered by our distributors against specific prescriptions, we believe that our distributors carry minimal levels of inventory.

We will begin generating product revenues from the launch of Somatuline® Depot in the United States in the fourth quarter 2007.

In the three and nine months ended September 30, 2007, we also recorded License revenues of $20.5 million and $20.9 million, respectively. In September 2007, per our Increlex License and Collaboration Agreement with Ipsen, we received a milestone payment from Ipsen of $20.3 million (or $19.3 million net of withholding taxes) upon the grant of marketing authorization for Increlex® in the European Union for the targeted product label. Additionally, 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.

Cost of Sales

Our cost of sales represented the cost of production, royalties owed to our licensors, distribution shipping and handling costs, 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® in August 2005, drug supply production costs were charged to research and development. Beginning in the fourth quarter of 2005, with the marketing approval of Increlex® by the FDA, we began capitalizing these production costs to inventory and began to charge cost of sales in the first quarter of 2006 as units of Increlex® 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 nine months ended September 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 of manufacturing operations to alternate manufacturing sites that totaled $0.7 million and $1.2 million for the three and nine months ended September 30, 2007, respectively. 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 $3.9 million, which we expect to incur over the next six 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. The costs associated with conducting clinical trials and post-marketing expenses, which include Phase IV and investigator-sponsored trials and product registries, are also included in research and development expenses. 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, or 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.

The $5.6 million in research and development expense for the three months ended September 30, 2007 was comprised primarily of personnel and related costs of $2.5 million, third party contract costs related to our clinical activities for Primary IGFD and severe Primary IGFD of $1.8 million, clinical drug supply of $0.7 million, and clinical activities for Somatuline® Depot activities in acromegaly of $0.2 million. The $14.6 million in research and development expense for the nine months ended September 30, 2007 was comprised primarily of personnel and related costs of $8.0 million, third party contract costs related to our clinical activities for Primary IGFD and severe Primary IGFD of $3.9 million, clinical activities for Somatuline® Depot activities in acromegaly of $0.7 million, clinical drug supply of $0.8 million and Increlex® activities in support of our MAA of $0.5 million.

During the three and nine months ended September 30, 2007, research and development expenses increased as compared to the three and nine months ended September 30, 2006 primarily due to an increase in third party contractor costs of $0.9 million and $0.6 million, respectively, clinical drug supply costs of $0.7 million and $0.8 million, respectively, as well as payroll related costs. The increase in third party contractor costs during the three and nine months ended September 30, 2007 was primarily due to an increase in clinical activities associated with Primary IGFD, severe Primary IGFD and Somatuline® Depot. The increase in payroll related costs during the three and nine months ended September 30, 2007 was primarily due to increased personnel compared to the same period in 2006. These increases in research and development costs were partially offset by a decrease in Increlex® activities associated with our European marketing authorization application, or MAA, during the nine months ended September 30, 2007.

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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 increased by $1.2 million for the three months ended September 30, 2007 compared to the three months ended September 30, 2006 primarily due to an increase in sales and marketing costs of $2.2 million associated with the launch of Somatuline® Depot, product promotions, medical education and free goods along with an increase in payroll and related costs of $1.3 million in the quarter ended September 2007 as compared to the same period in 2006, partially offset by decreased expenses associated with litigation of $2.2 million.

Selling, general and administrative expenses for the nine months ended September 30, 2007 were flat compared to the nine months ended September 30, 2006. During the nine months ended September 30, 2007, sales and marketing activities as well as payroll and related expenses increased by $3.5 million and $3.0 million, respectively. The increase in marketing and sales programs was primarily related to increased costs associated with product promotions, medical education, costs in support of Increlex® and the Somatuline® Depot launch in the U.S. and Canada, as well as costs associated with free goods. The increase in payroll and related expenses was due primarily to additional sales personnel in preparation for the launch of Somatuline® Depot, annualized effect of 2006 personnel increases, and non-cash stock compensation expense. These increases were almost exclusively offset by a decrease in litigation and consulting expenses of $6.2 million.

Interest Expense

Interest expense for the three and nine months ended September 30, 2007 represents interest on three convertible notes issued to Ipsen in connection with our License and Collaboration Agreement with Ipsen and related amortization of prepaid financing costs associated with the transaction (See Note 12 Ipsen Collaboration). There was no interest expense for the three and nine months ended September 30, 2006. We expect interest expense to increase over the same period from prior years as we continue to accrue interest on these convertible notes until the maturity date in October 2011 (See Note 5 Long-Term Debt).

Other Expense

Other expense for the three and nine months ended September 30, 2007 was due to an unfavorable foreign currency adjustment and an increase in the fair value of the embedded derivative conversion option related to the 30.0 million convertible note we issued to Ipsen in September 2007. The 30.0 million convertible note is denominated in euros and is revalued to US dollars at the end of each reporting period which resulted in a charge of $0.8 million in the three months and nine months ended September 30, 2007. Further, since the conversion option is denominated in euros, the conversion option is considered an embedded derivative and must be revalued at the end of each reporting period which resulted in a charge of $0.1 million for the three and nine months ended September 30, 2007. There were no such charges for the three and nine months ended September 30, 2006.

As currency rates, our stock price and our volatility assumptions change, we may record income or expense to Other Expense related to both the value of the note as well as the value of the embedded derivative. It is difficult to predict whether the expense will increase or decrease from quarter to quarter (see Item 3 Quantitative and Qualitative Disclosures about Market Risk).

Interest and Other Income, net

Interest and other income, net for the three and nine months ended September 30, 2007 increased compared to the three and nine months ended September 30, 2006 primarily due to interest income on higher average cash, cash equivalents and short-term investment balances in the three and nine months ended September 30, 2007. The higher cash balances in the three and nine months ended September 30, 2007, were due primarily to net cash proceeds from our License and Collaboration Agreements with Ipsen. In October 2006, we received net cash proceeds of $89.7 million from Ipsen in connection with sale of equity and Increlex® license payments. In September 2007, we received net cash proceeds of $34.3 from Ipsen in connection with an Increlex® milestone payment, net of withholding taxes, and issuance of a convertible note in the principal amount of $15.0 million. Additionally, we received gross cash proceeds of $6.9 million in July 2007 from the issuance of common stock to Genentech and Ipsen in connection with the Genentech combination product collaboration.

Liquidity and Capital Resources

Sources of Liquidity

As of September 30, 2007, we had approximately $127.7 million in cash, cash equivalents and short-term investments. We had an accumulated deficit of $270.5 million, which was primarily comprised of $227.5 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 September 30, 2007 from issuance of equity, convertible notes and receipt of milestone payments. To date we have received net cash proceeds of $208.2 million from equity issuances including equity sold to Ipsen and Genentech. To date we have issued three convertible notes to Ipsen from which we received net cash proceeds of $15.0 million, net of the balance which was used to make milestone payments to Ipsen related to the Somatuline® license and collaboration agreement. In addition, we have received $31.1 million from Ipsen, net of withholding taxes, for milestone payments related to the Increlex® license and collaboration agreement.

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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. Under the stock purchase and master transaction agreement with Ipsen we issued a second convertible note and a third convertible note to Ipsen in connection with our Somatuline® license and collaboration agreement as described below. Each of the convertible notes that we issued to Ipsen mature on the later of October 13, 2011 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 (or 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® Depot 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® Depot and Increlex®. In addition, we and Ipsen agreed to rights of first negotiation for our respective endocrine pipelines. In August 2007, the European Commission granted marketing authorization for Increlex® in the European Union for the long-term treatment of growth failure in children and adolescents with severe Primary IGFD. Under the license and collaboration agreement with respect to Increlex®, Ipsen made an upfront cash payment to us of 9.5 million (approximately $11.8 million) after tax withholding in October 2006, and paid us an additional milestone of approximately of 14.3 million (approximately $19.3 million), after tax withholding, in September 2007 for receiving marketing authorization for Increlex® in the European Union for the targeted product label. Ipsen is our marketing partner for Increlex® in the European Union. Assuming Increlex® is launched by Ipsen in Ipsen s territory, Ipsen will pay royalties to us on a sliding scale from 15% to 25% of the average net sales price, in addition to a supply price of 20% of net sales of Increlex®.

Under the license and collaboration agreement with respect to Somatuline® Depot, 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. In August 2007, we received marketing approval for Somatuline® Depot in the United States for the targeted product label (and the second closing under the stock purchase and master transaction agreement was consummated). Following receipt of the marketing approval, we made a milestone payment of 30.0 million (or approximately $41.6 million at September 17, 2007) to Ipsen, which was financed through the issuance by us of the second convertible note to Ipsen at the second closing. The milestone payment was capitalized as an intangible asset and will be amortized over the useful life of the asset. At the second closing, we also issued the third convertible note to Ipsen and Ipsen delivered $15.0 million to us, which will be used by us for working capital. Somatuline® Depot is expected to be commercially available in our territory in November 2007, for which we will pay royalties to Ipsen, on a sliding scale from 15% to 25% of net sales, in addition to a supply price of 20% of the average net sales price of Somatuline® Depot.

There can be no assurance that we will 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 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 AQ®, 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 11 Combination Product Development and Commercialization Agreement 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 11 Combination Product Development and Commercialization Agreement in the notes to our condensed financial statements, we may receive a cash milestone

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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 we issued 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 11 Combination Product Development and Commercialization Agreement in the notes to our condensed financial statements for more detail on the terms of the combination product agreement and stock purchase agreement.

Ipsen Purchase Agreement

In conjunction with the Combination Product Development and Commercialization Agreement, effective July 30, 2007, we 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 we 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 us (subject to certain exceptions).

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 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

	Nine Months ended September 30,	
	2007	2006
	(In thousands)	
Net cash provided by (used for):		
Operating activities	$ (19,672)	$ (38,331)
Investing activities	(14,785)	1,974
Financing activities	63,732	34,534

Net change in cash and cash equivalents	$ 29,275	$ (1,823)

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Cash, cash equivalents and short-term investments totaled $127.7 million at September 30, 2007, compared to $125.6 million at December 31, 2006. Cash and cash equivalents totaled $69.6 million at September 30, 2007, compared to $40.3 million at December 31, 2006. The increase in cash and cash equivalents was primarily due to proceeds from a milestone payment from Ipsen of $19.3 million, net of withholding taxes, the issuance of a convertible note for $15.0 million to Ipsen, and the issuance of $6.9 million of common stock to Ipsen and Genentech. Further, there was a convertible note issued to Ipsen for 30.0 million (or approximately $41.6 million at September 17, 2007 date of issuance) which was used to finance our milestone payment obligation to Ipsen.

The uses of cash in operations of $19.7 million during the nine months ended September 30, 2007 were primarily related to the manufacture of Increlex® inventories, sales, marketing and related support personnel and activities associated with severe Primary IGFD, clinical and regulatory activities related to severe Primary IGFD, Primary IGFD and acromegaly offset by a milestone payment from Ipsen of $19.3 million, net of taxes, for marketing authorization of Increlex® in the European Union. The decrease in cash used in operations during the nine months ended September 30, 2007 compared to the same period in 2006 of $18.7 million, was due primarily to the milestone payment received from Ipsen of $19.3 million, net of withholding taxes. We expect an increase in net cash used in operations for the remainder of 2007, primarily to support the commercial activities related to the Somatuline® Depot 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 used in investing activities totaled $14.8 million in the nine months ended September 30, 2007, compared to net cash provided by investing activities of $2.0 million in the same period in 2006. Net cash used in investing activities represented purchases, sales and maturities of investments offset by a milestone payment made to Ipsen of $41.6 million triggered by receipt of FDA approval of Somatuline® Depot in the United States, a milestone payment made to Genentech of $0.5 million and purchases of property and equipment of $0.6 million. Net proceeds from the sales and maturities of short-term investments were $27.9 million in the nine months ended September 30, 2007, compared to net proceeds of $2.9 million for the same period in 2006. The increase of $25.0 million in net proceeds from the sales and maturities of short-term investments in the nine months ended September 30, 2007, compared to the same period in 2006, was primarily due to the timing of maturities, sales and purchases of short-term investments.

Net cash provided by financing activities for the nine months ended September 30, 2007 was $63.7 million, compared to $34.5 million for the same period in 2006. Net cash provided by financing activities for the nine months ended September 30, 2007 was primarily due to issuance of two convertible notes to Ipsen of 30.0 million, or $41.6 million (used to fund the milestone payment to Ipsen) and $15.0 million, and issuance of common shares to Ipsen and Genentech of $6.9 million, as well as employee purchases of company stock of $241,000. Net cash provided by financing activities for the nine months ended September 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 nine months ended September 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 September 30, 2007 as well as internally generated funds will be sufficient to meet our projected operating and capital expenditure requirements through at least the third quarter 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;
- our ability to market and sell sufficient quantities of Increlex® and Somatuline® Depot at the anticipated level;
- the commercial status of the Increlex® bulk drug manufacturing operations at Lonza Baltimore, Inc. and Lonza Hopkinton Inc., including the success of our cGMP production activities;
- the success of Increlex® final drug product manufacturing;
- the costs, timing and scope of additional regulatory approvals for Increlex®;

Ipsen s ability to supply Somatuline® Depot to us in sufficient quantities;

the costs, timing and scope of additional regulatory approvals for Somatuline® Depot;

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 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 and legal expenses.

Due to the significant risks and uncertainties inherent in the manufacturing, clinical development and regulatory approval processes, the costs to complete our projects through product commercialization are not accurately predictable. Results from

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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, 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 nine months ended September 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:

- an extension to our manufacturing agreement with Lonza Baltimore;
- the entry into a manufacturing agreement with Lonza Hopkinton; and
- 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 $16.6 million through July 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 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 $2.0 million during 2008 for the production of bulk rhIGF-1 conformance lots, exclusive of required materials. As we reach certain future milestones, we may be committed to commercial production of Increlex® on a time and materials basis and per batch basis.

We presently lease approximately 34,400 square feet of office space in Brisbane, California. In July 2007, we entered into an amendment to our lease agreement that provides for the expansion of the leased premises by approximately 6,100 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 9 Commitments and Contingencies in the notes to our condensed financial statements for further discussion regarding our future operating lease commitments.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

During the nine months ended September 30, 2007, the material changes to our market risk disclosures as set forth in Part II, Item 7A, *Quantitative and Qualitative Disclosures About Market Risk* 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 was the issuance of a convertible note to Ipsen S.A.

The Second Convertible Note issued to Ipsen S.A. is denominated in euros and recorded at 20.8 million (or approximately $29.9 million), net of discount, at September 30, 2007. The face value of the note is 30.0 million and the discount of 9.2 million will be accreted over the life of the note. The convertible note accrues interest at a rate of 2.5% per year, compounded quarterly until

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maturity in October 2011. As currency rates change, the net recorded value of the note (which will also be increasing in value due to the accretion of the discount and accrued interest) will be revalued, and the corresponding translation adjustment will be recorded in the condensed statements of operations. A hypothetical change of 10% in currency rates could result in an adjustment to the consolidated statements of operations of approximately $3.0 million. Upon maturity of the Second Convertible Note in October 2011 if the holder of the note chooses to not convert, the Company would be required to repay the Second Convertible Note of 33.2 million which includes accrued interest. A hypothetical change of 10% in currency rates could result in the Company paying $4.6 million more or less in cash than anticipated upon issuance of the note.

Associated with the Second Convertible Note issued to Ipsen S.A., we recorded a derivative liability due to a conversion option denominated in a foreign currency. The terms of the convertible note include a conversion option not under our control. This conversion option is considered to be an embedded derivative liability and we determined the fair value of this derivative to be 9.2 million (or approximately $12.8 million) on the date of issuance, September 17, 2007. Due to the quarterly revaluation of the embedded derivative liability and due to foreign currency revaluation, we recorded in our condensed statements of operations other expense of $0.1 million for the three and nine months ended September 30, 2007. At September 30, 2007, the embedded derivative liability was valued at 9.1 million (or approximately $12.9 million). We determine the fair value of the derivative liability using the Black-Scholes-Merton valuation model. The valuations are based on the information available as of the various valuation dates. Factors affecting the amount of this liability include the market value of the value of the Company s common stock, exercise price of option, volatility of the Company s common stock, the expected life and the risk-free interest rate. A change in the market value of our common stock could have a significant impact on the results of our operations; however, there would not be any impact on our cash flows. A hypothetical change of 10% in currency rates could result in an adjustment to the consolidated statements of operations of approximately $1.3 million.

ITEM 4. CONTROLS AND PROCEDURES.

Evaluation of Disclosure Controls and Procedures

Based on their evaluation as of September 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 three months ended September 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 1A. RISK FACTORS.

We have identified the following additional risks and uncertainties that may have a material adverse effect on our business, financial condition or results of operations. Investors should carefully consider the risks described below before making an investment decision. The risks described below are not the only ones we face. Additional risks not presently known to us or that we currently believe are immaterial may also

significantly impair our business operations. Our business could be harmed by any of these risks. The trading price of our common stock could decline due to any of these risks, and investors may lose all or part of their investment.

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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.

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 have a limited operating history. Through September 30, 2007, we had an accumulated deficit of $270.5 million. We incurred a net loss of $21.8 million during the nine months ended September 30, 2007. We may not be able to generate significant revenues from operations and may not be able to attain profitability. Although we had net revenues of $23.4 million during the nine months ended September 30, 2007, of which $20.3 million resulted from a milestone payment we received from Ipsen, we expect to incur substantial net losses, in the aggregate and on a per share basis, for the foreseeable future as we attempt to develop, market and sell Increlex® for severe Primary IGFD and Primary IGFD and Somatuline® Depot for acromegaly, and as we attempt to 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® for the treatment of severe Primary IGFD and Primary IGFD, as well as on the successful commercialization by us of Somatuline® Depot 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® or Somatuline® Depot, 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. *

We estimate that the number of children in the United States with short stature is approximately 1,000,000, 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.

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

Prior to our January 2006 commercial launch of Increlex® in the United States for the treatment of severe Primary IGFD, rhIGF-1 had never been commercialized in the United States or Europe for any indication. Even though the FDA has approved Increlex® for sale in the United States, and Somatuline® Depot has received marketing approval in Canada and the United States, physicians may choose not to prescribe these products, and third-party payers may choose not to pay for them. Accordingly, 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 safe and effective treatments;
- reimbursement adoption;

product price;

the effectiveness of our and collaboration partners sales and marketing efforts;

storage requirements and ease of administration;

dosing regimen;

safety and efficacy;

prevalence and severity of side effects; and

competitive products.

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If we do not receive additional regulatory marketing approvals for Increlex® in Primary IGFD, 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. There is no assurance that we will receive marketing approvals in any foreign countries for Primary IGFD.

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

Even though Somatuline® Depot has received marketing approval from the FDA, the approval may not be maintained. We may also elect not to, or we may be unable to develop or obtain FDA approval of Somatuline® Depot for indications other than acromegaly, such as neuroendocrine tumors. Further, Ipsen may be unable to maintain the supply of the product. In addition, revenues from sales of Somatuline® Depot 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® Depot, 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® Depot 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® Depot 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 to Ipsen if Ipsen (or subsequent holders of the notes) 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; chemistry, manufacturing and controls data; and/or 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 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 our 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,

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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 do not approve an investigational new drug application or a clinical trial protocol, or they 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.

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® and Somatuline® Depot , 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® are incorrect, our expected revenues, including potential royalties from our collaboration with Ipsen, may be delayed or substantially reduced. Since Increlex® is approved by the FDA for severe Primary IGFD and Somatuline® Depot is approved by the FDA for the treatment of acromegaly, only prescriptions for those indications may be reimbursable. Also, we cannot be certain that the formulary status 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® 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 $31,000 per year. The actual cost per year per patient for Increlex® will depend on the weight of the child, the treatment dose prescribed and compliance. If our assumptions regarding the revenue per patient of Increlex® therapy for the treatment of severe Primary IGFD and Primary IGFD are incorrect, our expected revenues and the market opportunity for Increlex® therapy for the treatment of severe Primary IGFD and Primary IGFD may be substantially reduced.

We believe that the annual wholesale acquisition cost of Somatuline® Depot therapy for the treatment of acromegaly is approximately $27,000 at 100% compliance of the 90 microgram dose. The actual cost per year will depend on the treatment dose prescribed. If our assumptions regarding the average treatment dose per patients or revenue per patient for the treatment of acromegaly are incorrect, our expected revenues and the market opportunity for Somatuline® Depot for the treatment of acromegaly may be substantially reduced.

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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® 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® 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;
- 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.

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We cannot predict the relative competitive positions of Increlex®, Somatuline® Depot and our growth hormone/IGF-1 combination product candidates. However, we expect that the factors set forth under Item 1A. Risk Factors Our products may fail to achieve market acceptance, which could harm our business, among others, including manufacturing cost containment, will determine our ability to compete effectively.

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® for the treatment of severe Primary IGFD. If Increlex® receives regulatory approval for the treatment of patients with Primary IGFD, growth hormone products will also compete with Increlex® 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® for the treatment of children with Primary IGFD.

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.

In the United States and Canada, Somatuline® Depot competes directly with Sandostatin LAR® Depot and Somavert® for the treatment of acromegaly. Sandostatin LAR® Depot is a somatostatin analogue and has the same mechanism of action as Somatuline® Depot. 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 also compete with Somatuline® Depot 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® Depot 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® Depot.

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

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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. *

We currently source all of our Increlex® 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 Hospira Worldwide, Inc., or Hospira. It will take a significant amount of time and expense to complete the transfer to Hospira and validate Hospira as an alternative manufacturer. For us to complete the transfer to Hospira, Hospira s facilities and processes, prior to our use, may 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® by Hospira. If we are not able to complete the transfer of fill-finish manufacturing to Hospira, our ability to obtain commercial supplies of Increlex® and our revenue growth could be adversely affected. A delay in this transfer may also result in a shortage of Increlex® 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® could significantly adversely affect our commercial supply and ability to grow revenues. *

We currently source all of our Increlex® 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 a short-term commercial agreement with Lonza Baltimore, and during the term of this agreement, 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 Increlex® by Lonza Hopkinton. A delay in this transfer could result in a shortage of bulk Increlex® and a significant loss of revenues. If we are not able to complete this transfer, our ability to supply Increlex® 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® and/or Somatuline® Depot. *

The facilities and operations of our contract manufacturers to manufacture and test Increlex®, and of Ipsen to manufacture and test Somatuline® Depot, must undergo continuing inspections by the FDA for compliance with cGMP regulations in order to maintain their respective approvals. Currently, Lonza Baltimore is our sole provider of bulk rhIGF-1, and Ipsen is our sole provider of Somatuline® Depot. We have no alternative manufacturing facilities or plans for additional facilities at this time. We do not know if the Lonza Baltimore or Ipsen s facilities or their operations required for the commercial manufacture of Increlex® and Somatuline® Depot will continue to receive satisfactory cGMP inspections, and we do not know whether Lonza Hopkinton 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, Lonza Hopkinton, Ipsen 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.

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

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

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 and jeopardize our orphan drug marketing exclusivity. *

The manufacture of Increlex® requires successful coordination among all of our suppliers, contractors, service-providers, manufacturers and us. Coordination failures with these different elements of our supply chain, or with Ipsen s supply of Somatuline® Depot to us, could require us to delay sales of our products and/or impair our ability to distribute and supply Increlex® to Ipsen. Furthermore, uncertainties in estimating future demand for new products such as Increlex® and Somatuline® Depot 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. If we are unable to supply our products to all the patients that need them, the FDA could rescind our orphan drug marketing exclusivity to enable competitors to serve the affected markets. 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® Depot was approved in Canada and the United States 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 Somatuline® Depot, 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. The FDA has granted Increlex® orphan drug marketing exclusivity for the long-term treatment of patients with severe Primary IGFD and has granted Somatuline® Depot orphan drug marketing exclusivity for the long-term treatment of acromegaly. Although Increlex® and Somatuline® Depot have received marketing exclusivity, the FDA can still approve different drugs for use in treating the same indication or disease covered by our products, which would create a more competitive market for us.

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

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

Our products and manufacturing processes are subject to continued review and ongoing regulation by the FDA and foreign regulatory authorities 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 commercialization. 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 or lanreotide, which could adversely affect our competitive position. *

In the future, rhIGF-1 or lanreotide 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® , physicians may elect to prescribe a competitor s product containing rhIGF-1 to treat the indications for which Increlex® has received and may receive approval. This is commonly referred to as off-label use. While under FDA regulations a competitor is not allowed to promote off-label use of its product, the FDA does not regulate the practice of medicine and as a result cannot direct physicians as to which product containing rhIGF-1 to prescribe to their patients. In addition, a competitor could gain FDA approval of a product containing lanreotide for the treatment of an indication other than indication(s) covered by Somatuline® Depot, which would enable physicians to prescribe the competitor s product for the indication(s) covered by Somatuline® Depot. As a result, we would have limited ability to prevent off-label use of a competitor s product containing rhIGF-1 or lanreotide 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 or lanreotide 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® Depot 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® Depot product or a modified version of IGF-1 or Somatuline® Depot 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® or Somatuline® Depot 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.

We are 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® Depot 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.

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

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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® Depot) alone. We have licensed from Ipsen its rights to formulation and method of use patents for Somatuline® Depot that expire between 2015 and 2019. However, there can be no assurance that we have patent rights sufficient to prevent others from competing with us.

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® Depot 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® Depot 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 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®, we cannot predict whether our activities relating to the development and commercialization of Increlex® 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

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commercialization of Increlex® 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® commercially infeasible for us or otherwise curtail or cease any further development and commercialization of Increlex®.

We cannot be certain that others have not filed patent applications for technology covered by 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 13,046,346 shares of our common stock that we have issued to Ipsen, the conversion of the convertible notes and the exercise of the warrant that we have also 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 is 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 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, one of our directors, Christophe Jean, also serves as the Chief Operating Officer 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® for any indication, to develop, market and sell Somatuline® Depot, and to develop, manufacture, market and sell our growth hormone/IGF-1 combination product candidates. This may prevent us from continuing our business.

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

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.

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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.

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 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 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 subsequently issued two additional convertible notes to Ipsen in the principal amounts of 30.0 million and $15.0 million, respectively. All of these notes mature on the later of October 13, 2011 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 (or a subsequent holder) 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 are also subject to currency risk on the 30.0 million convertible note

that we issued 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 repay 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;

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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 September 30, 2007 as well as internally generated funds will be sufficient to meet our projected operating and capital expenditure requirements through at least the third quarter 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;

our ability to market and sell sufficient quantities of Increlex® and Somatuline® Depot at the anticipated level;

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

the success of Increlex® final drug product manufacturing;

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

Ipsen s ability to supply Somatuline® Depot to us in sufficient quantities;

the costs, timing and scope of additional regulatory approvals for Somatuline® Depot;

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 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 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. 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 September 30, 2007, we had 121 full-time employees, and we expect to hire additional employees in the near term. Our offices are located in the San Francisco Bay area where competition for personnel with biopharmaceutical skills is intense. If we fail to identify, attract, retain and motivate these highly skilled personnel, we may be unable to continue our development and commercialization activities.

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

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

One potential risk of using growth factors like rhIGF-1 is that it may increase the likelihood of developing cancer or, if patients already have cancer, that the cancer may develop more rapidly. Increlex® may also increase the risk that diabetic patients may develop or worsen an existing retinopathy, which could lead to the need for additional therapy such as laser treatment of the eyes or result in

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blindness. In our Phase III clinical trials for severe Primary IGFD, 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® Depot 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 hypothyrodism. 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® or Somatuline® Depot, 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®, Somatuline® Depot 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.

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

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

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

As a public reporting company, we must comply with the Sarbanes-Oxley Act of 2002 and the related rules and regulations of the 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

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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 September 30, 2007, our directors, executive officers and principal stockholders and their affiliates beneficially owned approximately 80.85% of our common stock. Our greater than five percent beneficial owners include Ipsen and its affiliates, which beneficially owned 42.6% (not including shares subject to limited voting agreements with certain of our stockholders); entities affiliated with MPM BioVentures III LLC, which beneficially owned 13.4%; entities affiliated with Prospect Management Co. II, LLC, which beneficially owned 6.0%; MedImmune, Inc., which beneficially owned 5.8%; and entities affiliated with Rho Capital Partners, which beneficially owned 5.8%. 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;
- 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® Depot;
- 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;

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prohibit stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders; and

establish advance notice requirements for nominations for election to our Board of Directors or for proposing matters that can be acted upon at stockholder meetings.

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

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, subject to adjustment, 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.

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.

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

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We are at risk of securities class action litigation.

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

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

If our stockholders sell substantial amounts of our common stock, including shares issued upon the exercise of outstanding options or pursuant to the CEFF, and the shares issued or issuable to Genentech and 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 September 30, 2007, we had 51,447,870 outstanding shares of common stock. As of September 30, 2007, we had 5,513,112 shares subject to outstanding options granted under our equity compensation plans. In addition, as of September 30, 2007, 15,507,982 shares were issuable upon the exercise of the warrant and conversion of the three convertible notes, which we have issued to Ipsen. 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 have issued 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 13,046,346 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 to Ipsen. In addition, certain holders of shares of our common stock that are parties to our amended and restated investors rights agreement, including Genentech, are entitled to registration rights.

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ITEM 5. OTHER INFORMATION.

On July 6, 2007, we entered into a Third Amendment to Lease (the Amendment) with 2000 Sierra Point Parkway LLC, the successor-in-interest to 2000 Sierra Point, LLC (the Lessor). The Amendment amends the terms of that certain Lease Agreement, dated March 7, 2005, as amended (the Lease Agreement), that we entered into with the Lessor for the lease of our office space in Brisbane, California. The Amendment amends the terms of the Lease Agreement to expand our leased premises by approximately 6,100 square feet for a period conterminous with term of the Lease Agreement, including renewal options. The Amendment increases our rental obligation beginning on July 1, 2007 by $20,183 per month (and increasing over the term of the Lease Agreement to $24,068 per month), and includes a proportionate increase to our percentage obligations for premises operating costs and tax expenses. The foregoing is only a brief description of the material terms of the Amendment and does not purport to be complete, and is qualified in its entirety by reference to the Amendment which is incorporated by reference to Exhibit 10.6I to this quarterly report on Form 10-Q.

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)
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)
4.5A	First Senior Convertible Promissory Note issued to Ipsen, S.A., dated October 13, 2006(4)
4.5B	Second Senior Convertible Promissory Note issued to Ipsen, S.A., dated September 17, 2007(6)
4.5C	Third Senior Convertible Promissory Note issued to Ipsen, S.A., dated September 17, 2007(6)
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)
10.6I	Third Amendment to Lease Agreement dated July 6, 2007 between 2000 Sierra Point Parkway LLC and the Registrant(7)
10.7E	Combination Product Development and Commercialization Agreement, dated as of July 6, 2007, between Genentech, Inc. and the Registrant.(7)
10.7F	Letter Agreement, dated as of July 6, 2007, between Genentech, Inc. and the Registrant.(7)
10.7G	Common Stock Purchase Agreement, dated as of July 6, 2007, between Genentech, Inc. and the Registrant(7)
10.9Z	Amendment to Employment Letter for Richard A. King, dated August 1, 2007(7)
10.10	Second Amended and Restated Investors Rights Agreement, dated July 30, 2007(7)
10.14E	Common Stock Purchase Agreement, dated as of July 9, 2007, between the Registrant, Suraypharm and Ipsen, S.A.(7)
10.14F	Amendment No. 1 to Registration Rights Agreement, dated as of July 30, 2007, between the Registrant, Suraypharm and Ipsen, S.A.(7)
10.16	Development and Supply Agreement, dated as of November 14, 2006, between Hospira Worldwide, Inc. and the Registrant

15.1 Letter regarding Unaudited Interim Financial Information.

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Exhibit Number	Description
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.

(6) 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 September 18, 2007.

(7) 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 August 2, 2007.

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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: November 1, 2007

TERCICA, INC.
(Registrant)

/s/ Ajay Bansal
Ajay Bansal

Chief Financial Officer
(Authorized Officer and Principal Financial Officer)