

TERCICA INC  
Form 10-Q  
May 12, 2008  
Table of Contents

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
**WASHINGTON, D.C. 20549**

**FORM 10-Q**

(Mark One)

**Quarterly report pursuant to Section 13 or 15(d) of the Securities and Exchange Act of 1934**  
For the quarterly period ended March 31, 2008

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)

Edgar Filing: TERCICA INC - Form 10-Q

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

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

Identification Number)

**2000 Sierra Point Parkway, Suite 400**

**Brisbane, San Francisco, CA 94005**

**(650) 624-4900**

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer  (Do not check if a smaller reporting company)

Smaller reporting company

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

As of April 30, 2008, there were 51,583,550 shares of the Registrant's Common Stock outstanding.

**Table of Contents**

**TERCICA, INC.**

**FORM 10-Q FOR THE QUARTER ENDED MARCH 31, 2008**

**INDEX**

	<b>Page</b>
<b><u>PART I FINANCIAL INFORMATION</u></b>	
<b><u>ITEM 1. FINANCIAL STATEMENTS (Unaudited)</u></b>	
<u>Condensed Balance Sheets March 31, 2008 and December 31, 2007</u>	3
<u>Condensed Statements of Operations Three months ended March 31, 2008 and 2007</u>	4
<u>Condensed Statements of Cash Flows Three months ended March 31, 2008 and 2007</u>	5
<u>Notes to the Condensed Financial Statements</u>	6
<u>Report of Independent Registered Public Accounting Firm</u>	16
<b><u>ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u></b>	17
<b><u>ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u></b>	27
<b><u>ITEM 4. CONTROLS AND PROCEDURES</u></b>	28
<b><u>PART II OTHER INFORMATION</u></b>	
<b><u>ITEM 1A. RISK FACTORS</u></b>	29
<b><u>ITEM 5. OTHER INFORMATION</u></b>	49
<b><u>ITEM 6. EXHIBITS</u></b>	49
<u>Signature</u>	51

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

	<b>March 31, 2008</b>	<b>December 31, 2007</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 65,919	\$ 72,353
Short-term investments	29,006	41,132
Accounts receivable, net (including amounts from related parties: 2008-\$223; 2007-\$165)	1,910	1,607
Inventories	18,762	13,891
Prepaid expenses and other current assets	2,569	2,117
Total current assets	118,166	131,100
Property and equipment, net	2,604	3,023
Intangible assets	40,969	41,672
Restricted cash	540	440
Other assets	418	448
Total assets	\$ 162,697	\$ 176,683
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable (including amounts due to related parties: 2008 - \$553; 2007 - none)	\$ 2,312	\$ 2,366
Accrued expenses (including amounts due to related parties: 2008 \$146; 2007 - none)	14,132	11,539
Other current liabilities	322	310
Deferred revenue, less long-term portion	1,062	881
Total current liabilities	17,828	15,096
Long-term convertible notes, net (refer to Note 5)	85,968	86,691
Deferred rent	979	1,062
Deferred revenue, long-term portion	10,481	10,675
Total liabilities	115,256	113,524
Commitments and contingencies		
Stockholders' equity:		
Preferred stock		
Common stock	52	52
Additional paid-in capital	354,015	352,278
Accumulated other comprehensive income	48	33
Accumulated deficit	(306,674)	(289,204)
Total stockholders' equity	47,441	63,159

Edgar Filing: TERCICA INC - Form 10-Q

Total liabilities and stockholders' equity	\$ 162,697	\$ 176,683
--	------------	------------

*See accompanying notes.*

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

	<b>Three months ended March 31,</b>	
	<b>2008</b>	<b>2007</b>
<b>Net revenues</b>		
Net product sales (including amounts from related parties: 2008 - \$310; 2007 - none)	\$ 4,348	\$ 1,091
License revenue	194	194
Royalty revenue (including amounts from related parties: 2008 - \$60; 2007 - none)	65	
<b>Total net revenues</b>	<b>4,607</b>	<b>1,285</b>
<b>Costs and expenses:</b>		
Cost of sales*	3,141	501
Manufacturing start-up costs*	1,544	98
Research and development*	6,109	4,912
Selling, general and administrative*	12,375	9,551
Amortization of intangibles	702	
<b>Total costs and expenses</b>	<b>23,871</b>	<b>15,062</b>
<b>Loss from operations</b>	<b>(19,264)</b>	<b>(13,777)</b>
Interest expense	(1,265)	(188)
Other income (expense)	1,957	
Interest and other income, net	1,107	1,571
<b>Loss before income taxes</b>	<b>(17,465)</b>	<b>(12,394)</b>
Provision for income taxes	5	
<b>Net loss</b>	<b>(17,470)</b>	<b>(12,394)</b>
<b>Basic and diluted net loss per share</b>	<b>\$ (0.34)</b>	<b>\$ (0.25)</b>
<b>Shares used to compute basic and diluted net loss per share</b>	<b>51,570</b>	<b>50,145</b>

\* Includes stock-based compensation expense as follows:

Cost of sales	\$ 35	\$
Manufacturing start-up costs	29	
Research and development	357	525
Selling, general and administrative	1,049	976
<b>Total</b>	<b>\$ 1,470</b>	<b>\$ 1,501</b>

Edgar Filing: TERCICA INC - Form 10-Q

*See accompanying notes.*

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

	<b>Three months ended March 31,</b>	
	<b>2008</b>	<b>2007</b>
<b>Cash flows from operating activities:</b>		
Net cash used in operating activities	\$ (18,981)	\$ (15,012)
<b>Cash flows from investing activities:</b>		
Purchases of property and equipment	(52)	(188)
Proceeds received from sale of equipment	11	
Purchases of available-for-sale securities	(15,690)	(33,490)
Proceeds from sales and maturities of available-for-sale securities	28,069	39,943
Net cash provided by investing activities	12,338	6,265
<b>Cash flows from financing activities:</b>		
Net proceeds from issuance of common stock	209	
Net cash provided by financing activities	209	
Net decrease in cash and cash equivalents	(6,434)	(8,747)
Cash and cash equivalents, beginning of period	72,353	40,339
Cash and cash equivalents, end of period	\$ 65,919	\$ 31,592

*See accompanying notes.*



**Table of Contents**

**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 currently has the following products and product candidates in its commercialization and development portfolio:

Increlex<sup>®</sup>, which is approved for marketing in both the United States and the European Union;

Somatuline<sup>®</sup> Depot, which is approved for marketing in both the United States and Canada; and

Two product candidates containing different combinations of Genentech Inc.'s recombinant human growth hormone (rhGH) (Nutropin AQ<sup>®</sup>), and recombinant human insulin-like growth factor-1 (rhIGF-1) (i.e., Increlex<sup>®</sup>). One product candidate is for the treatment of short stature associated with low insulin-like growth factor-1 (IGF-1) levels and the other product candidate is for the treatment of adult growth hormone deficiency (AGHD). In January 2008, the Company initiated dosing patients with Nutropin AQ<sup>®</sup> and Increlex<sup>®</sup> in a Phase II study for the treatment of short stature associated with low IGF-1 levels.

***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, 2007 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, 2007, included in the Company's Annual Report on Form 10-K for the year ended December 31, 2007, filed with the SEC on February 29, 2008.

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.

**2. Significant Accounting Policies**

During 2008, the Company applied the new accounting standard Statement of Financial Accounting Standards (SFAS) No. 157, *Fair Value Measurements* (SFAS No. 157), related to the fair value measurements of the Company's assets and liabilities as described more fully below. There have been no significant changes in the Company's significant accounting policies during the three months ended March 31, 2008 as compared to the significant accounting policies described in the Company's Annual Report on Form 10-K for the year ended December 31, 2007.

***Inventories***

## Edgar Filing: TERCICA INC - Form 10-Q

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 the Company's products. Due to the nature of the Company's business and our target markets, we believe levels of inventory in the distribution channel is not significant, and changes in demand due to price changes from competitors and the introduction of new products are not significant factors when estimating the Company's excess or obsolete inventory for Increlex<sup>®</sup> but can be significant factors in estimating excess or obsolete inventories for Somatuline<sup>®</sup> Depot. 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. Inventories may include products manufactured at facilities awaiting regulatory approval and are capitalized based on management's judgment of probable near term regulatory approval. In addition, inventories include employee stock-based compensation expenses capitalized under SFAS No. 123R.

---

**Table of Contents**

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 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;

the expiration date for each lot manufactured; and

any noncancelable open purchase orders associated with our commercial supply agreements.

In May 2007, the Company began to transfer its manufacturing process to new facilities and as such, there will be a period of time where the Company will need to cease production of Increlex<sup>®</sup> until the new manufacturing facilities are fully validated, approved by the Food & Drug Administration ( FDA ) and operational. The Company is increasing its inventory levels in an effort to ensure that the Company has adequate supplies to meet future demand and therefore the Company's long-term Increlex<sup>®</sup> sales forecast will become more critical in management's evaluation of excess Increlex<sup>®</sup> 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<sup>®</sup>. As of March 31, 2008, we had total inventories of \$18.8 million. The total inventory of \$18.8 million at March 31, 2008 included work-in-process inventory of \$5.5 million, at our new fill and finish manufacturing agent that will be available to us as finished goods only upon a successful approval of manufacturing process transfer by the FDA. The FDA requires that when technical processes are transferred to a new manufacturer, a certain number of conformance lots must be produced using the new manufacturer's facilities and evaluated for process consistency.

***Revenue Recognition***

The Company recognizes revenue from the sale of its products and license and collaboration agreements pursuant to SAB No. 104, *Revenue Recognition*, and Emerging Issues Task Force ( EITF ) Issue 00-21 *Revenue Arrangements with Multiple Deliverables* ( EITF 00-21 ). 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. 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 the Company's products, 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 each contract, are achieved.

**Table of Contents**

*Royalty revenues.* The Company recognizes royalty revenues from sales of Increlex® in Ipsen's territory on a sliding scale from 15% to 25% of net sales. Royalties are recognized as earned in accordance with the contract terms when royalties from Ipsen can be reasonably estimated and collectibility is reasonably assured.

***Manufacturing Start-up Costs***

Manufacturing start-up costs are comprised primarily of third-party costs related to the establishment of alternative manufacturers for the Company's drug substance rhIGF-1 and drug product Increlex® and absorption of personnel costs supporting these activities. These expenses include costs associated with the Company's contract manufacturers, pre-approval product manufacturing, process transfer, validation and qualification activities, and compliance-related support, pre-regulatory approval preparations for current good manufacturing practices ( cGMP ) and FDA approval.

***Valuation of Derivative Instruments***

The Company issued a convertible note denominated in Euros in September 2007 and valued certain features embedded therein as a derivative liability. The terms of the note provide that the holder may convert the note into shares of the Company's common stock based upon a fixed Euro amount per share. Because the conversion option is not fixed in the Company's functional currency (the U.S. dollar), the conversion option is not considered indexed to the Company's common stock. Therefore, under SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities* ( SFAS No. 133 ), the Company accounts for the conversion option as an embedded derivative that is bifurcated and measured separately from the convertible note (the host instrument). The note is denominated in Euros and the liability must be remeasured into U.S. dollars each quarter end based upon the then current Euro-U.S. dollar exchange ratio. Remeasurement of the liability is recorded as foreign currency gains or losses in other income and expense in the accompanying condensed statements of operations. The Company estimates the fair value of its derivative liabilities each quarter-end using the Black-Scholes-Merton valuation model. This model is complex and requires significant judgments in the estimation of fair values based on various factors, including the Company's current stock price and stock price volatility, the volatility of the Euro against the U.S. dollar, and other assumptions. Changes in the fair value of the embedded conversion option are recorded as non-cash gains and losses within other income (expense) in the Company's condensed statements of operations with offsetting amounts classified on the condensed balance sheet in the convertible note host debt instrument. Changes in the fair value of the embedded conversion option can have a material impact on the Company's financial statements. Upon conversion of the note into the Company's common stock in accordance with its terms or payment or expiration of the convertible note, the host debt instrument, including the fair value of the embedded conversion option, will be reclassified into common stock and additional paid in capital at then current estimated fair values. The timing of any such conversion is outside of the Company's control.

The embedded derivative liability does not qualify for hedge accounting under SFAS No. 133 and therefore, subsequent changes in fair value are recorded as non-cash valuation adjustments within other income (expense) in the condensed statements of operations.

***Recent Accounting Pronouncements***

On January 1, 2008, the Company adopted SFAS No. 157. SFAS No. 157 provides guidance for using fair value to measure assets and liabilities. SFAS No. 157 applies both to items recognized and reported at fair value in the financial statements and to items disclosed at fair value in the notes to the financial statements. SFAS No. 157 does not change existing accounting rules governing what can or must be recognized and reported at fair value and clarifies that fair value is defined as the price received to sell an asset, or paid to transfer a liability, in an orderly transaction between market participants at the measurement date. Additionally, SFAS No. 157 does not eliminate practicability exceptions that exist in accounting pronouncements amended by SFAS No. 157 when measuring fair value. As a result, the Company is not required to recognize any new assets or liabilities at fair value. SFAS No. 157 also establishes a framework for measuring fair value. Fair value is generally determined based on quoted market prices in active markets for identical assets or liabilities. If quoted market prices are not available, SFAS No. 157 provides guidance on alternative valuation techniques that place greater reliance on observable inputs and less reliance on unobservable inputs. See Note 9 – Fair Value of Financial Instruments in the notes to these condensed financial statements.

In February 2007, the FASB issued SFAS No. 159, *Fair Value Option for Financial Assets and Financial Liabilities* ( SFAS No. 159 ), which permits entities to elect to measure many financial instruments and certain other items at fair value that are not currently required to be measured at fair value. This election is irrevocable. SFAS No. 159 was effective in the first quarter of fiscal 2008. The Company did not elect to apply the fair value option to any of our financial instruments.

**Table of Contents**

In December 2007, the SEC issued SAB No. 110 ( SAB 110 ). SAB 110 expresses the views of the Staff regarding the use of the simplified method, as discussed in SAB No. 107, in developing an estimate of the expected term of plain vanilla share options in accordance with SFAS No. 123R. SAB 110 allows public companies that do not have historically sufficient experience to provide a reasonable estimate to continue use of the simplified method for estimating the expected term of plain vanilla share option grants after December 31, 2007. The Company currently uses the simplified method to estimate the expected term for share option grants as it does not have enough historical experience to provide a reasonable estimate. The Company will continue to use the simplified method until it has enough historical experience to provide a reasonable estimate of expected term in accordance with SAB 110. SAB 110 was effective for the Company on January 1, 2008.

In December 2007, the EITF ratified the consensus on EITF Issue No. 07-1, *Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property* ( EITF 07-1 ). EITF 07-1 concludes that transactions with third parties (that is, revenue generated and costs incurred by participants from transactions with parties outside of the collaborative arrangement) should be reported gross or net on the appropriate line item in each participant's respective financial statements pursuant to the guidance of EITF 99-19. EITF 07-1 is effective for fiscal years beginning after December 15, 2008, and requires retrospective application if practicable. The Company expects that the adoption of EITF 07-1 will not have an impact on its financial position or results of operations.

In March 2008, the FASB issued SFAS No. 161, *Disclosures about Derivative Instruments and Hedging Activities* ( SFAS No. 161 ), an amendment of SFAS No. 133. SFAS No. 161 requires enhanced disclosures about an entity's derivative and hedging activities. These enhanced disclosures will discuss (a) how and why an entity uses derivative instruments, (b) how derivative instruments and related hedged items are accounted for SFAS No. 133 and its related interpretations, and (c) how derivative instruments and related hedged items affect an entity's financial position, financial performance, and cash flows. SFAS No. 161 is effective for financial statements issued for fiscal years beginning after November 15, 2008, with earlier adoption allowed. The Company has not completed the process of evaluating the impact on its financial position or results of operations that will result from adopting SFAS No. 161.

In June 2007, the FASB ratified Emerging Issues Task Force ( EITF ) Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities* ( EITF No. 07-3 ). EITF No. 07-3 requires that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities be deferred and capitalized and recognized as an expense as the goods are delivered or the related services are performed. EITF No. 07-3 is effective, on a prospective basis, for fiscal years beginning after December 15, 2007. The adoption of EITF No. 07-3 did not have any impact on the Company's financial position or results of operations.

**Table of Contents****3. Balance Sheet Details**

	March 31, 2008	December 31, 2007
	(in thousands)	
<i>Accounts receivable, net:</i>		
Receivables	\$ 1,972	\$ 1,651
Less: allowance for discounts	(62)	(44)
	\$ 1,910	\$ 1,607
<i>Inventories:</i>		
Raw materials	\$ 1,946	\$ 2,453
Work-in-process	12,774	8,662
Finished goods	4,042	2,776
	\$ 18,762	\$ 13,891
<i>Property and equipment, net:</i>		
Office equipment	\$ 379	\$ 373
Furniture and fixtures	682	674
Computer equipment and software	2,909	2,919
Manufacturing equipment	1,305	1,305
Leasehold improvements	1,524	1,527
Construction in progress	39	
	6,838	6,798
Less: accumulated depreciation and amortization	(4,234)	(3,775)
	\$ 2,604	\$ 3,023
<i>Accrued expenses:</i>		
Accrued compensation and related liabilities	\$ 2,436	\$ 4,885
Accrued professional fees	858	1,259
Accrued contract manufacturing expenses	8,127	3,704
Clinical trial costs	372	248
Other accrued liabilities	2,339	1,443
	\$ 14,132	\$ 11,539

**4. Comprehensive Loss**

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

	Three months ended March 31, 2008 2007 (in thousands)	
Net loss, as reported	\$ (17,470)	\$ (12,394)
Change in unrealized gains (losses) on marketable securities, net of taxes	15	(1)

Comprehensive loss	\$ (17,455)	\$ (12,395)
--------------------	-------------	-------------

#### 5. Long-Term Debt

In October 2006, the Company issued to Ipsen a convertible note in the principal amount of \$25,037,000 (the First Convertible Note ). The First Convertible Note accrues interest at a rate of 2.5% per year, compounded quarterly, and is convertible into the Company s common stock at an initial conversion price of \$7.41 per share, subject to adjustment, which represents 3,504,530 shares at March 31, 2008.

**Table of Contents**

In September 2007, the Company issued to Ipsen two convertible notes in the principal amounts of 30,000,000, or \$41,640,000 on the date of issuance (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 5,135,854 and 2,051,569 shares, respectively, at March 31, 2008.

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 the subsequent holders of the 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 9,220,000 or \$12,797,000 on the date of issuance, September 17, 2007. This amount was accounted for as a reduction in the initial carrying value of the Second Convertible Note and separately accounted for as a derivative liability. 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 September 17, 2007 of the Second Convertible Note was 20,780,000, or approximately \$28,843,000, which is net of the discount plus accretion and accrued interest. At March 31, 2008 the carrying value was 22,173,000, or \$35,033,000 which approximates fair value.

The Convertible Notes including accrued interest, consisted of the following (in thousands):

	March 31, 2008	December 31, 2007
Convertible notes	\$ 76,203	\$ 72,610
Embedded derivative liability	9,765	14,081
<b>Total</b>	<b>\$ 85,968</b>	<b>\$ 86,691</b>

As of March 31, 2008, the Company accrued \$932,000 of cumulative interest expense on the First Convertible Note, of which \$161,000 was recorded as interest expense in the three months ended March 31, 2008. 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 March 31, 2008, the Company recorded valuation adjustment expense of \$4,316,000 representing a decrease in value of the derivative liability associated with the Second Convertible Note. This amount was recorded to other income in the condensed statements of operations. The Company accrued \$616,000 of cumulative interest expense on the Second Convertible Note, of which \$282,000 was recorded as interest expense in the three months ended March 31, 2008. The Company accrued \$1,562,000 of cumulative non-cash accretion charges, of which \$697,000 was recorded as amortization expense for the three months ended March 31, 2008. 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 March 31, 2008, the Company accrued \$202,000 of cumulative interest expense on the Third Convertible Note, of which \$94,000 was recorded as interest expense in the three months ended March 31, 2008. 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.



**Table of Contents***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:

	March 31, 2008	December 31, 2007
Market value of Company's common stock(1)	3.63	4.60
Volatility	62.7%	60.3%
Risk free interest rate	2.1%	3.3%
Exercise price of the conversion option	5.92	5.92
Expected life	3.5 years	3.8 years

(1) Represents the Euro equivalent of the Company's U.S. dollar common stock price.

**6. Stockholders' Equity***Ipsen Warrant*

Concurrently with the issuance of the First Convertible Note, the Company issued a warrant to Ipsen, which is exercisable for such number of shares of the Company's common stock equal to the greater of (i) 4,948,795 shares of the Company's common stock (the "Baseline Amount") or (ii) the Baseline Amount plus a variable amount of shares of the Company's common stock, which variable amount will fluctuate throughout the term of the warrant. The number of shares of the Company's common stock issuable upon exercise of the warrant as of October 13, 2006, the date of issue, was 5,026,712, with a fair value of \$13,622,000, estimated using the Black-Scholes-Merton valuation model, which was recorded to additional paid-in capital. The number of shares of the Company's common stock issuable upon exercise of the warrant as of March 31, 2008 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 antidilution adjustments.

**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 \$1,470,000 and \$1,501,000 was recorded during the three months ended March 31, 2008 and 2007, respectively.

*Stock Options*

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 March 31,	
	2008	2007
Expected volatility	62.3%	63.4%
Expected term (years)	6.2	6.3

## Edgar Filing: TERCICA INC - Form 10-Q

Risk-free interest rate	3.0%	4.6%
Dividend yield		

The Company's computation of expected volatility for the three months ended March 31, 2008 and 2007 is based on an average of the historical volatility of the Company's stock and the historical volatility of a peer-group of similar companies. The Company's computation of expected term in the three months ended March 31, 2008 and 2007 utilizes the simplified method in accordance with SAB 107, as modified by SAB 110. 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.

**Table of Contents**

As of March 31, 2008, unrecognized stock-based compensation expense related to stock options of \$13,058,000 was expected to be recognized over a weighted-average period of 2.7 years.

**Restricted Stock Units**

In February 2008, the Board of Directors of the Company amended the terms of the Company's 2004 Stock Plan (the Plan) to provide for the award of restricted stock units (RSUs). In March 2008, under the Plan, the Company granted RSUs to eligible employees, including executives. Each RSU represents a right to receive one share of the Company's common stock (subject to adjustment for certain specified changes in the capital structure of the Company) upon the completion of a specific period of continued service. The Company also provides eligible grantees with the opportunity to defer the delivery of shares.

The Company values the RSUs at the market price of the Company's common stock on the date of grant. The Company recognizes non-cash compensation expense for the fair values of these RSUs on a straight-line basis over the requisite service period of these awards, which is generally four years.

A summary of RSU activity is as follows:

	Shares (In thousands)	Weighted-Average Grant Date Fair Value
Nonvested at December 31, 2007		
Granted	203	6.13
Vested		
Forfeited	(3)	
Nonvested at March 31, 2008	200	\$ 6.13

The weighted-average grant date fair value of RSUs granted during the three months ended March 31, 2008 was \$6.13. As of March 31, 2008, unrecognized stock-based compensation expense related to non-vested RSUs of \$1,222,000 was expected to be recognized over a weighted-average period of four years. Stock-based compensation expense related to RSUs was approximately \$5,100 for the three months ended March 31, 2008.

**8. Net Loss Per Share**

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

	Three months ended March 31,	
	2008	2007
	(In thousands, except per share data)	
Numerator:		
Net loss	\$ (17,470)	\$ (12,394)
Denominator:		
Weighted-average common shares outstanding used to compute basic loss per share	51,570	50,145

Edgar Filing: TERCICA INC - Form 10-Q

Denominator for basic and diluted net loss per share	51,570	50,145
Basic and diluted net loss per share	\$ (0.34)	\$ (0.25)

**Table of Contents**

	<b>Three months ended March 31, 2008      2007 (In thousands)</b>	
<b>Outstanding dilutive securities not included in diluted net loss per share</b>		
Options to purchase common stock and restricted stock units	6,591	5,209
Convertible note	10,692	3,418
Warrants	5,209	5,247
	<b>22,492</b>	<b>13,847</b>

**9. Fair Value of Financial Instruments**

Financial instruments and derivative liabilities are presented at fair value. Fair value is defined as the price at which an asset could be exchanged in a current transaction between knowledgeable, willing parties. A liability's fair value is defined as the amount that would be paid to transfer the liability to a new obligor, not the amount that would be paid to settle the liability with the creditor. Where available, fair value is based on observable market prices or parameters or derived from such prices or parameters. Where observable prices or inputs are not available, valuation models are applied. These valuation techniques involve some level of management estimation and judgment, the degree of which is dependent on the price transparency for the instruments or market and the instrument's complexity.

Beginning January 1, 2008, assets and liabilities recorded at fair value in the condensed balance sheets are categorized based upon the level of judgment associated with the inputs used to measure their fair value. Hierarchical level defined by SFAS No. 157 and directly related to the amount of subjectivity associated with the inputs to fair valuation of these assets and liabilities are as follows:

Level 1 - Inputs are unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date. Fair valued assets that are generally included in this category are cash equivalents comprised of money market funds, and restricted cash.

Level 2 - Inputs (other than quoted prices included in Level 1) are either directly or indirectly observable for the asset or liability through correlation with market data at the measurement date and for the duration of the instrument's anticipated life. Fair valued assets and liabilities that are generally included in this category are corporate bonds, commercial paper, federal agency bonds, asset-backed securities and embedded derivative liabilities.

Level 3 - Inputs reflect management's best estimate of what market participants would use in pricing the asset or liability at the measurement date. Consideration is given to the risk inherent in the valuation technique and the risk inherent in the inputs to the model. The Company currently does not have any fair valued assets or liabilities classified as Level 3.

**Table of Contents***Fair Value on a Recurring Basis*

Assets and liabilities measured at fair value on a recurring basis are categorized in the tables below based upon the lowest level of significant input to the valuations as of March 31, 2008 (in thousands):

	Fair value March 31, 2008	Fair value measurements using		
		Level 1	Level 2	Level 3
<u>Assets</u>				
Cash equivalents	\$ 59,518	\$ 50,193	\$ 9,325	\$
Short-term investments	29,006		29,006	
Restricted cash	540	540		
<b>Total assets</b>	<b>\$ 89,064</b>	<b>\$ 50,733</b>	<b>\$ 38,331</b>	<b>\$</b>
<u>Liabilities</u>				
Total liabilities - Embedded derivative	\$ 9,765	\$	\$ 9,765	\$

**Table of Contents**

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 March 31, 2008, and the related condensed statements of operations for the three-month periods ended March 31, 2008 and 2007, and the condensed statements of cash flows for the three-month periods ended March 31, 2008 and 2007. 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, 2007, and the related statements of operations, stockholders' equity, and cash flows for the year then ended not presented herein and in our report dated February 27, 2008, we expressed an unqualified opinion on those financial statements and included explanatory paragraphs 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, 2007, 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

May 8, 2008

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

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

**Overview**

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

Increlex<sup>®</sup>, which is approved for marketing in both the United States and the European Union;

Somatuline<sup>®</sup> Depot, which is approved for marketing in both the United States and Canada; and

Two product candidates containing different combinations of Genentech Inc.'s recombinant human growth hormone, or rhGH (Nutropin AQ<sup>®</sup>), and recombinant human insulin-like growth factor-1, or rhIGF-1 (i.e., Increlex<sup>®</sup>). One product candidate is for the treatment of short stature associated with low insulin-like growth factor-1, or IGF-1, levels and the other product candidate is for the treatment of adult growth hormone deficiency, or AGHD. In January 2008, we initiated dosing patients with Nutropin AQ<sup>®</sup> and Increlex<sup>®</sup> in a Phase II study for the treatment of short stature associated with low IGF-1 levels.

*Increlex<sup>®</sup>*. We market Increlex<sup>®</sup> as a long-term replacement therapy for the treatment of short stature in children with severe primary insulin-like growth factor-1 deficiency, or severe Primary IGFD, and for children with growth hormone gene deletion who have developed neutralizing antibodies to growth hormone. We commenced marketing Increlex<sup>®</sup> in the United States in January 2006. We are currently conducting a Phase IIIb clinical trial for the use of Increlex<sup>®</sup> for the treatment of short stature in children with Primary IGFD, a less severe and more prevalent form of insulin-like growth factor-1 deficiency, or IGFD. Patient enrollment for this trial was completed in July 2007, and we expect to present data from this trial at a medical conference in the fourth quarter of 2008.

In August 2007, the European Commission granted marketing authorization for Increlex<sup>®</sup> in the European Union for the long-term treatment of growth failure in children and adolescents with severe Primary IGFD. Pursuant to our worldwide strategic collaboration with Ipsen that was completed in October 2006, we granted to Ipsen and its affiliates the exclusive right under our patents and know-how to develop and commercialize Increlex<sup>®</sup> in all countries of the world except the United States, Japan, Canada, and for a certain period of time, Taiwan and certain countries of the Middle East and North Africa for all indications, other than treatment of central nervous system and diabetes indications. In 2007, Ipsen launched Increlex<sup>®</sup> in Austria, Germany, Great Britain, Greece, Hungary, Spain and the Czech Republic, and expects to launch Increlex<sup>®</sup> in additional European countries during 2008.

Increlex<sup>®</sup> generated net product revenues of \$3.4 million in the three-month period ended March 31, 2008.

*Somatuline<sup>®</sup> 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<sup>®</sup> Depot in the United States and in Canada for all indications other than ophthalmic indications. In territories outside the United States, including Canada, the product is known as Somatuline<sup>®</sup> Autogel<sup>®</sup>. On August 30, 2007, Ipsen received notice of approval from the Food & Drug Administration (FDA) for marketing Somatuline<sup>®</sup> 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



## Edgar Filing: TERCICA INC - Form 10-Q

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. In July 2006, Somatuline® Autogel® was approved for marketing by Health Canada for the same indication. Somatuline® Autogel® has received provincial formulary listings for reimbursement approval in the

## **Table of Contents**

provinces of Quebec, Nova Scotia, Newfoundland and Labrador, New Brunswick, Saskatchewan, and for Alberta Blue Cross and we are awaiting reimbursement approval in the province of Ontario. At present, we have contracted sales and marketing operations in Canada to a third party. We launched Somatuline<sup>®</sup> Depot in November 2007 in the United States.

Somatuline<sup>®</sup> Depot generated net product revenues of \$1.0 million in the three-month period ended March 31, 2008.

*Growth hormone/IGF-1 Combination Product Candidates.* In July 2007, we entered into a combination product development and commercialization agreement with Genentech that governs the development, manufacture and worldwide commercialization of two product candidates containing Nutropin AQ<sup>®</sup>, Genentech's rhGH, and Increlex<sup>®</sup>, for the treatment of all indications except those of the central nervous system. In January 2008, we began dosing the first patients in a Phase II clinical study evaluating the combination of the Nutropin AQ<sup>®</sup> and Increlex<sup>®</sup> for the treatment of short stature associated with low IGF-1 levels. The primary objective of this trial is to assess the efficacy, measured as first-year height velocity, and safety of three different combination regimens of Nutropin AQ<sup>®</sup> and Increlex<sup>®</sup> compared to Nutropin AQ<sup>®</sup> alone in the treatment of short stature associated with low IGF-1 levels. Although the goal of the program is to develop a co-mixture of Nutropin AQ<sup>®</sup> and Increlex<sup>®</sup> administered as a single injection, the patients enrolled in this trial have received separate injections of each of Nutropin AQ<sup>®</sup> and Increlex<sup>®</sup>.

As of March 31, 2008, we had approximately \$94.9 million in cash, cash equivalents and short-term investments. We have generated limited revenues from product sales to date and we have funded our operations since inception primarily through the private placements of equity securities and public offerings of our common stock, as well as through our collaboration with Ipsen. Since our inception we have incurred substantial net losses and we expect to incur substantial net losses for the foreseeable future as we attempt to develop, market and sell Increlex<sup>®</sup> and Somatuline<sup>®</sup> Depot, and as we attempt to develop growth hormone/IGF-1 combination products under our combination product collaboration with Genentech. We are unable to predict the extent of any future losses or when we will become profitable, if ever.

### **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 2008, we adopted the new accounting standard Statement of Financial Accounting Standards, or SFAS, No. 157, *Fair Value Measurements*, related to the fair value measurements of our assets and liabilities as described more fully below. Other than the adoption of SFAS No. 157, there have been no significant changes in our significant accounting policies during the three months ended March 31, 2008 as compared to the significant accounting policies described in our Annual Report on Form 10-K for the year ended December 31, 2007. For a discussion of these critical accounting policies, please see the discussion in our Annual Report on Form 10-K for the fiscal year ended December 31, 2007.

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

#### ***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* (EITF 00-21). 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.

*Product revenues.* 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. The rebates and discounts may require management judgment to estimate percentage of eligible sales to these customers. 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 products, 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 the returns experience increases.



## **Table of Contents**

*License revenues.* License revenue generally includes upfront and continuing licensing fees and milestone payments. Nonrefundable upfront fees that require our continuing involvement in 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.

*Royalty revenues.* We recognize royalty revenues from sales of Increlex® in Ipsen's territory on a sliding scale from 15% to 25% of net sales. Royalties are recognized as earned in accordance with the contract terms and when collectibility is reasonably assured.

### ***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 management 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 for Increlex® but can be significant factors in estimating excess or obsolete inventories for Somatuline® Depot. 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. Inventories may include products manufactured at facilities awaiting regulatory approval and are capitalized based on our judgment of probable near term regulatory approval. In addition, inventories include employee stock-based compensation expenses capitalized under SFAS No. 123R.

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 factors considered in evaluating whether there exists excess or obsolete inventory are:

our forecast of future demand, which is updated on a quarterly basis;

the expiration date for each lot manufactured;

any noncancelable open purchase orders associated with our commercial supply agreements.

In May 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 Food & Drug Administration (or FDA), and operational. We are increasing our inventory levels in an effort to ensure that we have adequate supplies to meet future demand and therefore our long-term Increlex® sales forecast will become more critical in management's evaluation of excess Increlex® inventories over the next few quarters. Once the transfer of manufacturing facilities is complete, we will have more flexibility in the manufacturing schedule to ensure inventory supply is in line with a shorter forward demand forecast for Increlex®. As of March 31, 2008, we had total inventories of \$18.8 million. Total inventories of \$18.8 million included in work-in-process inventory of \$5.5 million at our new fill and finish manufacturing agent, that will be available to us as finished goods only upon a successful approval of manufacturing process transfer by the FDA. The FDA requires that when technical processes are transferred to a new manufacturer, a certain number of conformance lots must be produced using the new manufacturer's facilities and evaluated for process consistency.

### ***Valuation of Derivative Instruments***

We issued a convertible note denominated in Euros in September 2007 and valued certain features embedded therein as derivative liabilities under SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities* or SFAS No. 133. We estimate the fair value of our 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 market value of our common stock, changes in Euro to U.S. dollar currency exchange rates and other assumptions. Changes in value are recorded as non-cash valuation adjustments within other income (expense) in our statement of operations. These changes in the carrying value of derivatives can have a material impact on our financial statements (see Part I, Item 3 *Qualitative and Quantitative Disclosures about Market Risk* of this Form 10-Q). The derivative liabilities may be recorded into stockholders' equity upon conversion, payment or expiration of the convertible notes, the timing of which is outside our control.

## Edgar Filing: TERCICA INC - Form 10-Q

The embedded derivative liability does not qualify for hedge accounting under SFAS No. 133 and therefore, subsequent changes in fair value are recorded as non-cash valuation adjustments within other income (expense) in the condensed statements of operations.

---

## **Table of Contents**

### **Recent Accounting Pronouncements**

In the first quarter of 2008, we adopted SFAS No. 157, *Fair Value Measurements* ( SFAS No. 157 ), for financial assets and liabilities. This standard does not apply measurements related to share-based payments, nor does it apply to measurements related to inventory.

SFAS No. 157 discusses valuation techniques, such as the market approach (comparable market prices), the income approach (present value of future income or cash flow), and the cost approach (cost to replace the service capacity of an asset or replacement cost). The statement utilizes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value into three broad levels. The following is a brief description of those three levels:

Level 1: Inputs are unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date.

Level 2: Inputs (other than quoted prices included Level 1) are either directly or indirectly observable for the asset or liability through correlation with market data at the measurement date and for the duration of the instrument's anticipated life.

Level 3: Inputs reflect management's best estimate of what market participants would use in pricing the asset or liability at the measurement date. Consideration is given to the risk inherent in the valuation technique and the risk inherent in the inputs to the model.

The impact of adoption of SFAS No. 157 is discussed in Note 9, *Fair Value of Financial Instruments* in the Notes to Condensed Financial Statements of this Form 10-Q. The fair values of our short-term investments and derivative liabilities are based on Level 2 inputs that are either directly or indirectly observable for the asset or liability through correlation with market data at the measurement date and for the duration of the instrument's anticipated life.

In February 2007, the FASB issued SFAS No. 159, *Fair Value Option for Financial Assets and Financial Liabilities*, or SFAS No. 159, which permits entities to elect to measure many financial instruments and certain other items at fair value that are not currently required to be measured at fair value. This election is irrevocable. SFAS No. 159 was effective in the first quarter of fiscal 2008. We did not elect to apply the fair value option to any of our financial instruments.

In December 2007, the SEC issued SAB No. 110 or SAB 110. SAB 110 expresses the views of the staff regarding the use of the simplified method, as discussed in SAB No. 107, in developing an estimate of the expected term of plain vanilla share options in accordance with SFAS No. 123R. SAB 110 allows public companies which do not have historically sufficient experience to provide a reasonable estimate to continue use of the simplified method for estimating the expected term of plain vanilla share option grants after December 31, 2007. We currently use the simplified method to estimate the expected term for share option grants as it does not have enough historical experience to provide a reasonable estimate. We will continue to use the simplified method until it has enough historical experience to provide a reasonable estimate of expected term in accordance with SAB 110. SAB 110 was effective for us on January 1, 2008.

In December 2007, the EITF ratified the consensus on EITF Issue No. 07-1, *Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property*, or EITF 07-1. EITF 07-1 concludes that transactions with third parties (that is, revenue generated and costs incurred by participants from transactions with parties outside of the collaborative arrangement) should be reported gross or net on the appropriate line item in each participant's respective financial statements pursuant to the guidance of EITF 99-19. EITF 07-1 is effective for fiscal years beginning after December 15, 2008, and requires retrospective application if practicable. We expect that the adoption of EITF 07-1 will not have an impact on our financial position or results of operations.

In March 2008, the FASB issued SFAS No. 161, *Disclosures about Derivative Instruments and Hedging Activities*, or SFAS No. 161, an amendment of SFAS No. 133. SFAS No. 161 requires enhanced disclosures about an entity's derivative and hedging activities. These enhanced disclosures will discuss (a) how and why an entity uses derivative instruments, (b) how derivative instruments and related hedged items are accounted for under SFAS No. 133 and its related interpretations, and (c) how derivative instruments and related hedged items affect an entity's financial position, financial performance, and cash flows. SFAS No. 161 is effective for financial statements issued for fiscal years beginning after November 15, 2008, with earlier adoption allowed. We have not completed the process of evaluating the impact on our financial position or results of operations from adoption of SFAS No. 161.



**Table of Contents**

In June 2007, the FASB ratified Emerging Issues Task Force ( EITF ) Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities* ( EITF No. 07-3 ). EITF No. 07-3 requires that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities be deferred and capitalized and recognized as an expense as the goods are delivered or the related services are performed. EITF No. 07-3 is effective, on a prospective basis, for fiscal years beginning after December 15, 2007. The adoption of EITF No. 07-3 did not have any impact on our financial position or results of operations.

**Results of Operations**

	<b>Three months ended</b>		<b>Increase/ (Decrease)</b>
	<b>March 31,</b>		
	<b>2008</b>	<b>2007</b>	
	<b>(in thousands)</b>		
Net product sales	\$ 4,348	\$ 1,091	3,257
License revenue	194	194	
Royalty revenue	65		65
Cost of sales	3,141	501	2,640
Manufacturing start-up costs	1,544	98	1,446
Research and development expenses	6,109	4,912	1,197
Selling, general and administrative expenses	12,375	9,551	2,824
Amortization of intangible assets	702		702
Interest expense	(1,265)	(188)	1,077
Other income (expense)	1,957		1,957
Interest and other income, net	1,107	1,571	(464)
Taxes	5		5

**Net Revenues**

Net revenues consisted of net product sales of Increlex<sup>®</sup> and Somatuline<sup>®</sup> Depot, amortized license revenue associated with our Increlex<sup>®</sup> license and collaboration agreement with Ipsen, and royalty revenues from Ipsen for sales of Increlex<sup>®</sup> in the European Union.

**Net Product Sales**

Net product sales of \$4.3 million for the three-month period ended March 31, 2008 increased \$3.3 million over the same period in 2007, primarily due to growth in Increlex<sup>®</sup> net product sales of \$2.3 million and net product sales of Somatuline<sup>®</sup> Depot of \$1.0 million. The growth of net Increlex<sup>®</sup> product sales in the three-month period ended March 31, 2008 was primarily due to continued expansion of our patient base and three price increases since the first quarter of 2007, and to a lesser extent transition of a number of patients receiving IPLEX to treatment with Increlex<sup>®</sup> following the settlement agreement with Insmid Inc. in March 2007. In the fourth quarter of 2007, we began shipment of Increlex<sup>®</sup> to Ipsen for European Union commercial distribution which added \$0.3 million to net product sales in the three-month period ended March 31, 2008 compared to the same period in 2007. In November 2007, we launched Somatuline<sup>®</sup> Depot in the United States, which added \$1.0 million to net product sales in the three-month period ended March 31, 2008 compared to the same period in 2007.

We expect both Increlex<sup>®</sup> and Somatuline<sup>®</sup> Depot product sales to increase over the next several quarters, however, we do not expect net Increlex<sup>®</sup> product sales to increase at the same rate on a quarter over quarter basis as we experienced from the quarter ended March 31, 2007 to the quarter ended March 31, 2008.

**License Revenue**

License revenues represent amortization of the upfront license payment in connection with our Increlex<sup>®</sup> license and collaboration agreement with Ipsen which was \$0.2 million for both of the three months ended March 31, 2008 and 2007. 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. At present, we do not anticipate any significant additional licensing or milestone payments related to or for Increlex<sup>®</sup> in future periods.



## Edgar Filing: TERCICA INC - Form 10-Q

Under the terms of our combination product collaboration with Genentech, we may receive certain milestone payments in the future if Genentech elects to exercise their opt-in right; however, we are unable to predict the timing or the likelihood of any such payments.

---

**Table of Contents*****Royalty Revenue***

We recorded royalty revenue of \$65,000 in the three months ended March 31, 2008 from sales of Increlex<sup>®</sup> in the European Union by Ipsen. There were no royalty revenues in the first three months of 2007. We expect our royalty revenues to increase over the next several quarters as Ipsen continues to expand their Increlex<sup>®</sup> distribution in the European Union.

***Cost of Sales***

Our cost of sales represents the cost of production, royalties owed to our licensors, fixed and variable 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. Prior to regulatory approval of Increlex<sup>®</sup> in August 2005, drug supply production costs were charged to research and development. Beginning in the fourth quarter of 2005, with the marketing approval of Increlex<sup>®</sup> by the FDA, we began capitalizing these production costs to inventory and began to charge cost of sales in the first quarter of 2006 as units of Increlex<sup>®</sup> were sold.

Cost of sales for the three-month period ended March 31, 2008 increased \$2.6 million over the same period in 2007. The increase in 2008 was primarily due to higher sales volume as more Increlex<sup>®</sup> units were sold and we commenced marketing of Somatuline<sup>®</sup> Depot, and increased absorption of personnel and other costs. In the three months ended March 31, 2008, the cost of Increlex<sup>®</sup> sales were \$2.7 million and the cost of Somatuline<sup>®</sup> Depot sales were \$0.4 million.

Cost of sales as a percentage of net product sales in the three-month period ended March 31, 2008 was higher than the same period in 2007 primarily due to higher absorption of personnel and other costs under cost of sales. Some of these costs were previously allocated to research and development.

We expect cost of sales as a percentage of net product sales to decrease in future periods as fixed costs are absorbed over larger production volumes, as our sales mix changes over time and as manufacturing equipment related depreciation costs cease in the third quarter of 2008. The depreciation of manufacturing equipment is related to equipment owned by us at Lonza Baltimore. This facility will cease Increlex<sup>®</sup> production in the third quarter of 2008 and we will not own manufacturing equipment at our contract manufacturer's new facility.

Although we expect cost of sales as a percentage of net product sales to decrease in future periods, there can be no assurances that cost of sales as a percentage of net product sales will decrease due to uncertainties inherent in the manufacturing process.

***Manufacturing Start-up Costs***

Manufacturing start-up costs consisted primarily of costs associated with the transfer of our manufacturing operations to alternate sites. We commenced transfer of our fill and finish operations in November 2006 and the transfer of Increlex<sup>®</sup> drug substance production in May 2007. The increase in the three-month period ended March 31, 2008 was primarily due to the increase in manufacturing activities at both facilities in the first quarter of 2008 compared to the same period in 2007. An additional \$1.2 million of amortized costs associated with these projects will be recorded over the remaining transfer period, which is expected to occur through June 2008. There will be additional associated transfer activities and costs that will continue through the end of 2008, as we prepare for FDA approval of both transfer sites.

***Research and Development Expenses***

Research and development expenses consisted primarily of costs associated with clinical, regulatory, manufacturing development 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 included in research and development expenses. Manufacturing development activities included pre-regulatory approval activities associated with technology transfer, pharmaceutical development, process and 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.

Research and development expenses of \$6.1 million for the three months ended March 31, 2008 increased \$1.2 million over the same period in 2007. The increase in 2008 was primarily due to an increase in third party contractor costs of \$0.8 million and payroll related costs of \$0.4 million. The increase in third-party contractor costs in 2008 was primarily due to an increase in clinical activities associated with growth hormone/IGF-1 combination product candidates as well as the Increlex<sup>®</sup> product registry, partially offset by a decrease in activities associated

## Edgar Filing: TERCICA INC - Form 10-Q

with our European marketing authorization application, or MAA. The increase in payroll related costs in 2008 was primarily due to increased personnel compared to 2007.

**Table of Contents**

The \$6.1 million in research and development expense in the three-month period ended March 31, 2008 was comprised primarily of personnel and related costs of \$3.3 million, third-party contract costs related to our clinical activities for Increlex<sup>®</sup> Primary IGFD and severe Primary IGFD of \$1.5 million, clinical activities associated with growth hormone/IGF-1 combination product candidates of \$0.9 million and Somatuline<sup>®</sup> Depot clinical activities in acromegaly of \$0.4 million. The \$4.9 million in research and development expense recorded for the same period in 2007 was comprised primarily of personnel and related costs of \$2.9 million, third party contract costs related to our clinical activities for Increlex<sup>®</sup> Primary IGFD and severe Primary IGFD of \$1.7 million, and clinical activities for Somatuline<sup>®</sup> Depot in acromegaly of \$0.3 million.

We expect our research and development expenses to increase for the remainder of 2008 as we undertake clinical development activities for Increlex<sup>®</sup>, Somatuline<sup>®</sup> Depot, and growth hormone/IGF-1 combination product candidates and other projects. Our projects or intended projects may be subject to change from time to time as we evaluate our research and development priorities and available resources.

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

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

Selling, general and administrative expenses of \$12.4 million for the three-month period ended March 31, 2008 increased \$2.8 million over the same period in 2007. The increase in 2008 was primarily due to an increase in sales and marketing expenses of \$2.7 million and payroll and related costs of \$0.7 million, partially offset by decreased expenses associated with litigation of \$0.7 million. The increase in sales and marketing activities was primarily related to increased costs associated with product promotions, medical education, costs in support of the launch of Somatuline<sup>®</sup> Depot in the U.S. and Canada as well as additional physician focused programs in support of Increlex<sup>®</sup>. The increase in payroll and related expenses was primarily due to additional sales and medical science personnel and non-cash stock compensation expense.

The \$12.4 million in selling, general and administrative expenses for the three-month period ended March 31, 2008 was comprised primarily of payroll and related costs of \$7.1 million, sales and marketing activities including cost of free drug of \$3.3 million, professional services including legal and accounting services of \$1.0 million, medical education activities of \$0.7 million and other general administrative activities of \$0.3 million. The \$9.6 million in selling, general and administrative expenses recorded for the same period in 2007 was comprised primarily of payroll and related costs of \$6.4 million, professional services including legal and accounting services of \$1.6 million, sales and marketing activities including cost of free drug of \$1.4 million, and other general administrative activities including medical education activities of \$0.2 million.

We expect total selling, general and administrative expenses to increase modestly for the remainder of 2008 compared to those recorded in the three-month period ended March 31, 2008.

***Amortization of Intangible Assets***

Amortization of intangible assets of \$0.7 million in the three-month period ended March 31, 2008 represents expense recorded on a straight-line basis of milestone payments made to Ipsen and to Genentech in connection with the U.S. marketing approval of Somatuline<sup>®</sup> Depot and marketing approval of Increlex<sup>®</sup> in the European Union, respectively. Refer to Ipsen Collaboration, under Liquidity and Capital Resources below for further information on these milestone payments. We began amortization of these assets in November 2007 and expect to recognize the straight-line expense of \$2.8 million annually through October 2022. There was no amortization of intangibles expense recorded for the same period in 2007.

***Interest Expense***

Interest expense of \$1.3 million for the three-month period ended March 31, 2008 increased \$1.1 million over the same period in 2007. The increase in 2008 was primarily due to the timing of issuance of two convertible notes to Ipsen. The first convertible note was issued to Ipsen in October 2006. The second and third convertible notes were issued in September 2007.

We expect moderate increases in interest expense through October 2011, the remaining term on the convertible notes, as the stated interest rate of 2.5% is applied to the outstanding balance of the convertible notes which includes the principal and accrued interest.

---

**Table of Contents*****Other Income (Expense)***

Other income of \$2.0 million in the three-month period ended March, 31 2008 was largely due to a decrease in the fair value of the embedded derivative conversion option related to a convertible note we issued to Ipsen in September 2007 partially offset by an unfavorable foreign currency adjustment. This convertible note is denominated in Euros and the conversion option is considered an embedded derivative. The conversion option must be revalued at the end of each reporting period, which resulted in a benefit of \$4.3 million in the first quarter of 2008. Further, this convertible note is revalued to U.S. dollars at the end of each reporting period, which resulted in a charge of \$2.4 million in the first quarter of 2008. There were no such charges recorded for the same period in 2007.

As currency rates, our stock price and our volatility assumptions change, we may record income or expense to Other Income (Expense) related to both the value of the note as well as the value of the embedded derivative. It is difficult to forecast changes to Other Income (Expense) as we are unable to predict fluctuations in currency rates, our stock price and stock price volatility (see Part I, Item 3 Quantitative and Qualitative Disclosures about Market Risk of this Form 10-Q).

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

Net interest and other income, net of \$1.1 million for the three-month period ended March 31, 2008 decreased \$0.5 million compared to the same period in 2007. The decrease was primarily due to interest income on lower average cash, cash equivalents and short-term investment balances during 2008 as well as lower interest rates. The lower cash balances in 2008 were primarily due to net cash used in operations.

Assuming we do not raise additional funds during 2008, we expect net interest and other income to decrease for the remainder of 2008 as we use cash and short-term investments to fund our operations.

***Provision for income taxes***

The provision for income taxes recorded in the three-month period ended March 31, 2008, represents French foreign income taxes withheld on royalties paid to us by Ipsen under our Increlex<sup>®</sup> license and collaboration agreement with Ipsen. There were no income taxes withheld for the same period in 2007 as Ipsen began selling Increlex<sup>®</sup> in the fourth quarter of 2007. We did not record domestic provisions for income taxes in the three-month periods ended March 31, 2008 and 2007 because we have incurred operating losses to date.

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

As of March 31, 2008, we had approximately \$94.9 million in cash, cash equivalents and short-term investments. We had an accumulated deficit of \$306.7 million, which was primarily comprised of \$262.6 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 March 31, 2008 primarily from issuance of equity, convertible notes and the receipt of up-front and milestone payments under our collaboration with Ipsen. To date we have received net cash proceeds of \$283.2 million from equity issuances including equity sold to Ipsen and Genentech. 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<sup>®</sup> license and collaboration agreement. In addition, we have received \$31.7 million from Ipsen, net of withholding taxes, for milestone payments related to the Increlex<sup>®</sup> license and collaboration agreement.

***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<sup>®</sup> license and collaboration agreement as described below. Each of the convertible notes that we issued to Ipsen matures on the later of October 13, 2011 or two years from the date of notification of non-convert and carries a coupon of 2.5% per annum from the date of issuance, compounded quarterly, and is 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 13,046,346 shares of our common stock that we have issued to Ipsen (and/or an affiliate of Ipsen) to date, 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.

**Table of Contents**

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<sup>®</sup> in all countries of the world except the United States, Japan, Canada, and for a certain period of time, Taiwan and certain countries of the Middle East and North Africa, and Ipsen granted to us exclusive rights to develop and commercialize Somatuline<sup>®</sup> 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<sup>®</sup> Depot and Increlex<sup>®</sup>. 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<sup>®</sup> in the European Union for the long-term treatment of growth failure in children and adolescents with severe Primary IGF1D. Under the license and collaboration agreement with respect to Increlex<sup>®</sup>, Ipsen made an upfront cash payment to us of \$9.5 million, or \$11.8 million, after tax withholding in October 2006, and paid us an additional milestone of approximately \$14.3 million, or \$19.3 million, after tax withholding, in September 2007 for receiving marketing authorization for Increlex<sup>®</sup> in the European Union for the targeted product label. Ipsen is our marketing partner for Increlex<sup>®</sup> in the European Union. In November 2007, Increlex<sup>®</sup> was launched by Ipsen in Ipsen's territory. We are entitled to royalties on Increlex<sup>®</sup> sales made in Ipsen's territory 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<sup>®</sup>.

Under the license and collaboration agreement with respect to Somatuline<sup>®</sup> 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<sup>®</sup> 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 \$41.6 million, 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. We launched Somatuline<sup>®</sup> Depot in the United States in November 2007. We 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<sup>®</sup> 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 product candidates containing Genentech's rhGH, Nutropin AQ<sup>®</sup>, and our rhIGF-1, Increlex<sup>®</sup>, 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 product candidates 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 in Note 8, "Combination Product Development and Commercialization Agreement" in the Notes to Financial Statements of Part II, Item 8 of the Form 10-K filed for the year ended December 31, 2007. 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 will be owed to Genentech. Genentech would receive such profit share in lieu of its royalty payment. Under the combination product agreement, we may receive a cash milestone payment in certain circumstances and we may be entitled to royalties on net sales of certain combination products. In addition, 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. Please refer to Note 8, "Combination Product Development and Commercialization Agreement," in the Notes to Financial Statements of the Form 10-K filed for the year ended December 31, 2007 for more detail on the terms of the combination product agreement and stock purchase agreement.

**Table of Contents****Committed Equity Financing Facility**

Under the terms of a committed equity financing facility, or CEFF, we entered into with Kingsbridge Capital Limited, or Kingsbridge, 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**

	<b>Three months ended March 31,</b>	
	<b>2008</b>	<b>2007</b>
	<b>(In thousands)</b>	
Net cash provided by (used for):		
Operating activities	\$ (18,981)	\$ (15,012)
Investing activities	12,338	6,265
Financing activities	209	
<b>Net change in cash and cash equivalents</b>	<b>\$ (6,434)</b>	<b>\$ (8,747)</b>

Cash, cash equivalents and short-term investments totaled \$94.9 million at March 31, 2008, compared to \$113.5 million at December 31, 2007. The net decrease in cash, cash equivalents and short-term investments in 2008 was primarily due to cash used in operating activities of \$19.0 million offset by cash provided by net sales of short-term investments as discussed below.

**Operating Activities**

Net cash used in operating activities totaled \$19.0 million in the three-month period ended March 31, 2008. Cash used in operating activities during 2008 was primarily driven by our net losses from operations of \$17.5 million, increase in inventory of \$4.8 million, adjusted for the non-cash compensation charge of \$1.5 million related to SFAS No. 123R and a net non-cash income of \$1.3 million related to the Euro-denominated convertible note we issued to Ipsen. The increase in inventories was primarily due to the manufacture of Increlex® and purchases of Somatuline® Depot that were partially funded by an increase in accrued expenses.

**Investing Activities**

Net cash provided by investing activities totaled \$12.3 million in the three-month period ended March 31, 2008. Cash provided by investing activities represented net proceeds from purchase, sales and maturities of investments.

**Financing Activities**

Net cash provided by financing activities totaled \$0.2 million in the three-month period ended March 31, 2008. Cash provided by financing activities was primarily due to issuances of common stock under our equity compensation plans.





## Table of Contents

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 March 31, 2008 will be sufficient to meet our projected operating and capital expenditure requirements through at least March 31, 2009 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<sup>®</sup> and Somatuline<sup>®</sup> Depot at the anticipated level;

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

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

the costs, timing and scope of additional regulatory approvals for Increlex<sup>®</sup> use in Primary IGFD and/or other regions;

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

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

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

any required repayment of the convertible notes we issued 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 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 three-month period ended March 31, 2008, there were no 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, 2007.

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

The primary objective of our investment activities is to preserve our capital for the purpose of funding operations while at the same time maximizing the income we receive from our investments without significantly increasing risk. To achieve these objectives, our investment policy allows us to maintain a portfolio of cash equivalents and short-term investments in a variety of securities, including asset-backed securities, commercial paper, corporate bonds, government sponsored entity bonds and money market funds.

**Table of Contents*****Interest Rate Risk***

As of March 31, 2008, we held \$65.9 million in cash and cash equivalents consisting of highly liquid investments having original maturity dates of less than 90 days. Declines of interest rates over time would reduce our interest income from our highly liquid short-term investments. Based upon our balance of cash and cash equivalents, a decrease in interest rates of 100 basis points would cause a corresponding decrease in our annual interest income of approximately \$0.7 million for these investments. Due to the nature of our highly liquid cash equivalents, a change in interest rates would not materially change the fair market value of our cash and cash equivalents.

As of March 31, 2008, we held \$29.0 million in short-term investments, which consisted primarily of money market funds held by large institutions in the United States, federal agency bonds, commercial paper, corporate bonds and asset-backed securities maturing in less than twelve months. The weighted average interest rate of our investments held was approximately 4.2% during the three-month period ended March 31, 2008. A decline in interest rates over time would reduce our interest income from our short-term investments. A decrease in interest rates of 100 basis points would cause a corresponding decrease in our annual interest income of approximately \$0.3 million for these investments. Due to the nature of our highly liquid cash equivalents, a change in interest rates would not materially change the fair market value of our short-term investments.

***Foreign Currency Exchange Risk***

The Euro-denominated convertible note we issued to Ipsen was recorded at 22.2 million or approximately \$35.0 million, net of discount and including accrued interest, at March 31, 2008. The face value of the note is 30.0 million plus accrued interest of 0.4 million and the discount of 8.2 million will be accreted over the life of the convertible note. The convertible note accrues interest at a rate of 2.5% per year, compounded quarterly until maturity in October 2011. As currency rates change, the net recorded value of the convertible 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 statements of operations. A hypothetical change of 10% in currency rates could result in an adjustment to the consolidated statements of operations of approximately \$3.5 million. Upon maturity of the convertible note in October 2011, if the holder of the note chooses to not convert, we would be required to repay the convertible note of 33.2 million which includes accrued interest. A hypothetical change of 10% in currency rates could result in our paying \$5.2 million more or less in cash than anticipated upon issuance of the convertible note.

Associated with the issuance of this convertible note to Ipsen, 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 statements of operations other income of \$2.0 million for the quarter ended March 31, 2008. At March 31, 2008, the embedded derivative liability was valued at 6.2 million or approximately \$9.8 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 our common stock, the conversion price of note, volatility of our common stock, the expected life, the Euro to U.S. dollar currency exchange rate 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 statements of operations of approximately \$1.0 million.

**ITEM 4. CONTROLS AND PROCEDURES.*****Evaluation of Disclosure Controls and Procedures***

Based on their evaluation as of March 31, 2008, 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 quarter ended March 31, 2008 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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

## Edgar Filing: TERCICA INC - Form 10-Q

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

---

**Table of Contents**

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.*

*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 February 29, 2008.*

**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 March 31, 2008, we had an accumulated deficit of \$306.7 million. We incurred a net loss of \$17.5 million during the quarter ended March 31, 2008. We may not be able to generate significant revenues from operations and may not be able to attain profitability. We expect to incur substantial net losses, in the aggregate and on a per share basis, for the foreseeable future as we attempt to develop, market and sell Increlex<sup>®</sup> for severe Primary IGFD and Primary IGFD and Somatuline<sup>®</sup> 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<sup>®</sup> for the treatment of severe Primary IGFD and Primary IGFD, as well as on the successful commercialization by us of Somatuline<sup>®</sup> 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<sup>®</sup> or Somatuline<sup>®</sup> Depot, or attain profitability, we will not be able to sustain our operations.

---

**Table of Contents**

***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<sup>®</sup> in the United States for the treatment of severe Primary IGFD, rhIGF-1 had never been commercialized in the United States or Europe for any indication. Even though the FDA has approved Increlex<sup>®</sup> for sale in the United States, and Somatuline<sup>®</sup> 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.

***If we do not receive additional regulatory marketing approvals for Increlex<sup>®</sup> in Primary IGFD, our business will be harmed.***

## Edgar Filing: TERCICA INC - Form 10-Q

We are currently developing Increlex<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> Depot and/or Increlex<sup>®</sup> or share the costs of such developments in a manner that is commercially feasible for us. In addition to cross-licensing agreements for Somatuline<sup>®</sup> Depot and Increlex<sup>®</sup>, we and Ipsen have granted to each other a right of first negotiation for



**Table of Contents**

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. We may encounter development difficulties that delay, increase the costs of, or preclude any further progress of either or both of our growth hormone/IGF-1 combination product candidates. In addition, the FDA and other countries' regulatory authorities have substantial discretion in the approval process. They may decide that our pre-clinical data, 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. There can be no assurance that we will receive all or any remaining portion of the anticipated proceeds from our 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, 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;

Edgar Filing: TERCICA INC - Form 10-Q

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;

**Table of Contents**

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;

suppliers, supply partners, and/or contract manufacturers fail to follow good manufacturing practices;

interim results of the clinical trial are inconclusive or negative;

clinical trial drug supplies may not be available, may not be available in sufficient quantities, may not be available in the preferred formulation, 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;

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<sup>®</sup> and Somatuline<sup>®</sup> 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<sup>®</sup> are incorrect, our expected revenues, including potential royalties from our collaboration with Ipsen, may be delayed or substantially reduced. Since Increlex<sup>®</sup> is approved by the FDA for severe Primary IGFD and Somatuline<sup>®</sup> 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. Even if a patient receives reimbursement approval, the patient may still choose not to begin, or to discontinue, treatment with either of our drugs.

We believe that the annual wholesale acquisition cost, at present, of Increlex<sup>®</sup> therapy for the treatment of severe Primary IGFD for a 24 kilogram child at a 120mcg/kg twice daily dose at 100% compliance is approximately \$36,000 per year. The actual cost per year per patient for Increlex<sup>®</sup> will depend on the price charged by wholesalers and distributors that purchase from Tercica, and will vary by the weight of the child, the treatment dose prescribed and the level of compliance. If our assumptions regarding the revenue per patient of Increlex<sup>®</sup> therapy for the treatment of severe Primary IGFD and Primary IGFD are incorrect, our expected revenues and the market opportunity for Increlex<sup>®</sup> therapy for the treatment of severe Primary IGFD and Primary IGFD may be substantially reduced.

## Edgar Filing: TERCICA INC - Form 10-Q

We believe that the annual wholesale acquisition cost, at present, of Somatuline<sup>®</sup> Depot therapy for the treatment of acromegaly is approximately \$28,800 at 100% compliance of the 90 microgram dose. The actual cost per year will depend on the price charged by wholesalers and distributors that purchase from Tercica, and will vary by the treatment dose prescribed and the level of compliance. 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<sup>®</sup> Depot for the treatment of acromegaly may be substantially reduced.

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

---

## **Table of Contents**

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 our 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 destroy 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.*

## Edgar Filing: TERCICA INC - Form 10-Q

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

We cannot predict the relative competitive positions of Increlex<sup>®</sup>, Somatuline<sup>®</sup> Depot and any growth hormone/IGF-1 combination product candidates that we may develop. However, we expect that the factors set forth under **Risks Related to Our Business** 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.

---

## **Table of Contents**

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

Growth hormone products compete with Increlex<sup>®</sup> for the treatment of severe Primary IGFD. If Increlex<sup>®</sup> receives regulatory approval for the treatment of patients with Primary IGFD, growth hormone products will also compete with Increlex<sup>®</sup> for the treatment of patients in that indication. The major suppliers of commercially available growth hormone products in the United States are Genentech Inc., Eli Lilly and Company, Teva Pharmaceutical Industries Ltd., Novo Nordisk A/S, Pfizer Inc and Merck-Serono International S.A. Investigators from a Novo Nordisk clinical trial in 2003 presented initial 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, Accretropin by Cangene, and Valtropin<sup>®</sup> by LG Life Sciences have been approved in the United States and may be approved in other countries. Accordingly, we expect that several growth hormone products will compete directly with Increlex<sup>®</sup> for the treatment of children with Primary IGFD. We are also aware that several companies are developing long-acting formulations of growth hormone for the treatment of short stature including Altus Pharmaceuticals and LG Life Sciences.

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<sup>®</sup>.

We believe that Bristol-Myers 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 that Elixir Pharmaceuticals Inc. has licensed certain rights to Bristol-Myers Squibb Company's growth hormone secretagogues and that both companies are actively developing these compounds for use in various indications including 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<sup>®</sup>.

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<sup>®</sup>, and other products.

In the United States and Canada, Somatuline<sup>®</sup> Depot competes directly with Sandostatin LAR<sup>®</sup> Depot and Somavert<sup>®</sup> for the treatment of acromegaly. Sandostatin LAR<sup>®</sup> Depot is a somatostatin analogue and has the same mechanism of action as Somatuline<sup>®</sup> Depot. Sandostatin LAR<sup>®</sup> 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<sup>®</sup>, a growth hormone antagonist, and Sandostatin LAR<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> Depot. We are also aware that Novartis is developing pasireotide (SOM 230), DeveloGen AG is developing Somatoprin (DG 3173), and that Ipsen is developing dopastatin for the treatment of acromegaly and other hormone secreting tumors. If approved, these therapies would compete with Somatuline<sup>®</sup> 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<sup>®</sup> or Somatuline<sup>®</sup> Depot.

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

We source all of our Increlex<sup>®</sup> 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.





---

**Table of Contents**

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

We currently source all of our Increlex<sup>®</sup> fill-finish manufacturing and portions of release testing through a single-source third-party supplier. This supplier is the only FDA-approved manufacturer currently available to us, and could only be replaced by qualification of a new site for the same operations. We have negotiated a short-term commercial agreement with this fill-finish manufacturer and during the term of this agreement, we are attempting to move our process to 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<sup>®</sup> 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<sup>®</sup> and our revenue growth could be adversely affected. A delay in this transfer may also result in a shortage of Increlex<sup>®</sup> and a loss of revenues.

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

We currently source all of our Increlex<sup>®</sup> bulk manufacturing and portions of release testing through a single-source third-party supplier, Lonza Baltimore, Inc. This supplier is the only FDA-approved manufacturer currently available to us, and could only be replaced by qualification of a new manufacturing site for the same operations. We have negotiated 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, Inc. 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<sup>®</sup> by Lonza Hopkinton. A delay in this transfer could result in a shortage of bulk Increlex<sup>®</sup> and a significant loss of revenues. If we are not able to complete this transfer, our ability to supply Increlex<sup>®</sup> will be impaired and our business will suffer irreparable harm.

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

The facilities and operations of our contract manufacturers to manufacture and test Increlex<sup>®</sup>, and of Ipsen to manufacture and test Somatuline<sup>®</sup> 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<sup>®</sup> Depot. Other than with respect to our agreement with Lonza Hopkinton, 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<sup>®</sup> and Somatuline<sup>®</sup> 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



**Table of Contents**

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.

***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 any replacement supplier 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.

***If product is lost or damaged during manufacturing, storage or shipment, our business may suffer.\****

We rely entirely on third-party contractors for the manufacturing, shipping and storage of our products. If product in filled, finished, or other form, or its active ingredient, is lost or damaged while in the possession of our third-party contractors, we may not have adequate rights to seek indemnification from our third-party contractors or their insurance companies for the replacement cost of the lost or damaged goods. Our agreement with the third-party contractor responsible for the loss or damage may waive their liability altogether or limit their liability to an amount well below the replacement cost of the lost or damaged goods. In addition, our insurance policies may not provide coverage or may provide inadequate coverage for the lost or damaged goods, or we may decide not to file an insurance claim in order to avoid increasing in the cost of or cancellation of our insurance and/or to avoid the negative impact such claim could have on our prospective ability to insure our business operations at a commercially reasonable cost or at all. If we cannot recover the replacement cost of the lost or damaged goods from the responsible third-party contractor or their insurance companies, or our insurance companies, our financial performance may be negatively affected and our business may suffer. In addition, such losses or damages could delay or prevent us from manufacturing and supplying commercial or clinical product in the time frames or in the quantities that we anticipate will be required for the support of our collaborators product sales or product development activities, all of which would harm the development and commercial potential of our product.

---

**Table of Contents**

***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<sup>®</sup> 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<sup>®</sup> 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 or an unfavorable risk-benefit ratio 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<sup>®</sup> or Somatuline<sup>®</sup> 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 from the date of approval. The orphan drug rules are similar in the European Union and marketing exclusivity is for a period of ten years from the date of approval.

The FDA has granted Increlex<sup>®</sup> orphan drug marketing exclusivity for the long-term treatment of patients with severe Primary IGFD and has granted Somatuline<sup>®</sup> Depot orphan drug marketing exclusivity for the long-term treatment of acromegaly. In the European Union, the European Medicines Agency (EMA) has granted Increlex orphan drug marketing exclusivity for the long-term treatment of patients with severe Primary IGFD. Although Increlex<sup>®</sup> and Somatuline<sup>®</sup> Depot have received marketing exclusivity, the FDA and EMA 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<sup>®</sup> or Somatuline<sup>®</sup> Depot that demonstrate clinical superiority or provide a major contribution to patient care may be approved for marketing by the FDA and EMA 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.

***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 AG (through the acquisition of Chiron Corporation) has developed a process to manufacture rhIGF-1 using yeast expression and has intellectual property with respect to that process. In the event there are other rhIGF-1 products approved by the FDA to treat indications other than those covered by Increlex<sup>®</sup>, physicians may elect to prescribe a competitor's product containing rhIGF-1 to treat the indications for which Increlex<sup>®</sup> has received and may receive approval. This is commonly referred to as off-label use. While under FDA regulations a competitor is not allowed to promote off-label use of its product, the FDA does not regulate the practice of medicine and as a result cannot direct physicians as to which product containing rhIGF-1 to prescribe to their patients. 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<sup>®</sup> Depot, which would enable physicians to prescribe

## Edgar Filing: TERCICA INC - Form 10-Q

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.

**Table of Contents**

***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 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

---

**Table of Contents**

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<sup>®</sup> Depot or Increlex<sup>®</sup>. 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<sup>®</sup>, or any growth hormone/IGF-1 combination product or Somatuline<sup>®</sup> 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<sup>®</sup>. 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<sup>®</sup>, we cannot predict whether our activities relating to the development and commercialization of Increlex<sup>®</sup> in the United States will be found to infringe Novartis's patent in the event Novartis brings patent infringement proceedings against us. We may not be able to obtain a license to Novartis's patent under commercially reasonable terms, if at all. If we are unable to obtain a license to Novartis's patent, and if in any patent infringement proceeding Novartis brings against us the court decides that our activities relating to the development and commercialization of Increlex<sup>®</sup> in the United States infringe Novartis's patent, the court may award damages and/or injunctive relief to Novartis. Any such damages, injunctive relief and/or other remedies the court may award could render any further development and commercialization of Increlex<sup>®</sup> commercially infeasible for us or otherwise curtail or cease any further development and commercialization of Increlex<sup>®</sup>.

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

some patent applications in the United States may be maintained in secrecy until the patents are issued,



**Table of Contents**

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 (and/or an affiliate of 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. 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 (and under our charter documents, holders of at least 60% of the outstanding shares of our common stock may remove any director or the entire Board of Directors without cause). 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 with one in 2008 and up to four after our 2009 annual meeting of stockholders. 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's license to develop, manufacture, market and sell Increlex<sup>®</sup>, to develop, market and sell Somatuline<sup>®</sup> Depot, or to develop, manufacture, market and sell our growth hormone/IGF-1 combination product candidates. This may prevent us from continuing our business.

**Table of Contents**

***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. Under a letter agreement of July 2007, we and Genentech amended the U.S. license and collaboration agreement to provide that until such time as we initiate the development of rhIGF-1 for diabetes (or a substitute indication mutually agreed to by us and Genentech that has a potential market of greater than \$250 million and is not an indication for the central nervous system), Genentech may elect to initiate such development for diabetes or, upon our and Genentech's mutual agreement, the development of a substitute indication that has a potential market size of greater than \$250 million and is not an indication of the central nervous system. In addition, if we elect to discontinue the development of rhIGF-1 for diabetes or a substitute indication selected by us with Genentech's consent, Genentech has the right to assume development of such indication. In the event that Genentech initiates the development of rhIGF-1 for any such indication before we do or assumes the development of rhIGF-1 for any such indication after such development is discontinued by us, our rights under the agreement for such indication would terminate and Genentech would be granted a non-exclusive license under our rhIGF-1 intellectual property and technology to manufacture, use and sell rhIGF-1 products for diabetes, or if applicable the substitute indication, subject to an obligation to pay us milestone payments and/or royalties to be negotiated by Genentech and us in good faith on sales of these products.

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. Upon opt-in, Genentech may also choose to exercise a commercial option to acquire the right for the deciding vote on all commercialization matters pertaining to short stature indications; however, we would remain the lead commercialization party for short stature indications. 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.

---

**Table of Contents**

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

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

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

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

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

a minimum price for our common stock;

the accuracy of representations and warranties made to Kingsbridge;

compliance with laws;

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

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

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

## Edgar Filing: TERCICA INC - Form 10-Q

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.

---

**Table of Contents**

***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 to Ipsen convertible notes in the principal amounts of \$25.0 million, 30.0 million and \$15.0 million. 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 principal amount 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;

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 March 31, 2008 will be sufficient to meet our projected operating and capital expenditure requirements through at least March 31, 2009 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<sup>®</sup> and Somatuline<sup>®</sup> Depot at the anticipated level;

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

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

the costs, timing and scope of additional regulatory approvals for Increlex<sup>®</sup> use in Primary IGFD and/or other regions;

## Edgar Filing: TERCICA INC - Form 10-Q

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 CEF. 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,

---

## **Table of Contents**

we must first obtain Ipsen's approval to issue shares of common stock to Genentech under our 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 March 31, 2008, we had 139 full-time employees, and we expect to hire additional employees in the near term. Our offices are located in the San Francisco Bay area where competition for personnel with biopharmaceutical skills is intense. If we fail to identify, attract, retain and motivate these highly skilled personnel, we may be unable to continue our development and commercialization activities.

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

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

One potential risk of using growth factors like rhIGF-1 is that it may increase the likelihood of developing cancer or, if patients already have cancer, that the cancer may develop more rapidly. Increlex<sup>®</sup> may also increase the risk that diabetic patients may develop or worsen an existing retinopathy, which could lead to the need for additional therapy such as laser treatment of the eyes or result in blindness. In our Phase III clinical trials for severe Primary IGF1, the data of which we submitted to the FDA in our NDA, some patients experienced hypoglycemia, or low blood glucose levels. Other side effects noted in some patients include hearing deficits, enlargement of the tonsils and intracranial hypertension.

Somatuline<sup>®</sup> 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 hypothyroidism. Cardiac conduction abnormalities have also occurred during treatment with this class of drugs.

There may also be other adverse events associated with the use of Increlex<sup>®</sup> or Somatuline<sup>®</sup> 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<sup>®</sup>, Somatuline<sup>®</sup> Depot and our growth hormone/IGF-1 combination product candidates in certain indications, with the exception of certain liabilities covered up to certain limits by our insurance policies, we are not indemnified by any third party, including our contract manufacturers, for any liabilities that we bear and that arise 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.

In addition, we are contractually obligated to indemnify certain contract manufacturers for certain liabilities that they would otherwise bear and that arise from use of our products or product candidates. Because such contractually assumed liabilities are not covered by any of our insurance policies, the negative financial impact of any such liability could hinder or prevent us from continuing our business.

*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.





---

**Table of Contents**

***We must implement additional finance and accounting systems, procedures and controls as we grow our business and organization.***

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. Section 404 requires annual management assessments of the effectiveness of our internal control over financial reporting and an opinion by our independent registered public accountants on the effectiveness of internal controls over financial reporting. 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 commercial, medical, scientific, regulatory and pharmaceutical operations personnel, whose knowledge of our industry and technical expertise would be extremely difficult to replace. We have at-will employment contracts with all of our executive officers. They may terminate their employment without cause or good reason and without notice to us.

**Risks Related to Our Common Stock**

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

Analysts who cover our business and operations provide valuations regarding our stock price and make recommendations whether to buy, hold or sell our stock. Our stock price may be dependent upon such valuations and recommendations. Analysts' valuations and recommendations are based primarily on our reported results and our and their forecasts and expectations concerning our future results regarding, for example, expenses, revenues, clinical trials, regulatory marketing approvals and competition. Our future results are subject to substantial uncertainty, and we may fail to meet or exceed our and analysts' forecasts and expectations as a result of a number of factors, including those discussed under the section entitled "Risks Related to Our Business" above. If our results do not meet our and analysts' forecasts and expectations, our stock price could decline as a result of analysts lowering their valuations and recommendations or otherwise.

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

As of March 31, 2008, our directors, executive officers and principal stockholders and their affiliates beneficially owned approximately 81.2% of our common stock. Our greater than five percent beneficial owners include Ipsen and its affiliates, which beneficially owned 42.7% (not including shares subject to limited voting agreements with certain of our stockholders); entities affiliated with MPM BioVentures III LLC, which beneficially owned 13.4%; entities affiliated with Prospect Management Co. II, LLC, which beneficially owned 5.9%; 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;

**Table of Contents**

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<sup>®</sup> 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 October 13, 2008 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 include, among others, provisions that:

authorize the issuance of blank check preferred stock that could be issued by our Board of Directors to increase the number of outstanding shares and hinder a takeover attempt;

limit who may call a special meeting of stockholders;

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

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

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

## Edgar Filing: TERCICA INC - Form 10-Q

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.

**Table of Contents**

*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.

## Edgar Filing: TERCICA INC - Form 10-Q

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

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

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

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

If our stockholders sell substantial amounts of our common stock, including shares issued upon the exercise of outstanding options or pursuant to the CEFF, and the shares issued or issuable to 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 March 31, 2008, we had 51,583,550 outstanding shares of common stock. As of March 31, 2008, we had 6,591,205 shares subject to outstanding options and restricted stock units granted under our equity compensation plans. In addition, as of March 31, 2008, 15,640,748 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.

**Table of Contents**

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, 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.

**Table of Contents****ITEM 5. OTHER INFORMATION.**

On February 26, 2008, our Board of Directors amended the Tercica, Inc. 2004 Stock Plan, or the 2004 Plan, to provide for the grant thereunder of restricted stock unit awards. Prior to such amendment, the 2004 Plan provided for the grant of restricted stock awards, but not restricted stock unit awards. Under the terms of the 2004 Plan, as amended, restricted stock unit awards may be granted under the 2004 Plan pursuant to restricted stock unit award agreements adopted by the plan administrator, generally our Board of Directors or the Compensation Committee of the Board. Under the 2004 Plan, as amended, restricted stock unit awards may vest over the passage of time, the achievement of performance goals, or the occurrence of other events determined by the plan administrator. Upon meeting vesting criteria applicable to a restricted stock unit award, a participant is entitled to receive a payout in the form of cash or shares of our common stock. The timing of such payments is determined by the plan administrator. In addition, the plan administrator may permit participants to defer the payment of such payouts. Dividend equivalents may be credited in respect of shares of our common stock covered by restricted stock units, as determined by the plan administrator and contained in the applicable restricted stock unit award agreement. The amendments to the 2004 Plan also effected certain technical amendments to the 2004 Plan, including with respect to compliance with Section 409A of the Internal Revenue Code of 1986, as amended. The foregoing is only a brief description of the 2004 Plan amendments, does not purport to be complete and is qualified in its entirety by reference to the 2004 Plan, as amended, that is filed as Exhibit 10.3A to this quarterly report on Form 10-Q.

**ITEM 6. EXHIBITS.**

<b>Exhibit Number</b>	<b>Description</b>
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)
10.3A	2004 Stock Plan, as amended
10.3C	Form of Employee Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement under the 2004 Stock Plan
10.9S	2008 Executive Officer Compensation Arrangements
10.9AA	Form of Letter Agreement amending terms of Executive Officer Employment Agreements
15.1	Letter regarding Unaudited Interim Financial Information
31.1	Certification of Chief Executive Officer of Tercica, Inc., as required by Rule 13a-14(a) or Rule 15d-14(a)
31.2	Certification of Chief Financial Officer of Tercica, Inc., as required by Rule 13a-14(a) or Rule 15d-14(a)





**Table of Contents**

**Exhibit**

<b>Number</b>	<b>Description</b>
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)

- (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.

**Table of Contents**

**SIGNATURE**

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

Dated: May 12, 2008

TERCICA, INC.  
(Registrant)

/s/ Ajay Bansal  
Ajay Bansal  
Chief Financial Officer  
(Authorized Officer and Principal Financial Officer)