

TERCICA INC  
Form 10-Q  
November 03, 2006  
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 September 30, 2006

OR

**Transition report pursuant to Section 13 or 15(d) of the Securities and Exchange Act of 1934**  
For the Transition Period from to

Commission File Number 000-50461

\_\_\_\_\_  
**TERCICA, INC.**

(Exact name of Registrant as specified in its charter)

\_\_\_\_\_

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

2000 Sierra Point Parkway, Suite 400

Brisbane, San Francisco, CA 94005

(650) 624-4900

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

Identification Number)

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

(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, or a non-accelerated filer. (Check one):

Large accelerated filer  Accelerated filer  Non-accelerated filer

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

As of October 26, 2006, there were 50,117,193 shares of the Registrant's Common Stock outstanding.

---

**Table of Contents**

**TERCICA, INC.**

**FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2006**

**INDEX**

	<b>Page</b>
<b><u>PART I FINANCIAL INFORMATION</u></b>	
ITEM 1. <b><u>FINANCIAL STATEMENTS (Unaudited)</u></b>	
<b><u>Condensed Balance Sheets</u></b> September 30, 2006 and December 31, 2005	3
<b><u>Condensed Statements of Operations</u></b> Three and nine months ended September 30, 2006 and 2005, and the period from October 1, 2000 (inception) through September 30, 2006	4
<b><u>Condensed Statements of Cash Flows</u></b> Nine months ended September 30, 2006 and 2005, and the period from October 1, 2000 (inception) through September 30, 2006	5
<b><u>Notes to the Condensed Financial Statements</u></b>	6
ITEM 2. <b><u>MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u></b>	20
ITEM 3. <b><u>QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u></b>	31
ITEM 4. <b><u>CONTROLS AND PROCEDURES</u></b>	31
<b><u>PART II OTHER INFORMATION</u></b>	
ITEM 1. <b><u>LEGAL PROCEEDINGS</u></b>	32
ITEM 1A. <b><u>RISK FACTORS</u></b>	34
ITEM 5. <b><u>OTHER INFORMATION</u></b>	52
ITEM 6. <b><u>EXHIBITS</u></b>	53
<b><u>Signatures</u></b>	54

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

	September 30,	December 31,
	2006	2005
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 12,994	\$ 14,817
Short-term investments	41,283	43,809
Accounts receivable, net	128	
Inventories, net	1,728	1,636
Prepaid expenses and other current assets	2,103	1,673
Total current assets	58,236	61,935
Property and equipment, net	4,088	4,021
Restricted cash	340	340
Other assets	813	20
Total assets	\$ 63,477	\$ 66,316
<b>Liabilities and stockholders equity</b>		
Current liabilities:		
Accounts payable	\$ 1,800	\$ 2,245
Accrued expenses	6,141	5,750
Other current liabilities	302	70
Total current liabilities	8,243	8,065
Deferred rent	1,469	1,429
Other liabilities		24
Total liabilities	9,712	9,518
Commitments and contingencies		
Stockholders equity:		
Common stock	38	32
Additional paid-in capital	261,484	225,100
Deferred stock compensation		(2,591)
Accumulated other comprehensive loss		(2)
Deficit accumulated during the development stage	(207,757)	(165,741)
Total stockholders equity	53,765	56,798

Edgar Filing: TERCICA INC - Form 10-Q

Total liabilities and stockholders' equity	\$ 63,477	\$ 66,316
--	-----------	-----------

*See accompanying notes.*

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

	Three Months Ended		Nine Months Ended		Period from
	September 30,		September 30,		October 1, 2000
					(inception)
					through
					September 30,
	2006	2005	2006	2005	2006
Net product sales	\$ 316	\$	\$ 567	\$	\$ 567
Costs and expenses:					
Cost of product sales	516		1,156		1,156
Research and development*	3,513	5,681	12,739	16,871	83,951
Selling, general and administrative*	10,162	6,393	31,252	17,031	77,155
Acquired in-process research and development					8,158
Total costs and expenses	14,191	12,074	45,147	33,902	170,420
Operating loss	(13,875)	(12,074)	(44,580)	(33,902)	(169,853)
Interest expense		(106)		(899)	(1,186)
Interest and other income, net	812	662	2,564	1,774	6,310
Net loss	(13,063)	(11,518)	(42,016)	(33,027)	(164,729)
Deemed dividend related to beneficial conversion feature of convertible preferred stock					(44,153)
Net loss allocable to common stockholders	\$ (13,063)	\$ (11,518)	\$ (42,016)	\$ (33,027)	\$ (208,882)
Basic and diluted net loss per share	\$ (0.35)	\$ (0.37)	\$ (1.14)	\$ (1.09)	
Shares used to compute basic and diluted net loss per share	37,550	31,394	36,906	30,272	

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

Research and development	\$ 525	\$ 308	\$ 1,502	\$ 935	\$ 4,871
Selling, general and administrative	1,027	179	2,814	807	5,533
Total	\$ 1,552	\$ 487	\$ 4,316	\$ 1,742	\$ 10,404

*See accompanying notes.*

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

	Nine Months Ended September 30,	2005	Period from October 1, 2000 (inception) through September 30, 2006
	2006	2005	2006
<b>Cash flows from operating activities:</b>			
Net cash used in operating activities	\$ (38,331)	\$ (30,788)	\$ (142,233)
<b>Cash flows from investing activities:</b>			
Purchases of property and equipment	(900)	(2,446)	(6,578)
Proceeds from sale of equipment			300
Purchases of available-for-sale securities	(38,254)	(89,391)	(325,732)
Proceeds from sales and maturities of available-for-sale securities	41,128	80,600	284,568
Net cash provided by (used in) investing activities	1,974	(11,237)	(47,442)
<b>Cash flows from financing activities:</b>			
Net proceeds from issuance of preferred stock			63,960
Net proceeds from issuance of common stock	34,534	51,619	137,290
Other, net		(76)	1,419
Net cash provided by financing activities	34,534	51,543	202,669
Net increase (decrease) in cash and cash equivalents	(1,823)	9,518	12,994
Cash and cash equivalents, beginning of period	14,817	14,126	
Cash and cash equivalents, end of period	\$ 12,994	\$ 23,644	\$ 12,994

*See accompanying notes.*



---

**Table of Contents**

**TERCICA, INC.**

**(A DEVELOPMENT STAGE COMPANY)**

**NOTES TO THE CONDENSED FINANCIAL STATEMENTS**

**(Unaudited)**

**1. Company and Summary of Significant Accounting Policies**

**Organization and Business**

Tercica, Inc. (the Company) is a biopharmaceutical company committed to improving endocrine health by partnering with the endocrine community to develop and commercialize new therapeutics for short stature and other metabolic disorders. The Company's predecessor, Tercica Limited, a New Zealand Company, was formed in October 2000. Tercica Medica, Inc. was incorporated in Delaware in December 2001, and subsequently changed its name to Tercica, Inc.

In April 2002, the Company licensed the rights of Genentech, Inc. to develop, manufacture and commercialize rhIGF-1 products for a broad range of indications in the United States, including short stature and diabetes, but excluding diseases and conditions of the central nervous system. In July 2003, the Company signed an international license and collaboration agreement with Genentech obtaining the rights to develop and commercialize rhIGF-1 products outside of the United States for all indications other than diseases and conditions of the central nervous system. The international license and collaboration agreement provides that the Company must enter into a written agreement with another company if it desires to commercialize Increlex for the treatment of diabetes outside of the United States.

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

In October 2006, the Company finalized its worldwide strategic collaboration with Ipsen, S.A ( Ipsen ). Pursuant to the collaboration, Ipsen granted to the Company the exclusive right under Ipsen's patents and know-how to develop and commercialize Somatuline® Autogel® in the United States and Canada for all indications other than ophthalmic indications. In July 2006, Somatuline® Autogel® was approved for marketing by Health Canada for the treatment of acromegaly. Acromegaly is a hormonal disorder that results when a tumor in the pituitary gland produces excess growth hormone. In October 2006, Ipsen submitted a New Drug Application ( NDA ) with the U.S. Food and Drug Administration ( FDA ) for this indication. Pursuant to the collaboration, the Company granted to Ipsen and its affiliates the exclusive right under the Company's patents and know-how to develop and commercialize Increlex in all countries of the world except the United States, Japan, Canada, and for a certain period of time, Taiwan and certain countries of the Middle East and North Africa, for all indications, other than treatment of central nervous system indications and diabetes indications. A decision regarding the Company's MAA for Increlex by the European Medicines Evaluation Agency ( EMEA ), is expected in late 2006 or early 2007. See Note 10 Ipsen Collaboration for further detail on the Company's collaboration with Ipsen.

Although the Company began commercializing Increlex in 2006, the Company is considered to be a development stage company as it has not yet generated significant revenue from product sales. The Company has devoted substantially all of its efforts since incorporation to the development and commercialization of Increlex for the treatment of severe Primary IGFD and Primary IGFD. These efforts have included establishing its facilities, recruiting personnel, conducting research and development, business development, business and financial planning and raising capital.



**Table of Contents**

**TERCICA, INC.**

**(A DEVELOPMENT STAGE COMPANY)**

**NOTES TO THE CONDENSED FINANCIAL STATEMENTS (continued)**

**(Unaudited)**

**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 results of the Company's operations can vary during each quarter of the year. Therefore, the results and trends in these interim financial statements may not be the same as those for the full year. The information included in this Quarterly Report on Form 10-Q should be read in conjunction with the audited financial statements for the year ended December 31, 2005, included in the Company's Annual Report on Form 10-K for the year ended December 31, 2005, filed with the Securities and Exchange Commission on March 16, 2006, as amended.

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

**Follow-on Public Offering**

On September 9, 2005, the Company filed a shelf registration statement with the SEC pursuant to which the Company may, from time to time, offer and sell shares of the Company's common stock and preferred stock, various series of debt securities and/or warrants to purchase any of such securities, either individually or in units, in one or more offerings, with a total value of up to \$75,000,000, at prices and on terms to be determined by market conditions at the time of any offering made under the shelf registration statement. On January 27, 2006, the Company completed the sale of 5,750,000 shares of its common stock under this shelf registration statement, at a price to the public of \$6.40 per share, including the exercise of the over-allotment option by the underwriters. Net cash proceeds from this offering were \$34,186,000 after deducting underwriter discounts and other offering expenses.

**Use of Estimates**

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

**Concentrations**

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

The Company sources all of its fill-finish manufacturing and testing and final product storage and distribution operations, as well as its bulk manufacturing, testing, and shipping operations, through single-source third-party suppliers and contractors, and the Company obtains specific components and raw materials used to manufacture Increlex from either single-source or sole-source suppliers. If these contract facilities, suppliers or contractors become unavailable to the Company for any reason, the Company may be delayed in manufacturing Increlex or may be unable to maintain validation for the manufacturing of Increlex, which could delay or prevent the supply of commercial and clinical product, or delay or otherwise adversely affect revenues. The Company strives to maintain an adequate level of inventory to mitigate this potential negative impact. Further, the Company is responsible for the manufacture and supply of Increlex to Ipsen (through its contract manufacturer) for Ipsen's clinical development and commercial needs. In the event the Company fails to meet Ipsen's supply obligations, Ipsen would have the right to

exercise its option to manufacture Increlex on its own or to engage a third-party manufacturer to do so.

**Table of Contents****TERCICA, INC.****(A DEVELOPMENT STAGE COMPANY)****NOTES TO THE CONDENSED FINANCIAL STATEMENTS (continued)****(Unaudited)****Inventories**

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

Products released from inventory for product that is sold are recorded in cost of goods sold. Products released from inventory as free goods are recorded in selling, general and administrative expenses. Accordingly, cost of inventory write-downs are allocated to cost of goods sold and selling, general and administrative expenses as appropriate.

The Company recorded write-offs of approximately \$636,000 and \$1,663,000, during the three and nine months ended September 30, 2006, respectively. Inventory write-offs for the nine months ended September 30, 2006 primarily related to manufacturing lot failures in the second and third quarters of 2006. Cost of inventory write-offs allocated to cost of goods sold and selling, general and administrative expenses were \$290,000 and \$346,000, respectively, for the three months ended September 30, 2006. Cost of inventory write-offs allocated to cost of goods sold and selling, general and administrative expenses were \$732,000 and \$931,000, respectively, for the nine months ended September 30, 2006.

Inventories consisted of the following (in thousands):

	September 30,	December 31,
	2006	2005
Raw materials	\$ 1,022	\$ 319
Work-in-process	320	1,229
Finished goods	386	88
Total	\$ 1,728	\$ 1,636

As of September 30, 2006 and December 31, 2005, the Company's finished goods included obsolescence write downs of \$246,000 and \$45,000, respectively.

**Revenue Recognition**

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

**Research and Product Development Costs**

In accordance with Statement of Financial Accounting Standards (SFAS) No. 2, *Accounting for Research and Development Costs*, research and development costs are expensed as incurred. Research and development expenses consist primarily of costs associated with manufacturing

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

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

**Table of Contents****TERCICA, INC.****(A DEVELOPMENT STAGE COMPANY)****NOTES TO THE CONDENSED FINANCIAL STATEMENTS (continued)****(Unaudited)****Clinical Trial Expenses**

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

**Acquired In-Process Research and Development**

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

**Stock-Based Compensation**

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

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

**Comprehensive Loss**

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

	Three Months Ended	Nine Months Ended
--	--------------------	-------------------

Edgar Filing: TERCICA INC - Form 10-Q

	September 30,		September 30,	
	2006	2005	2006	2005
Net loss, as reported	\$ (13,063)	\$ (11,518)	\$ (42,016)	\$ (33,027)
Change in unrealized losses on marketable securities	15	11	2	60
Comprehensive loss	\$ (13,048)	\$ (11,507)	\$ (42,014)	\$ (32,967)



**Table of Contents****TERCICA, INC.****(A DEVELOPMENT STAGE COMPANY)****NOTES TO THE CONDENSED FINANCIAL STATEMENTS (continued)****(Unaudited)****Recent Accounting Pronouncement**

In June 2006, the FASB issued Interpretation No. 48, *Accounting for Uncertainty in Income Taxes*, ( FIN 48 ). FIN 48 clarifies the accounting for uncertainty in income taxes recognized in financial statements in accordance with SFAS No. 109, *Accounting for Income Taxes*. FIN 48 prescribes a recognition threshold and measurement attribute of tax positions taken or expected to be taken on a tax return. FIN 48 is effective for fiscal years beginning after December 15, 2006. The Company is currently evaluating the impact of adopting FIN 48 on its financial statements.

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

**2. Net Loss Per Share**

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

	Three Months Ended		Nine Months Ended	
(In thousands, except per share data)	September 30, 2006	September 30, 2005	September 30, 2006	September 30, 2005
<b>Numerator:</b>				
Net loss	\$ (13,063)	\$ (11,518)	\$ (42,016)	\$ (33,027)
<b>Denominator:</b>				
Weighted-average common shares outstanding	37,550	31,417	36,906	30,306
Less: Weighted-average unvested common shares subject to repurchase		(23)		(34)
Denominator for basic and diluted net loss per share	37,550	31,394	36,906	30,272
Basic and diluted net loss per share	\$ (0.35)	\$ (0.37)	\$ (1.14)	\$ (1.09)

	September 30, 2006 2005 (In thousands)	
<b>Outstanding dilutive securities not included in diluted net loss per share</b>		
Options to purchase common stock	3,982	2,789

Warrants	260
	4,242 2,789

**Table of Contents****3. Cash, Cash Equivalents and Short-Term Investments**

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

**TERCICA, INC.****(A DEVELOPMENT STAGE COMPANY)****NOTES TO THE CONDENSED FINANCIAL STATEMENTS (continued)****(Unaudited)**

	September 30, 2006			Estimated Fair Value
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	
Available-for-sale debt securities maturing within 1 year:				
Auction market preferred	\$ 23,350	\$	\$	\$ 23,350
Commercial paper	11,073	2		11,075
Corporate bonds	2,777		(2)	2,775
Federal agency bonds	4,483		(1)	4,482
Repurchase agreements	3,620			3,620
Asset-backed securities	6,302	1		6,303
Total available-for-sale debt securities	\$ 51,605	\$ 3	\$ (3)	\$ 51,605

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

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

	September 30,	December 31,
	2006	2005
Cash	\$ 3,012	\$ 873
Cash equivalents	9,982	13,944

Edgar Filing: TERCICA INC - Form 10-Q

Cash and cash equivalents	12,994	14,817
Short-term investments	41,283	43,809
Long-term restricted cash	340	340
Total	\$ 54,617	\$ 58,966

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

**4. Accrued expenses**

Accrued expenses consist of the following (in thousands):

	September 30,	December 31,
	2006	2005
Accrued compensation and related liabilities	\$ 2,604	\$ 2,626
Accrued professional fees	2,355	1,577
Accrued contract manufacturing expenses	259	543
Clinical trial costs	504	276
Other accrued liabilities	419	728
	\$ 6,141	\$ 5,750

---

**Table of Contents**

**TERCICA, INC.**

**(A DEVELOPMENT STAGE COMPANY)**

**NOTES TO THE CONDENSED FINANCIAL STATEMENTS (continued)**

**(Unaudited)**

**5. Litigation**

On December 20, 2004, the Company initiated patent infringement proceedings against Avecia Limited and Insmmed Incorporated as co-defendants in the High Court of Justice (Chancery Division Patents Court) in the United Kingdom. On December 23, 2004, the Company, with Genentech, initiated patent infringement proceedings against Insmmed Incorporated in the U.S. District Court for the Northern District of California. The Company initiated these proceedings because it believes that Insmmed and Avecia are infringing and/or have infringed on the Company's patents that cover Insmmed's product's use and manufacture. Please refer to the Company's disclosures under Part I, Item 3 of the Company's Annual Report on Form 10-K for the year ended December 31, 2005, filed with the SEC on March 16, 2006, as amended, for more information regarding the Company's patent infringement litigation against Avecia and Insmmed in the United Kingdom and the Company's patent infringement litigation against Insmmed in the United States. There were no material developments in the Company's patent infringement litigation against Avecia and Insmmed in the United Kingdom during the nine months ended September 30, 2006.

On June 30, 2006, the court issued rulings on several claims construction issues and cross-motions for summary judgment in the Company's patent infringement litigation against Insmmed in the United States. The court granted the Company summary judgment that Insmmed infringes claims 1, 2 and 9 of U.S. Patent No. 6,331,414, and granted the Company summary judgment that certain publications asserted by Insmmed against the validity of U.S. Patent No. 5,187,151 do not qualify as prior art and cannot be used to attack the validity of that patent. In addition, the court denied Insmmed summary judgment that Insmmed does not infringe any of claims 1 through 4, 9 and 10 of U.S. Patent No. 6,331,414, denied Insmmed summary judgment that claims 1 through 4, 9 and 10 of U.S. Patent No. 6,331,414 are invalid under 35 U.S.C. §101 and §112, denied Insmmed summary judgment that Insmmed does not infringe claims 1, 4, 5 and 7 of U.S. Patent No. 5,187,151, and granted Insmmed summary judgment that no recovery can be had against it based on any activities conducted by Celtrix Pharmaceuticals, Inc. prior to December 23, 1998. On July 14, 2006, Insmmed filed a motion for partial reconsideration of the summary judgment order with respect to infringement of claims 1 and 2 of U.S. Pat. No. 6,331,414, and filed a request seeking the court's permission to file the motion. On September 29, 2006, the court granted its permission to Insmmed for the filing of that motion. Apart from the court's rulings on claims construction issues and cross-motions for summary judgment, and apart from Insmmed's motion for partial reconsideration of the court's summary judgment order with respect to infringement of claims 1 and 2 of U.S. Pat. No. 6,331,414, there were no material developments in the Company's patent infringement litigation against Insmmed in the United States during the nine months ended September 30, 2006. Subsequent to the nine months ended September 30, 2006, on October 13, 2006, the Company and Genentech filed an opposition to Insmmed's motion for partial reconsideration of the court's summary judgment order and the Company, with Genentech, and Insmmed filed our respective pretrial motions and other filings relating to the jury trial scheduled to commence on November 6, 2006. On October 31, 2006, the court issued a written ruling denying Insmmed's motion for partial reconsideration of the court's June 30, 2006 summary judgment order.

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

Insmmed and Avecia have challenged the validity of European Patent No. 0 571 417 in the Company's litigation in the United Kingdom, and Insmmed has challenged the validity of U.S. Patent Nos. 5,187,151, 6,331,414 and 5,258,287 in the Company's litigation in the United States. Even if the Company voluntarily drops its claims of patent infringement in its



---

**Table of Contents**

**TERCICA, INC.**

**(A DEVELOPMENT STAGE COMPANY)**

**NOTES TO THE CONDENSED FINANCIAL STATEMENTS (continued)**

**(Unaudited)**

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

In December 2005, the Company filed a complaint against Insmed for False Advertising and Unfair Competition, Case No. C-05-5027 SBA, in the U.S. District Court for the Northern District of California. The complaint alleged that Insmed made false, misleading and deceptive statements about Increlex and its product. On June 9, 2006, the Court granted Insmed's motion to dismiss the case. On June 12, 2006, the Company filed a complaint against Insmed for False Advertising, Unfair Competition and Intentional Interference with Prospective Business Relations, Case No. 3:06cv403, in the U.S. District Court for the Eastern District of Virginia. The complaint alleges that Insmed made false, misleading and deceptive statements about Increlex and its product and intentionally interfered with the Company's business relationships. The Company is seeking monetary and injunctive relief. On June 23, 2006, the Company filed its First Amended Complaint. On July 27, 2006, Insmed filed a motion to dismiss the case. On October 3, 2006, the Court denied in part and granted in part Insmed's motion to dismiss, and ordered the case, with the Company's allegations narrowed, to move forward with a March 2007 trial date. On October 13, 2006, Insmed filed a counterclaim in the case, alleging that the Company made false and misleading statements regarding Insmed's product and Increlex.

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

**6. Senior Credit Facility**

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

**7. Committed Equity Financing Facility**

On October 14, 2005, the Company entered into a committed equity financing facility ("CEFF") with Kingsbridge Capital Limited ("Kingsbridge"), which entitles the Company to sell and obligates Kingsbridge to purchase, a maximum of approximately 6.0 million newly issued shares of the Company's common stock over a period of three years for cash up to an aggregate of \$75,000,000, subject to certain conditions and restrictions. The Company may draw down under the CEFF in tranches of up to the lesser of \$7,000,000 or 2% of the Company's market capitalization at the time of the draw down of such tranche, subject to certain conditions. The common stock to be issued for each draw down will be issued and priced over an eight-day pricing period at discounts ranging from 6% to 10% from the volume weighted average price of the Company's common stock during the pricing period. During the term of the CEFF, Kingsbridge may not short the Company's stock, nor may it enter into any

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

derivative transaction directly related to the Company's stock. The minimum acceptable purchase price, prior to the application of the appropriate discount for any shares to be sold to Kingsbridge during the eight-day pricing



**Table of Contents**

**TERCICA, INC.**

**(A DEVELOPMENT STAGE COMPANY)**

**NOTES TO THE CONDENSED FINANCIAL STATEMENTS (continued)**

**(Unaudited)**

period, is determined by the greater of \$3.00 or 90% of the Company's closing share price on the trading day immediately prior to the commencement of each draw down. In connection with the CEFF, the Company issued a warrant to Kingsbridge to purchase up to 260,000 shares of the Company's common stock at an exercise price of \$13.12 per share. The exercise term of the warrant is five years beginning on April 14, 2006. The warrant was valued on the date of grant using the Black-Scholes method using the following assumptions: a risk-free interest rate of 4.1%, a life of 5.5 years, no dividend yield and a volatility factor of 0.5. The estimated value of this warrant was \$1,196,000 and was recorded as a contra-equity amount in additional paid-in capital in 2005.

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

During the nine months ended September 30, 2006, the Company did not draw down any funds under the CEFF and had not issued any shares pursuant to the CEFF as of September 30, 2006. Under the terms of an affiliation agreement the Company entered into pursuant to its collaboration with Ipsen, the Company has only a limited ability to raise capital through the sale of its equity without first obtaining Ipsen's approval, and would generally not have the ability to draw down any funds under the CEFF without Ipsen's prior approval.

**8. Stock-Based Compensation**

On January 1, 2006, the Company adopted the provisions of SFAS No. 123R, *Share-Based Payment*. SFAS No. 123R establishes accounting for stock-based awards made to employees and directors. Accordingly, stock-based compensation expense is measured at the grant date, based on the fair value of the award, and is recognized as expense over the remaining requisite service period. The Company previously applied APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and related interpretations and provided the required pro forma disclosures of SFAS No. 123, *Accounting for Stock-Based Compensation*. Total stock-based compensation expense of \$1,552,000 and \$4,316,000 was recorded during the three and nine months ended September 30, 2006, respectively.

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

**2004 Stock Plan**

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

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

1,250,000 shares, or

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

an amount the Company's Board of Directors may determine.

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

**Table of Contents**

**TERCICA, INC.**

**(A DEVELOPMENT STAGE COMPANY)**

**NOTES TO THE CONDENSED FINANCIAL STATEMENTS (continued)**

**(Unaudited)**

of the total combined voting power of all classes of stock expire no later than five years from the date of grant. Options granted under the 2004 Stock Plan vests over periods determined by the Company's Board of Directors, generally over four years. The 2004 Stock Plan has a term of 10 years.

**2002 Stock Plan and 2002 Executive Stock Plan**

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

As of September 30, 2006, there were a total of 6,453,834 shares authorized for issuance under the 2004 Stock Plan and the 2002 Plans.

**2004 Employee Stock Purchase Plan**

The Company's Board of Directors adopted the 2004 Employee Stock Purchase Plan (formerly the 2003 Stock Purchase Plan) in September 2003 and the Company's stockholders approved it in October 2003. The 2004 Employee Stock Purchase Plan (the "Purchase Plan") became effective on March 16, 2004. As of September 30, 2006, there were a total of 347,979 shares reserved for issuance under the Purchase Plan. In addition, the Purchase Plan provides for annual increases in the number of shares available for issuance under the Purchase Plan on the first day of each year, beginning with January 1, 2005 equal to the lesser of:

0.5% of the outstanding shares of common stock on the first day of the Company's fiscal year,

125,000 shares, or

such other amount as may be determined by the Company's Board of Directors.

The Purchase Plan permits eligible employees to purchase common stock at a discount through payroll deductions during defined offering periods. Offering periods are successive and overlapping of 24 months' duration. Each offering period includes four six-month purchase periods and generally begins on the first trading day on or after May 15 and November 15 of each year. The price at which the stock is purchased is equal to the lower of 85% of the fair market value of the common stock at the beginning of an offering period or after a purchase period ends.

**Adoption of SFAS No. 123R**

On January 1, 2006, the Company adopted SFAS No. 123R using the modified prospective transition method. Under that transition method, non-cash compensation expense was recognized in the three and nine month periods ended September 30, 2006 and included the following: (a) compensation expense related to any share-based payments granted through, but not yet vested as of January 1, 2006, and (b) compensation expense for any share-based payments granted subsequent to January 1, 2006, based on the grant-date fair value estimated in accordance with the provisions of SFAS No. 123R. The Company recognizes non-cash compensation expense for the fair values of these share-based awards on a straight-line basis over the requisite service period of each of these awards. Because non-cash stock compensation expense is based on awards ultimately expected to vest, it has been reduced by an estimate for future forfeitures. SFAS No. 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The Company's financial

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

statements as of and for the three and nine months ended September 30, 2006 reflect the impact of SFAS No. 123R. In accordance with the modified prospective transition method, the Company's financial statements for prior periods have not been restated to reflect, and do not include, the impact of SFAS No. 123R.

During the period from February 1, 2003 through January 31, 2004, certain stock options were granted with exercise prices that were below the reassessed fair value of the common stock at the date of grant. Total deferred stock compensation of \$10,873,000 was recorded in accordance with APB Opinion No. 25, and was being amortized to expense over the related vesting period of the options. From inception through December 31, 2005, stock-based compensation expense of \$5,740,000

**Table of Contents****TERCICA, INC.****(A DEVELOPMENT STAGE COMPANY)****NOTES TO THE CONDENSED FINANCIAL STATEMENTS (continued)****(Unaudited)**

was recognized and \$2,542,000 was reversed as a result of employee terminations. The remaining deferred stock compensation balance of \$2,591,000 as of December 31, 2005 was reversed on January 1, 2006 upon adoption in accordance with the provisions of SFAS No. 123R.

The non-cash stock-based compensation expense related to SFAS No. 123R for the three and nine months ended September 30, 2006 was \$1,552,000 and \$4,316,000, respectively. As a result of adopting SFAS No. 123R on January 1, 2006, the Company's net loss for the three and nine months ended September 30, 2006 was \$1,132,000 and \$3,056,000 higher, respectively, and \$0.03 and \$0.08 higher, respectively, than if the Company had continued to account for stock-based compensation expense under APB Opinion No. 25.

The following table presents the pro forma effect on net loss and net loss per share if the Company had applied the fair value recognition provisions of SFAS No. 123 to options granted under the Company's share-based compensation arrangements during the three and nine months ended September 30, 2005 (in thousands, except per share amounts):

	<b>Three Months</b>	<b>Nine Months</b>
	<b>Ended</b>	<b>Ended</b>
	<b>September 30,</b>	<b>September 30</b>
<b>(In thousand except per share data)</b>	<b>2005</b>	<b>2005</b>
Net loss, as reported	\$ (11,518)	\$ (33,027)
Plus: Employee stock compensation expense based on intrinsic value method	467	1,658
Less: Employee stock compensation expense determined under the fair value method for all awards	(1,033)	(3,745)
Pro forma net loss	\$ (12,084)	\$ (35,114)
Net loss per share:		
Basic and diluted, as reported	\$ (0.37)	\$ (1.09)
Basic and diluted, pro forma	\$ (0.38)	\$ (1.16)

Other than options granted to non-employee service providers and the grant of certain stock options to employees with exercise prices that were below the reassessed fair value of the common stock as the date of the grant, there was no other stock-based compensation recognized during the three and nine months ended September 30, 2005.

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

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 30,</b>	<b>September 30,</b>	<b>September 30,</b>	<b>September 30,</b>
	<b>2006</b>	<b>2005</b>	<b>2006</b>	<b>2005</b>
Expected volatility	72%	50%	76%	50%
Expected term (years)	6.3	3.8	6.2	3.6
Risk-free interest rate	5.0%	4.0%	5.2%	3.8%

Dividend yield

The Company's computation of expected volatility for the three and nine months ended September 30, 2006 is based on an average of the historical volatility of the Company's stock and the historical volatility of a peer-group of similar companies. The Company's computation of expected term in the three and nine months ended September 30, 2006 utilizes the simplified method in accordance with SAB 107. The risk-free interest rate for periods within the contractual life of the option is based on interest rate swap 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****TERCICA, INC.****(A DEVELOPMENT STAGE COMPANY)****NOTES TO THE CONDENSED FINANCIAL STATEMENTS (continued)****(Unaudited)**

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

		Weighted- Average	Weighted- Average	Weighted- Average	Aggregate
	Shares	Price	Term	Contractual	Intrinsic
					Value
Outstanding at December 31, 2005	2,945	\$ 7.49			
Options granted	1,604	6.87			
Options exercised	(189)	0.97			
Options forfeited	(378)	9.88			
Outstanding at September 30, 2006	3,982	\$ 7.32	8.7		\$ 1,711
Exercisable at September 30, 2006	3,139	\$ 7.02	8.6		\$ 1,571

The aggregate intrinsic value in the table above represents the total pre-tax intrinsic value, based on the Company's closing stock price of \$5.33 on September 29, 2006, which would have been received by the option holders had all option holders exercised their options on September 30, 2006. This amount changes based on the fair market value of the Company's stock. Total intrinsic value of options exercised for the three and nine months ended September 30, 2006 was \$52,000 and \$1,054,000, respectively. The weighted-average grant date fair value of options granted during the three and nine months ended September 30, 2006 was \$3.49 and \$4.88 per share, respectively. Total fair value of options vested for the three and nine months ended September 30, 2006 was \$1,064,000 and \$2,616,000, respectively.

As of September 30, 2006, unrecognized stock-based compensation expense related to stock options of \$11,847,000 was expected to be recognized over a weighted-average period of 2.7 years.

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

	Shares	Value	Weighted- Average	Grant Date Fair
Nonvested stock options at December 31, 2005	2,259	\$ 8.01		
Granted	1,604	6.87		
Vested	(794)	7.00		
Forfeited	(190)	9.08		

Nonvested stock options at September 30, 2006	2,879	\$	7.58
---	-------	----	------

### Employee Stock Purchase Plan

For the three and nine months ended September 30, 2006, the Company recorded \$95,000 and \$260,000, respectively, of compensation expense related to the Purchase Plan. During the nine months ended September 30, 2006, 42,371 shares were purchased under the Purchase Plan. The fair value of awards issued under the Purchase Plan is measured using assumptions similar to those used for stock options, except that the term of the award is 1.19 years

### Disclosures Pertaining to All Stock-Based Compensation Plans

Cash received from option exercises and the Purchase Plan contributions under all share-based payment arrangements for the nine months ended September 30, 2006 and 2005 was \$348,000 and \$579,000, respectively. Because of the Company's net operating losses, the Company did not realize any tax benefits for the tax deductions from share-based payment arrangements during the nine months ended September 30, 2006 and 2005.

### 9. Commitments

In December 2002, the Company entered into a development and commercial supply agreement (the "Manufacturing Agreement") with Cambrex Bio Science Baltimore, Inc. ("Cambrex Baltimore"). At that time, the Company began to transfer its manufacturing technology to Cambrex Baltimore in order for them to establish the process for rhIGF-1 fermentation and purification. Further, under the terms of the Manufacturing Agreement, Cambrex Baltimore is obligated to annually provide the Company with certain minimum quantities of bulk rhIGF-1 drug substance. The Company has a non-cancelable obligation to reimburse Cambrex Baltimore on a time and materials and per batch basis in connection with the commercial production of Increlex of approximately \$4,482,000 through December 31, 2006.



**Table of Contents****TERCICA, INC.****(A DEVELOPMENT STAGE COMPANY)****NOTES TO THE CONDENSED FINANCIAL STATEMENTS (continued)****(Unaudited)**

The Company's operating lease commitments disclosed in the notes to the financial statements of its Annual Report on Form 10-K for year ended December 31, 2005, as amended, have not changed significantly.

**10. Ipsen Collaboration**

On July 18, 2006, the Company entered into a Stock Purchase and Master Transaction Agreement (the "Purchase Agreement") with Ipsen. Under the terms of the Purchase Agreement, the Company agreed to issue to Ipsen (or its designated affiliate): (i) 12,527,245 shares of common stock (the "Shares") for an aggregate purchase price of \$77,318,944; (ii) a convertible note in the principal amount of \$25,037,000 (the "First Convertible Note"); (iii) a second convertible note in the principal amount of \$30,000,000 (the "Second Convertible Note"); (iv) a third convertible note in the principal amount of \$15,000,000 (the "Third Convertible Note"); and (v) a warrant to purchase a minimum of 4,948,795 shares of the Company's common stock (the "Warrant"). The initial closing under the Purchase Agreement was consummated on October 13, 2006 (the "First Closing") after receiving approval by the Company's stockholders of the required aspects of the transactions contemplated by the Purchase Agreement at a Special Meeting of Stockholders held on October 12, 2006. In accordance with the Purchase Agreement, at the First Closing, the Company issued the Shares, the First Convertible Note and the Warrant, and the Company and Ipsen (and/or affiliates thereof) entered into an Increlex License and Collaboration Agreement ("Increlex License"), a Somatuline License and Collaboration Agreement ("Somatuline License" and together with the Increlex License, the "License Agreements"), a Registration Rights Agreement and an Affiliation Agreement. In connection with the First Closing, the Company also adopted certain amendments to its amended and restated certification of incorporation and adopted a Rights Agreement implementing a stockholder rights plan (the "Rights Agreement"). Pursuant to the Somatuline License, Ipsen granted to the Company the exclusive right under Ipsen's patents and know-how to develop and commercialize Somatulin® Autogel® in the United States and Canada for all indications other than ophthalmic indications. Ipsen's territory would expand, subject to Genentech's approval, to include Taiwan and any of the excluded countries of the Middle East or North Africa upon termination or expiry of certain third-party distribution agreements in such countries. Pursuant to the Increlex License, the Company granted to Ipsen and its affiliates the exclusive right under the Company's patents and know-how to develop and commercialize Increlex in all countries of the world except the United States, Japan, Canada, and for a certain period of time, Taiwan and certain countries of the Middle East and North Africa, for all indications, other than treatment of central nervous system indications and diabetes indications. Pursuant to the License Agreements, the Company and Ipsen granted to each other product development rights and agreed to share the costs for improvements to, or new indications for, Somatuline® Autogel® and Increlex, and also agreed to rights of first negotiation for their respective endocrine pipelines.

At the First Closing, the Company received from Ipsen proceeds of \$77,318,944 for the issuance of the Shares, which Shares represented 25% of the Company's outstanding common stock on a non-diluted basis. Further, the Company received from Ipsen, net of withholding taxes, \$9,500,000 as an upfront license fee under the Increlex License. As indicated above, the First Convertible Note in the principal amount of \$25,037,000 was issued to Ipsen at the First Closing. The amount delivered to the Company by Ipsen for the First Convertible Note was offset by approximately the same amount that the Company was obligated to pay Ipsen as the upfront license fee under the Somatuline License. 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 a fixed conversion price of \$7.41 per share. The entire principal balance and accrued interest under the First Convertible Note is due and payable on the later to occur of (i) October 13, 2011; or (ii) the second anniversary of the date on which Ipsen (or a subsequent holder of the First Convertible Note) notifies the Company that it will not convert the First Convertible Note in full. Additionally, the Company issued the 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 Tercica's common stock, which variable amount will fluctuate throughout the term of the Warrant. The Warrant is exercisable, in full or in part, at any time during the five years following the date of the First Closing at an exercise price of \$7.41 per share.

The Purchase Agreement provides that, at the second closing of the transactions contemplated by the Purchase Agreement, subject to the satisfaction or waiver of the conditions thereto, the Company would issue the Second Convertible Note and the Third Convertible Note, and Ipsen would deliver the sum of \$30,000,000 and \$15,000,000 to the Company (the "Second Closing"). The issuance of the Second Convertible Note and the Third Convertible Note, together with the Shares and the Warrant, would enable Ipsen to increase its equity ownership in the Company to approximately 40% on a fully diluted basis. Conditions to the Second Closing include the occurrence of the milestone event provided for in the Somatuline



**Table of Contents**

**TERCICA, INC.**

**(A DEVELOPMENT STAGE COMPANY)**

**NOTES TO THE CONDENSED FINANCIAL STATEMENTS (continued)**

**(Unaudited)**

License related to marketing approval of Somatuline® Autogel® by the FDA for the targeted product label. The 30,000,000 to be delivered to the Company for the Second Convertible Note would be offset by approximately the same amount that the Company would owe Ipsen as a milestone payment under the Somatuline License. The \$15,000,000 to be delivered to the Company for the Third Convertible Note would be used for working capital. There can be no assurance that the Second Closing will occur on a timely basis or at all.

Upon closing of the Ipsen transaction on October 13, 2006, a \$1,900,000 transaction fee became due to Lehman Brothers.

The Company is currently evaluating the accounting treatment with respect to the foregoing transactions.

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

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

**Overview**

We are a biopharmaceutical company committed to improving endocrine health by partnering with the endocrine community to develop and commercialize new therapeutics for short stature and other metabolic disorders. Our predecessor, Tercica Limited, a New Zealand Company, was formed in October 2000. Tercica Medica, Inc. was incorporated in Delaware in December 2001 and subsequently changed its name to Tercica, Inc.

In April 2002, we licensed from Genentech intellectual property to develop, manufacture and commercialize rhIGF-1 for a broad range of indications in the United States, including short stature and diabetes, but excluding diseases and conditions of the central nervous system. In December 2002, we entered into a development and commercial supply contract for the manufacture of bulk rhIGF-1 drug substance with Cambrex Bio Science Baltimore, Inc., or Cambrex Baltimore. In July 2003, we signed an international license and collaboration agreement with Genentech obtaining the rights to develop and commercialize rhIGF-1 products outside of the United States for all indications other than diseases and conditions of the central nervous system. The international license and collaboration agreement provides that we must enter into a written agreement with another company if we desire to commercialize Increlex for the treatment of diabetes outside of the United States.

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

In October 2006, we finalized our worldwide strategic collaboration with Ipsen, S.A., or Ipsen. Pursuant to the collaboration, Ipsen granted to us the exclusive right under Ipsen's patents and know-how to develop and commercialize Somatuline® Autogel® in the United States and Canada for all indications other than ophthalmic indications. In July 2006, Somatuline® Autogel® was approved for marketing by Health Canada for the treatment of acromegaly. Acromegaly is a hormonal disorder that results when a tumor in the pituitary gland produces excess growth hormone. In October 2006, Ipsen submitted a New Drug Application, or NDA, with the U.S. Food and Drug Administration, or FDA, for this indication.

---

## **Table of Contents**

Pursuant to the collaboration, we granted to Ipsen and its affiliates the exclusive right under our patents and know-how to develop and commercialize Increlex in all countries of the world except the United States, Japan, Canada, and for a certain period of time, Taiwan and certain countries of the Middle East and North Africa, for all indications, other than treatment of central nervous system indications and diabetes indications. A decision regarding our MAA for Increlex by the EMEA is expected in late 2006 or early 2007. See the discussion below under Liquidity and Capital Resources Ipsen Collaboration for further details on our collaboration with Ipsen.

As of September 30, 2006, we had approximately \$54.3 million in cash, cash equivalents and short-term investments. We have funded our operations since inception through the private placement of equity securities and public offerings of our common stock, including a follow-on public offering of common stock completed on January 27, 2006 in which we raised net cash proceeds of approximately \$34.2 million. In October 2006, we also received cash proceeds in connection with our strategic partnership with Ipsen as described under Liquidity and Capital Resources Ipsen Collaboration below.

### ***Net Product Sales***

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

### ***Research and Development Expenses***

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

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

We expect our project costs for the remainder of 2006 to be primarily focused on clinical and regulatory activities, our MAA filing, and new product development activities in both severe Primary IGFD and Primary IGFD. For the remainder of 2006, we also expect to incur project costs in connection with our development activities for Somatuline® Autogel®. Our projects or intended projects may be subject to change from time to time as we evaluate our research and development priorities and available resources.

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

Selling, general and administrative expenses consist primarily of payroll and related costs associated with sales and marketing personnel, executive management, corporate administration, legal fees, commercial planning activities, cost of free goods, facility costs, insurance, information technology, medical education and accounting services. During 2004, we



---

**Table of Contents**

expanded our corporate staffing and infrastructure and initiated planning for sales and marketing activities. During 2005, we continued to expand our corporate and sales staffing and infrastructure, increased our pre-launch activities and implemented Section 404 of the Sarbanes-Oxley Act of 2002. During the first nine months of 2006, we made significant expenditures to support our marketing and sales activities, as we focused on our commercial launch activities for Increlex. We expect total selling, general and administrative expenses for the remainder of 2006 to increase due to litigation with Inamed, as well as preparations for the commercial launch of Somatuline® Autogel® in Canada and the United States. We also expect to pay substantial transaction costs related to the Ipsen collaboration in the fourth quarter of 2006.

**Critical Accounting Policies and the Use of Estimates**

Our management's discussion and analysis of our financial condition and results of operations are based on our financial statements which have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP, for interim financial information. The preparation of our financial statements requires management to make estimates and assumptions that affect the amounts reported in our financial statements and accompanying notes. Actual results could differ materially from those estimates.

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

***Revenue Recognition***

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

***Stock-Based Compensation***

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

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

We adopted SFAS No. 123R using the modified prospective transition method. Under that transition method, non-cash compensation expense has been recognized beginning in the first quarter of fiscal 2006 and includes the following: (a) compensation expense related to any share-based payments granted through, but not yet vested as of January 1, 2006, and (b) compensation expense for any share-based payments granted subsequent to January 1, 2006 based on the grant-date fair value estimated in accordance with the provisions of SFAS No. 123R. We recognize non-cash compensation expense for the fair values of these share-based awards on a straight-line basis over the requisite service period of each of these awards. Because non-cash stock compensation expense is based on awards ultimately expected to vest, it has been reduced by estimated forfeitures. SFAS No. 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Our financial statements as of September 30, 2006 and for the three and nine months ended September 30, 2006 reflect the impact of SFAS No. 123R. In accordance with the modified prospective transition method, our financial statements for prior periods have not been restated to reflect, and do not include, the impact of SFAS No. 123R.





---

**Table of Contents**

As a result of adopting SFAS No. 123R, we recognized stock-based compensation expense of \$1.6 million and \$4.3 million during the three and nine months ended September 30, 2006, respectively, which primarily affected our reported research and development and selling, general, and administrative expenses. Approximately \$525,000 and \$1.5 million are included in research and development expenses for the three and nine months ended September 30, 2006, respectively, and approximately \$1.0 million and \$2.8 million are included in selling, general and administrative expenses for the three and nine months ended September 30, 2006, respectively. We calculated this expense based on the fair values of the stock-based compensation awards as estimated using the Black-Scholes model. Use of this model requires us to make assumptions about expected future volatility of our stock price and the expected term of the options that we grant. Calculating stock-based compensation expense under SFAS No. 123R also requires us to make assumptions about expected future forfeiture rates for our option awards. As of September 30, 2006, total unrecognized compensation expense related to unvested share-based compensation arrangements previously granted under our various plans was \$11.8 million, which we expect to recognize over a weighted-average period of 2.7 years. However, it is difficult to predict the actual amount of share-based compensation expense that we will recognize in future periods as that expense can be affected by changes in the amount or terms of our share-based compensation awards issued in the future, changes in the assumptions used in our model to value those future awards, changes in our stock price, and changes in interest rates, among other factors.

For more information on stock-based compensation expense recorded for the three and nine months ended September 30, 2006, please refer to Note 8 Stock Based Compensation in the notes to our condensed financial statements.

***Inventories***

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

***Clinical Trial Expenses***

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

***Recent Accounting Pronouncement***

In June 2006, the FASB issued Interpretation No. 48, *Accounting for Uncertainty in Income Taxes*, or FIN 48. FIN 48 clarifies the accounting for uncertainty in income taxes recognized in financial statements in accordance with SFAS No. 109, *Accounting for Income Taxes*. FIN 48 prescribes a recognition threshold and measurement attribute of tax positions taken or expected to be taken on a tax return. FIN 48 is effective for fiscal years beginning after December 15, 2006. We are currently evaluating the impact of adopting FIN 48 on our financial statements.

In September 2006, the FASB issued Statement of Financial Accounting Standards No. 157, *Fair Value Measurements*, or SFAS No. 157. SFAS No. 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. SFAS No. 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. We are currently evaluating the impact of adopting SFAS No. 157 on our financial statements.

**Results of Operations*****Three Months Ended September 30, 2006 and 2005***

*Net Product Sales.* We began shipment of Increlex to specialty pharmacy distributors in January 2006. Product sales less product returns and cash discounts were \$316,000 for the quarter ended September 30, 2006. There were minimal governmental rebates to state Medicaid agencies in the third quarter of 2006. As Increlex is generally ordered by our distributors for specific prescriptions, we believe that our distributors carry minimal levels of inventory.



**Table of Contents**

*Cost of Product Sales.* Cost of product sales was \$516,000 for the quarter ended September 30, 2006, and included write-offs of inventory totaling \$290,000 which were due to manufacturing lot failures. Cost of product sales represents the cost of production, shipping, distribution and handling costs, inventory write-downs/write-offs based on our review of obsolete, excess, expired and failed inventory lots, and royalties owed to Genentech based on sales of Increlex. Prior to regulatory approval of Increlex in August 2005, drug supply production costs were charged to research and development. Beginning in the fourth quarter of 2005, with the marketing approval of Increlex by the FDA, we began capitalizing these production costs to inventory and began to charge cost of product sales in the first quarter of 2006 as these units of Increlex were sold. In addition to these capitalized drug supply production costs, there are also certain variable and fixed shipping, distribution and handling costs charged to cost of product sales. Our cost of product sales as a percentage of net product sales may fluctuate over time as the drug supply produced prior to August 2005 is sold, as the mix of the fixed versus variable costs change over time and the percentage of manufacturing lots are successfully completed.

*Research and Development Expenses.* Research and development expenses decreased \$2.2 million to \$3.5 million for the quarter ended September 30, 2006, from \$5.7 million for the same period in 2005. The \$2.2 million decrease was due primarily to:

payment in 2005 of \$1.0 million related to an approval related milestone;

\$687,000 of lower project costs in 2006 compared to 2005 as expenses in the prior year quarter included costs associated with production and validation of Tercica's rhIGF-1 manufacturing process; and

decreased personnel and other costs of \$482,000.

The \$3.5 million in expenses during the quarter ended September 30, 2006 were comprised primarily of internal personnel and other costs of \$2.3 million and \$1.2 million in external project costs associated with Primary IGFD and MAA filing related activities.

*Selling, General and Administrative Expenses.* Selling, general and administrative expenses increased \$3.8 million to \$10.2 million for the quarter ended September 30, 2006, from \$6.4 million for the same period in 2005. The \$3.8 million increase was primarily attributable to:

additional expenditures associated with sales and marketing activities of \$1.8 million, which includes stock-based compensation expense;

increased general and administrative personnel and other costs of \$1.6 million; and

increased free goods expense of \$454,000, of which \$346,000 was related to write-offs of inventory due to manufacturing lot failures.

*Interest expense.* There was no interest expense for the quarter ended September 30, 2006. Interest expense was \$106,000 for the quarter ended September 30, 2005. In January 2005, we entered into a loan agreement with Venture Leasing & Lending IV, Inc., or VLL, under which we issued 75,000 shares of our common stock to VLL. The common stock was valued at \$720,000 on the date of issuance, and that value was amortized over the period of the initial loan commitment, through April 30, 2005, as interest expense. In May 2005, we extended our loan agreement with VLL through December 31, 2005, and in connection with that we issued 37,500 shares of our common stock to an affiliate of VLL. The 37,500 shares of common stock were valued at \$282,000 on the date of issuance, and that value was amortized over the extended eight-month commitment period through December 31, 2005, as interest expense.

*Interest and Other Income, net.* Interest and other income, net, increased to \$812,000 for the quarter ended September 30, 2006, from \$662,000 for the same period in 2005. The increase was due primarily to an increase in interest rates.

***Nine Months Ended September 30, 2006 and 2005***

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

*Net Product Sales.* Product sales less product returns and cash discounts were \$567,000 for the nine months ended September 30, 2006. There were minimal governmental rebates to state Medicaid agencies in the nine months ended September 30, 2006. As Increlex is generally ordered by our distributors for specific prescriptions, we believe that our distributors carry minimal levels of inventory.

*Cost of Product Sales.* Cost of product sales was \$1.2 million for the nine months ended September 30, 2006, and included write-offs of inventory totaling \$654,000 which were due to manufacturing lot failures and write-downs of excess

---

**Table of Contents**

inventory totaling \$78,000. Cost of product sales represents the cost of production, shipping, distribution and handling costs, inventory write-downs/write-offs based on our review of obsolete, excess, expired and failed inventory lots, and royalties owed to Genentech based on sales of Increlex. Prior to regulatory approval of Increlex in August 2005, drug supply production costs were charged to research and development. Beginning in the fourth quarter of 2005, with the marketing approval of Increlex by the FDA, we began capitalizing these production costs to inventory and began to charge cost of product sales in the first quarter of 2006 as these units of Increlex were sold. In addition to these capitalized drug supply production costs, there are also certain variable and fixed shipping, distribution and handling costs charged to cost of product sales. Our cost of product sales as a percentage of net product sales may fluctuate over time as the drug supply produced prior to August 2005 is sold, as the mix of the fixed versus variable costs change over time and the percentage of manufacturing lots that are successfully completed.

*Research and Development Expenses.* Research and development expenses decreased \$4.2 million to \$12.7 million for the nine months ended September 30, 2006, from \$16.9 million for the same period in 2005. The \$4.2 million decrease was due primarily to:

\$3.5 million of lower project costs in 2006 compared to 2005 as expenses in the nine months ended September 30, 2006 included costs associated with production and validation of Tercica's rhIGF-1 manufacturing process; and

payment in 2005 of \$1.0 million related to an approval related milestone;

partially offset by higher personnel and other costs of \$349,000, which includes stock-based compensation expense.

The \$12.7 million in expenses during the nine months ended September 30, 2006 were comprised of internal personnel and other costs of \$8.0 million and \$4.6 million of external project costs associated with Primary IGFD and MAA filing related activities.

*Selling, General and Administrative Expenses.* Selling, general and administrative expenses increased \$14.3 million to \$31.3 million for the nine months ended September 30, 2006, from \$17.0 million for the same period in 2005. The \$14.3 million increase was primarily attributable to:

additional expenditures associated with sales and marketing activities of \$7.4 million, which includes stock-based compensation expense;

increased general and administrative personnel and other costs of \$3.9 million, which includes stock-based compensation expense;

increased legal expenses primarily associated with litigation of \$1.3 million;

increased free goods expense of \$1.2 million, of which \$808,000 was related to inventory write-offs due to manufacturing lot failures and \$123,000 for inventory write-downs; and

increased expenses of \$366,000 associated with medical education.

*Interest expense.* There was no interest expense for the nine months ended September 30, 2006. Interest expense was \$899,000 for the nine months ended September 30, 2005 due to the issuance of our common stock to VLL. In January 2005, we entered into a loan agreement with VLL under which we issued 75,000 shares of our common stock to VLL. The common stock was valued at \$720,000 on the date of issuance, and that value was amortized over the period of the initial loan commitment, through April 30, 2005, as interest expense. In May 2005, we extended our loan agreement with VLL through December 31, 2005, and in connection with that we issued 37,500 shares of our common stock to an affiliate of VLL. The 37,500 shares of common stock were valued at \$282,000 on the date of issuance, and that value was amortized over the extended eight-month commitment period through December 31, 2005, as interest expense.

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

*Interest and Other Income, net.* Interest and other income, net, increased to \$2.6 million for the nine months ended September 30, 2006, from \$1.8 million for the same period in 2005. The increase was due to primarily to an increase in interest rates.

## **Table of Contents**

### **Liquidity and Capital Resources**

#### ***Sources of Liquidity***

As of September 30, 2006, we had an accumulated deficit of \$207.8 million, which was primarily comprised of \$164.7 million of accumulated net losses and \$44.1 million of a non-cash deemed dividend related to the beneficial conversion feature of convertible preferred stock. We have funded our operations and growth from inception through September 30, 2006 with net cash proceeds of \$66.0 million in private equity financings and \$135.3 million from our public offerings of common stock.

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

Under the terms of the CEFF, Kingsbridge committed to purchase a maximum of approximately 6.0 million newly issued shares of our common stock over a three-year period beginning in October 2005, for cash up to an aggregate of \$75.0 million, subject to certain conditions. We may draw down under the CEFF in tranches of up to the lesser of \$7.0 million or 2% of our market capitalization at the time of the draw down of such tranche, subject to certain conditions. The common stock to be issued for each draw down will be issued and priced over an eight-day pricing period at discounts ranging from 6% to 10% from the volume weighted average price of our common stock during the pricing period. During the term of the CEFF, Kingsbridge may not short our stock, nor may it enter into any derivative transaction directly related to our stock. The minimum acceptable purchase price, prior to the application of the appropriate discount for any shares to be sold to Kingsbridge during the eight-day pricing period, is determined by the greater of \$3.00 or 90% of our closing share price on the trading day immediately prior to the commencement of each draw down. In connection with the CEFF, we issued a warrant to Kingsbridge to purchase up to 260,000 shares of our common stock at an exercise price of \$13.12 per share. We may exercise our right to draw down amounts under the CEFF, if and to the extent available, at such times as we have a need for additional capital and when we believe that sales of our common stock under the CEFF provide an appropriate means of raising capital. However, we are not obligated to sell any of the \$75.0 million of common stock available under the CEFF, and there are no minimum commitments or minimum use penalties. During the nine months ended September 30, 2006, we did not draw down any funds under the CEFF and had not issued any shares pursuant to the CEFF as of September 30, 2006.

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, and would generally not have the ability to draw down any funds under the CEFF without Ipsen's prior approval.

#### ***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. Simultaneously with the initial closing, we and Ipsen (and/or affiliates thereof) entered into licensing agreements with respect to Somatuline® Autogel® and Increlex, and entered into certain other agreements, including an affiliation agreement with respect to certain corporate governance matters and providing Ipsen with the right to nominate a certain number of directors for election to our Board of Directors. Additionally, we effected certain amendments to our amended and restated certification of incorporation and adopted a rights agreement implementing a stockholder rights plan. The stock purchase and master transaction agreement we entered into with Ipsen in July 2006 also provides for the issuance by us of a second convertible note and a third convertible note to Ipsen in the principal amounts of \$30.0 million and \$15.0 million, respectively, at the second closing thereunder. Each of the convertible notes we issued or that we may issue to Ipsen mature five years from the date of issuance and carry a coupon of 2.5% per annum from the date of issuance, compounded quarterly, and are convertible into shares of our common stock at an initial conversion price per share equal to \$7.41 per share ( \$5.92 per share with respect to the second convertible note). Together with the shares issued at the initial closing, the conversion of all three convertible notes and the exercise of the warrant in full would enable Ipsen to acquire an ownership interest in us of approximately 40% on a fully diluted basis.

Pursuant to the licensing agreements we entered into with Ipsen (and/or affiliates thereof) in connection with the initial closing under the stock purchase and master transaction agreement, we granted to Ipsen and its affiliates exclusive rights to develop and commercialize Increlex in all countries of the world except the United States, Japan, Canada, and for a certain period of time, Taiwan and certain countries of the Middle East and North Africa, and Ipsen granted to us exclusive rights to develop and commercialize Somatuline® Autogel® in the United States and Canada. Further, we and Ipsen granted to each other product development rights and agreed to share the costs for improvements to, or new indications for, Somatuline® Autogel® and Increlex. In addition, we and Ipsen agreed to rights of first negotiation for our respective endocrine pipelines. Under the license and collaboration agreement with respect to Increlex, Ipsen made an upfront cash payment to us of \$9.5 million after tax withholding and has agreed to pay us a milestone of \$15.0 million upon approval of the Increlex MAA in the European Union for the targeted

product label. If Increlex is launched in Ipsen's territory, Ipsen would pay royalties to



## **Table of Contents**

us on a sliding scale from 15% to 25% of net sales, in addition to a supply price of 20% of net sales of Increlex. Under the license and collaboration agreement with respect to Somatuline® Autogel®, we made an upfront payment of \$25.0 million to Ipsen, 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. If Somatuline® Autogel® is approved in the United States for the targeted product label (and the second closing under the under the stock purchase and master transaction agreement is consummated), we would make a milestone payment of 30.0 million to Ipsen, which would be financed through the issuance by us of the second convertible note to Ipsen at the second closing. If the second closing is consummated, we would also issue the third convertible note to Ipsen and Ipsen would deliver \$15.0 million to us, which would be used by us for working capital. Once Somatuline® Autogel® is launched in our territory, we would pay royalties to Ipsen, on a sliding scale from 15% to 25% of net sales, in addition to a supply price of 20% of net sales of Somatuline® Autogel®. For additional information on our collaboration with Ipsen, please refer to Note 10 Ipsen Collaboration in the notes to our condensed financial statements.

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

### ***Cash Flow***

Cash, cash equivalents and short-term investments totaled \$54.3 million at September 30, 2006, compared to \$58.6 million at December 31, 2005. The decrease was primarily due to net cash used in operating activities of \$38.3 million, offset by net proceeds of \$34.2 million from the issuance of common stock from our January 2006 follow-on public offering. During the nine months ended September 30, 2006, the uses of cash in operations were primarily related to sales, marketing and related support personnel and their activities associated with severe Primary IGFD, clinical and regulatory activities related to severe Primary IGFD and Primary IGFD and other general and administrative expenses as well as litigation related expenses. The increase in cash used in operations of \$7.5 million in the nine months ended September 30, 2006, compared to the same period in 2005, was due primarily to increases in sales, marketing and litigation activities. We expect an increase in net cash used in operations for the remainder of 2006, primarily to support the commercial activities associated with marketing Increlex for severe Primary IGFD and clinical, regulatory, and new product development activities in severe Primary IGFD and Primary IGFD, as well as preparations for the commercial launch of Somatuline® Autogel® in Canada and the United States.

Net cash provided by investing activities totaled \$2.0 million in the nine months ended September 30, 2006, compared to net cash used in investing activities of \$11.2 million in the same period in 2005. Net cash provided by and used in investing activities represented purchases, sales and maturities of investments and purchases of property and equipment. Net proceeds of short-term investments were \$2.9 million in the nine months ended September 30, 2006, compared to net purchases of short-term investments of \$8.8 million for the same period in 2005. The decrease of \$11.7 million in net purchases of short-term investments in the nine months ended September 30, 2006, compared to the same period in 2005, was primarily due to the timing of maturities, sales and purchases of short-term investments. Purchases of property and equipment were \$900,000 and \$2.5 million in the nine months ended September 30, 2006 and 2005, respectively. The decrease in purchases of property and equipment primarily relate to purchases of leasehold improvements and office furniture for our corporate headquarters in 2005.

Net cash provided by financing activities for the nine months ended September 30, 2006 was \$34.5 million, compared to \$51.5 million for the same period in 2005. Net cash provided by financing activities primarily related to net proceeds received from our public offerings of common stock which totaled \$34.2 million and \$51.1 million in the nine months ended September 30, 2006 and 2005, respectively.

### ***Litigation***

On December 20, 2004, we initiated patent infringement proceedings against Avecia Limited and Insmmed Incorporated as co-defendants in the High Court of Justice (Chancery Division Patents Court) in the United Kingdom. On December 23, 2004, we, with Genentech, initiated patent infringement proceedings against Insmmed Incorporated in the U.S. District Court for the Northern District of California. We initiated these proceedings because we believe that Insmmed and Avecia are infringing and/or have infringed on our patents that cover Insmmed's product's use and manufacture. Please refer to our disclosures under Part I, Item 3 of our Annual Report on Form 10-K for the year ended December 31, 2005, filed with the SEC on March 16, 2006, as amended, for more information regarding our patent infringement litigation against Avecia and Insmmed in the United Kingdom and our patent infringement litigation against Insmmed in the United States. There were no material developments in our patent infringement litigation against Avecia and Insmmed in the United Kingdom during the nine months ended September 30, 2006.



**Table of Contents**

On June 30, 2006, the court issued rulings on several claims construction issues and cross-motions for summary judgment in our patent infringement litigation against Insmmed in the United States. The court granted us summary judgment that Insmmed infringes claims 1, 2 and 9 of U.S. Patent No. 6,331,414, and granted us summary judgment that certain publications asserted by Insmmed against the validity of U.S. Patent No. 5,187,151 do not qualify as prior art and cannot be used to attack the validity of that patent. In addition, the court denied Insmmed summary judgment that Insmmed does not infringe any of claims 1 through 4, 9 and 10 of U.S. Patent No. 6,331,414, denied Insmmed summary judgment that claims 1 through 4, 9 and 10 of U.S. Patent No. 6,331,414 are invalid under 35 U.S.C. §101 and §112, denied Insmmed summary judgment that Insmmed does not infringe claims 1, 4, 5 and 7 of U.S. Patent No. 5,187,151, and granted Insmmed summary judgment that no recovery can be had against it based on any activities conducted by Celtrix Pharmaceuticals, Inc. prior to December 23, 1998. On July 14, 2006, Insmmed filed a motion for partial reconsideration of the summary judgment order with respect to infringement of claims 1 and 2 of U.S. Pat. No. 6,331,414, and filed a request seeking the court's permission to file the motion. On September 29, 2006, the court granted its permission to Insmmed for the filing of that motion. Apart from the court's rulings on claims construction issues and cross-motions for summary judgment, and apart from Insmmed's motion for partial reconsideration of the court's summary judgment order with respect to infringement of claims 1 and 2 of U.S. Pat. No. 6,331,414, there were no material developments in our patent infringement litigation against Insmmed in the United States during the nine months ended September 30, 2006. Subsequent to the nine months ended September 30, 2006, on October 13, 2006, we and Genentech filed an opposition to Insmmed's motion for partial reconsideration of the court's summary judgment order and we, with Genentech, and Insmmed filed our respective pretrial motions and other filings relating to the jury trial scheduled to commence on November 6, 2006. On October 31, 2006, the court issued a written ruling denying Insmmed's motion for partial reconsideration of the court's June 30, 2006 summary judgment order.

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

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

---

## **Table of Contents**

In December 2005, we filed a complaint against Insmed for False Advertising and Unfair Competition, Case No. C-05-5027 SBA, in the U.S. District Court for the Northern District of California. The complaint alleged that Insmed made false, misleading and deceptive statements about Increlex and its product. On June 9, 2006, the Court granted Insmed's motion to dismiss the case. On June 12, 2006, we filed a complaint against Insmed for False Advertising, Unfair Competition and Intentional Interference with Prospective Business Relations, Case No. 3:06cv403, in the U.S. District Court for the Eastern District of Virginia. The complaint alleges that Insmed made false, misleading and deceptive statements about Increlex and its product and intentionally interfered with our business relationships. We are seeking monetary and injunctive relief. On June 23, 2006, we filed our First Amended Complaint. On July 27, 2006, Insmed filed a motion to dismiss the case. On October 3, 2006, the Court denied in part and granted in part Insmed's motion to dismiss, and ordered the case, with our allegations narrowed, to move forward with a March 2007 trial date. On October 13, 2006, Insmed filed a counterclaim in the case, alleging that we made false and misleading statements regarding Insmed's product and Increlex.

### ***Contractual Obligations and Commercial Commitments***

Under our agreement with Cambrex Baltimore, we have a non-cancelable obligation to reimburse Cambrex Baltimore on a time and materials and per batch basis in connection with the commercial production of Increlex. We estimate that our total purchase commitment to Cambrex Baltimore is approximately \$4.5 million through December 31, 2006. Further, as we reach certain milestones, we will be committed to make certain future purchases.

Upon closing of the Ipsen transaction on October 13, 2006, a \$1.9 million transaction fee became due to Lehman Brothers.

Our operating lease commitments disclosed in Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2005, as amended, have not changed significantly.

### ***Operating Capital and Capital Expenditure Requirements***

In August 2005, we obtained approval for the long-term treatment of growth failure in children with severe Primary IGFD or with growth hormone gene deletion who have developed neutralizing antibodies to growth hormone from the FDA, and we are marketing Increlex for those indications. In addition, we submitted an MAA to the EMEA seeking approval to market Increlex in the European Union for a similar indication. We are also conducting clinical study MS 301, a study of Increlex for treatment of children with Primary IGFD and clinical study MS 308, a once-daily dosing study of Increlex. In addition we are involved in other clinical and non-clinical development activities related to Increlex. We plan to make significant expenditures to support our marketing, sales, clinical trial, regulatory, and product development activities for Increlex. We also expect significant legal and other expenditures for our ongoing litigation with Insmed.

We are preparing for the launch of Somatuline<sup>®</sup> Autogel<sup>®</sup> in Canada. We have also started working on a potential launch, subject to regulatory approval, of Somatuline<sup>®</sup> Autogel<sup>®</sup> in the U.S. In addition, we have started implementing our development activities related to Somatuline<sup>®</sup> Autogel<sup>®</sup>. All of these activities will require us to make significant expenditures.

Our projects may be subject to change from time-to-time as we evaluate our research and development priorities and available resources. These projects may also yield varying results that could delay, limit or change the timing of a project's advancement through various stages of product development and could significantly impact the costs to be incurred in bringing a project to completion. As a result, the costs to complete such projects, as well as the timing of net cash outflows, are not reasonably estimable.

We believe that our cash, cash equivalents and short-term investments as of September 30, 2006, together with the funds that we have received and would potentially receive from our collaboration with Ipsen, would be sufficient to meet our projected operating and capital expenditure requirements through at least the end of 2007. However, our future capital needs and the adequacy of our available funds will depend on many factors, including:

changes to our business plan;

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

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

the commercial status of the Increlex bulk drug manufacturing operations at Cambrex Baltimore, including the success of our cGMP production activities;

the success of Increlex final drug product manufacturing;

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

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

the cost, timing and scope of additional regulatory approvals for Somatuline® Autogel®;

**Table of Contents**

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

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

the status of competing products;

the rate of progress and cost of our future clinical trials and other research and development activities; 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, and the CEFF. However, there can be no assurance that additional financing will be available when needed, or, if available, that the terms will be favorable. In addition, under the terms of an affiliation agreement we entered into pursuant to our collaboration with Ipsen, we have only a limited ability to raise capital through the sale of our equity without first obtaining Ipsen's approval. If additional funds are not available, we may be forced to curtail or cease operations.

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.

**Table of Contents**

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

During the nine months ended September 30, 2006, there were no material changes to our market risk disclosures as set forth in Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2005, as amended.

**ITEM 4. CONTROLS AND PROCEDURES.**

*Evaluation of Disclosure Controls and Procedures*

Based on their evaluation as of September 30, 2006, our Chief Executive Officer and Chief Financial Officer, with the participation of management, have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934) are effective to ensure that the information required to be disclosed by us in the reports that we file or submit under the Securities and Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms.

*Changes in Internal Control over Financial Reporting*

There were no changes in our internal control over financial reporting during the quarter ended September 30, 2006 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

*Limitations on the Effectiveness of Controls*

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

**Table of Contents****Part II Other Information****ITEM 1. LEGAL PROCEEDINGS**

On December 20, 2004, we initiated patent infringement proceedings against Avecia Limited and Insmmed Incorporated as co-defendants in the High Court of Justice (Chancery Division Patents Court) in the United Kingdom. On December 23, 2004, we, with Genentech, initiated patent infringement proceedings against Insmmed Incorporated in the U.S. District Court for the Northern District of California. We initiated these proceedings because we believe that Insmmed and Avecia are infringing and/or have infringed on our patents that cover Insmmed's products use and manufacture. Please refer to our disclosures under Part I, Item 3 of our Annual Report on Form 10-K for the year ended December 31, 2005, filed with the SEC on March 16, 2006, as amended, for more information regarding our patent infringement litigation against Avecia and Insmmed in the United Kingdom and our patent infringement litigation against Insmmed in the United States. There were no material developments in our patent infringement litigation against Avecia and Insmmed in the United Kingdom during the nine months ended September 30, 2006.

On June 30, 2006, the court issued rulings on several claims construction issues and cross-motions for summary judgment in our patent infringement litigation against Insmmed in the United States. The court granted us summary judgment that Insmmed infringes claims 1, 2 and 9 of U.S. Patent No. 6,331,414, and granted us summary judgment that certain publications asserted by Insmmed against the validity of U.S. Patent No. 5,187,151 do not qualify as prior art and cannot be used to attack the validity of that patent. In addition, the court denied Insmmed summary judgment that Insmmed does not infringe any of claims 1 through 4, 9 and 10 of U.S. Patent No. 6,331,414, denied Insmmed summary judgment that claims 1 through 4, 9 and 10 of U.S. Patent No. 6,331,414 are invalid under 35 U.S.C. §101 and §112, denied Insmmed summary judgment that Insmmed does not infringe claims 1, 4, 5 and 7 of U.S. Patent No. 5,187,151, and granted Insmmed summary judgment that no recovery can be had against it based on any activities conducted by Celtrix Pharmaceuticals, Inc. prior to December 23, 1998. On July 14, 2006, Insmmed filed a motion for partial reconsideration of the summary judgment order with respect to infringement of claims 1 and 2 of U.S. Pat. No. 6,331,414, and filed a request seeking the court's permission to file the motion. On September 29, 2006, the court granted its permission to Insmmed for the filing of that motion. Apart from the court's rulings on claims construction issues and cross-motions for summary judgment, and apart from Insmmed's motion for partial reconsideration of the court's summary judgment order with respect to infringement of claims 1 and 2 of U.S. Pat. No. 6,331,414, there were no material developments in our patent infringement litigation against Insmmed in the United States during the nine months ended September 30, 2006. Subsequent to the nine months ended September 30, 2006, on October 13, 2006, we and Genentech filed an opposition to Insmmed's motion for partial reconsideration of the court's summary judgment order and we, with Genentech, and Insmmed filed our respective pretrial motions and other filings relating to the jury trial scheduled to commence on November 6, 2006. On October 31, 2006, the court issued a written ruling denying Insmmed's motion for partial reconsideration of the court's June 30, 2006 summary judgment order.

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

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



**Table of Contents**

from our rhIGF-1 programs and/or render any further development and commercialization of rhIGF-1 commercially infeasible for us and/or Ipsen. If in our litigation in the United Kingdom, the court awards a declaratory judgment finding invalid one or more of the claims of European Patent No. 0 571 417, and if the court's finding of invalidity in such declaratory judgment is upheld in whole or in part on appeal or if no appeal is taken, we would be unable to exclude others from using the affected claim or claims in the United Kingdom, and any such finding of invalidity may have a similar adverse impact on the enforceability of the affected claim or claims in one or more of the other European countries in which European Patent No. 0 571 417 would otherwise be in force, which may decrease our ability to generate significant revenue from our rhIGF-1 programs and/or render any further development and commercialization of rhIGF-1 commercially infeasible for us and/or Ipsen.

In December 2005, we filed a complaint against Insmmed for False Advertising and Unfair Competition, Case No. C-05-5027 SBA, in the U.S. District Court for the Northern District of California. The complaint alleged that Insmmed made false, misleading and deceptive statements about Increlex and its product. On June 9, 2006, the Court granted Insmmed's motion to dismiss the case. On June 12, 2006, we filed a complaint against Insmmed for False Advertising, Unfair Competition and Intentional Interference with Prospective Business Relations, Case No. 3:06cv403, in the U.S. District Court for the Eastern District of Virginia. The complaint alleged that Insmmed made false, misleading and deceptive statements about Increlex and its product and intentionally interfered with our business relationships. We are seeking monetary and injunctive relief. On June 23, 2006, we filed our First Amended Complaint. On July 27, 2006, Insmmed filed a motion to dismiss the case. On October 3, 2006, the Court denied in part and granted in part Insmmed's motion to dismiss, and ordered the case, with our allegations narrowed, to move forward with a March 2007 trial date. On October 13, 2006, Insmmed filed a counterclaim in the case, alleging that we made false and misleading statements regarding Insmmed's product and Increlex.

**Table of Contents****ITEM 1A. RISK FACTORS.**

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

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

**Risks Related to Our Business**

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

We are a development stage company focused on the development and commercialization of products for the treatment of short stature and other endocrine disorders. From our inception in October 2000 through September 30, 2006, we had an accumulated deficit during the development stage of \$207.8 million. We had revenues of \$567,000 and incurred a net loss of \$42.0 million during the nine months ended September 30, 2006. 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 for severe Primary IGFD and Primary IGFD and Somatuline® Autogel® for acromegaly. We are unable to predict the extent of these future net losses, or when we may attain profitability, if at all. These net losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity and net current assets.

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

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

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

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

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



---

**Table of Contents**

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

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

reimbursement adoption;

product price;

the effectiveness of our sales and marketing efforts;

storage requirements and ease of administration;

dosing regimen;

safety and efficacy;

prevalence and severity of side effects; and

competitive products.

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

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

We believe that the annual wholesale acquisition cost of Increlex therapy for the treatment of severe Primary IGFD for a 24 kilogram child at a 120mg/kg twice daily dose is approximately \$23,000 per year. The actual cost per year per patient for Increlex will depend on the weight of the child, the treatment dose prescribed and compliance. If our assumptions regarding the revenue per patient of Increlex therapy for the treatment of severe Primary IGFD and Primary IGFD are incorrect, our expected revenues and the market opportunity for Increlex therapy for the treatment of severe Primary IGFD and Primary IGFD may be substantially reduced.

In recent years, officials have made numerous proposals to change the health care system in the United States. These proposals include measures that would limit or prohibit payments for certain medical treatments or subject the pricing of drugs to government control. In addition, in many foreign countries, particularly in Canada and the countries of the European Union, the pricing of prescription drugs is subject to government control. If our products become subject to government legislation that limits or prohibits payment for our products, or that subjects the price of our products to governmental control, we may not be able to generate revenues, attain profitability or market and sell our products. Because

these initiatives are subject to substantial political debate, which we cannot predict, the trading price of biotechnology stocks, including ours, may become more volatile as this debate proceeds.

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

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

Somatuline® Autogel® may not receive U.S. regulatory approval in a timely manner, for the label that we anticipate, or at all. Even if Somatuline® Autogel® receives U.S. regulatory approval, the approval may not be maintained, including as a result of the failure to maintain compliance with cGMP regulations, and Ipsen may be unable to maintain the supply of the product. In addition, revenues from sales of Somatuline® Autogel® in the United States and Canada may not meet our

**Table of Contents**

expectations, including as a result of competing products or unavailable or limited reimbursement by third-party payers. Under the license and collaboration agreement with respect to Somatuline® Autogel®, Ipsen may terminate the agreement in a particular country if we fail to meet certain minimum sales and promotional requirements with respect to that country. It is also possible that Ipsen will not be successful in marketing and selling Increlex in the licensed territories, or may be delayed in doing so, in which case we would not receive royalties on the timeframe and to the extent that we currently anticipate. We also may not be able to successfully develop additional products or improvements to, or new indications for, Somatuline® Autogel® and/or Increlex or share the costs of such developments in a manner that is commercially feasible for us. In addition to cross-licensing agreements for Somatuline® Autogel® and Increlex, we and Ipsen have granted to each other a right of first negotiation for products in our respective endocrine pipelines and have agreed on a framework for joint clinical development and subsequent commercialization of endocrine products on a worldwide basis. However, the development of Ipsen's endocrine pipeline may not advance at the rate we currently expect 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.

*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. 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 invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation;

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

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

the collaborations may be terminated or allowed to expire, which would delay product development and commercialization efforts.  
***We face significant competition from large pharmaceutical, biotechnology and other companies that could harm our business.\****

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

## Table of Contents

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

acceptance of Increlex and Somatuline<sup>®</sup> Autogel<sup>®</sup> by physicians and patients as a safe and effective treatment;

reimbursement adoption;

product price;

manufacturing costs;

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

storage requirements and ease of administration;

dosing regimen;

safety and efficacy;

prevalence and severity of side effects; and

competitive products.

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

Insmed Incorporated's combination product was launched and competes directly with Increlex for the treatment of patients with severe Primary IGFD. Insmed's combination product was approved by the FDA for the treatment of patients with severe Primary IGFD or with growth hormone gene deletion who have developed neutralizing antibodies to growth hormone. Insmed has also announced that its application to market its combination product in the European Union has been validated and that they could therefore receive a marketing approval in 2007.

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

In addition, children with Primary IGFD may be diagnosed as having idiopathic short stature, or ISS. Eli Lilly and Company and Genentech have received FDA approval for their respective growth hormone products for the treatment of children with ISS in the United States, and Ipsen is seeking ISS approval for its growth hormone product in Europe. Moreover, biosimilar growth hormone products, including Omnitrope marketed by Sandoz, a division of the Novartis group, have been or may be approved in the United States and other countries. Accordingly, we



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

expect that several growth hormone products will compete directly with Increlex for the treatment of children with Primary IGFD.

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

We believe that Bristol-Meyers Squibb Company, Genentech, Merck & Co., Inc., Novo Nordisk and Pfizer Inc. have conducted research and development of orally available small molecules that cause the release of growth hormone, known as growth hormone secretagogues. We believe that Sapphire Therapeutics has licensed certain rights to Novo Nordisk's growth hormone secretagogues and is actively developing one of these compounds for use in cancer cachexia, a wasting disorder affecting some cancer patients. These products work by increasing the levels of rhIGF-1 and, if approved, could potentially compete with Increlex.

Somatuline<sup>®</sup> Autogel<sup>®</sup> is approved in Canada for the treatment of acromegaly and together with Ipsen, we plan to seek regulatory approval for the same indication in the United States. In Canada, and in the United States if approved, Somatuline<sup>®</sup> Autogel<sup>®</sup> will compete directly with Sandostatin<sup>®</sup> LAR<sup>®</sup> Depot and Somavert<sup>®</sup>. Sandostatin<sup>®</sup> LAR<sup>®</sup> Depot is a somatostatin analogue and has the same mechanism of action as Somatuline<sup>®</sup> Autogel<sup>®</sup>. Sandostatin<sup>®</sup> 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<sup>®</sup> 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 will also compete with Somatuline<sup>®</sup> Autogel<sup>®</sup> for the treatment of patients with acromegaly.

**Table of Contents**

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

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

We are currently developing Increlex for the treatment of Primary IGFD. The FDA has substantial discretion in the approval process and may decide that the data from our clinical trials is insufficient to allow approval of Increlex for Primary IGFD. If we do not receive regulatory marketing approval in the United States for Primary IGFD, our business will be harmed. We will also need to file applications with regulatory authorities in foreign countries to market Increlex for Primary IGFD in foreign countries. Although we have submitted a marketing authorization application in Europe for severe Primary IGFD, there is no assurance that we will receive marketing approval in Europe for either severe Primary IGFD or Primary IGFD. In addition, if we fail to obtain European marketing approval for Increlex for the target label under our license and collaboration agreement with Ipsen (or for a label which provides access to an agreed upon number of patients), we would not receive the European Medicines Agency, or EMEA, approval-related milestone payment provided for under our agreement with Ipsen. Further, even if European marketing authorization for Increlex is obtained but the target label or access to the agreed upon patient population is not approved within three years from the date of obtaining such initial marketing authorization, we would not be owed the EMEA approval-related milestone payment provided for under our agreement with Ipsen. Further, if EMEA approvals are delayed, it would postpone our ability to receive royalties from the commercialization of Increlex in Europe. In addition, if the FDA does not approve Somatuline® Autogel® for the treatment of acromegaly, or for the label that we anticipate, our ability to generate revenues would be adversely affected, and our business would be harmed. We may also determine not to, or we may be unable to develop or obtain FDA approval of Somatuline® Autogel® for indications other than acromegaly, such as neuroendocrine tumors.

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

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

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

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

We currently source all of our Increlex fill-finish manufacturing and portions of release testing through a single-source third-party supplier. This supplier is the only FDA-approved manufacturer currently available to us, and could only be replaced by qualification of a new site for the same operations. We have negotiated a short-term commercial agreement with this fill-finish manufacturer and during the term of this agreement, we will attempt to move our process to another fill-finish manufacturer. It will take a significant amount of time and expense to arrange for an alternative manufacturer. For us to change to another commercial fill-finish manufacturer, such manufacturer's facilities and processes, prior to our use, will need to undergo pre-approval and/or cGMP compliance inspections. In addition, we would need to transfer and validate the processes and certain analytical methods necessary for the production and testing of rhIGF-1 to this new manufacturer. A delay in such a transfer may also result in a shortage of our commercial product and a loss of revenues.

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

The facilities used by and operations of our contract manufacturers to manufacture and test Increlex must undergo continuing inspections by the FDA for compliance with cGMP regulations in order to maintain our Increlex approval for the treatment of severe Primary IGF1D. Similarly, the facilities used by and operations of Ipsen to manufacture Somatuline® Autogel® must undergo an inspection by the FDA for compliance with cGMP regulations before Somatuline® Autogel® can be approved. Currently, Cambrex Bio Science Baltimore, Inc. is our sole provider of bulk rhIGF-1 and Ipsen is our sole provider of Somatuline® Autogel®. We have no alternative manufacturing facilities or plans for additional facilities at this time. We do not know if the Cambrex Baltimore facilities or their operations required for the commercial manufacture of Increlex will continue to receive satisfactory cGMP inspections and we do not know if Ipsen's facilities or their operations required for the commercial manufacture of Somatuline® Autogel® will receive a satisfactory cGMP inspection. In the event these facilities or operations do not receive, or continue to receive, satisfactory cGMP inspections for the manufacture of our products, or for the operation of their facilities in general, we may need to invest in significant compliance improvement programs, fund additional modifications to our manufacturing processes, conduct additional validation studies, or find alternative manufacturing facilities, any of which would result in significant cost to us as well as result in a delay or prevention of commercialization, and may result in our failure to obtain or maintain approvals. In addition, Cambrex Baltimore, and any alternative contract manufacturer we may utilize, will be subject to ongoing periodic inspection by the FDA and corresponding state and foreign agencies for compliance with cGMP regulations and similar foreign standards. We do not have direct control over 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 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.\****

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



## **Table of Contents**

As a consequence, we may have inadequate capacity to meet unexpected demand, which could negatively affect our operating results and our ability to meeting our supply obligations to Ipsen. Further, our operating results and financial performance may suffer if we experience more than anticipated manufacturing lot failures.

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

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

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

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

However, more than one product may be approved by the FDA for the same orphan indication or disease. As a result, although Increlex has been approved and has received marketing exclusivity for severe Primary IGFD, the FDA can still approve other drugs for use in treating the same indication or disease covered by our product, which would create a more competitive market for us. For example, the FDA approved Insmed Incorporated s combination product for the treatment of severe Primary IGFD and granted Insmed s product orphan drug designation. Accordingly, notwithstanding our orphan drug designation for rhIGF- 1, Insmed s combination product for rhIGF-1 and BP-3 was deemed by the FDA to be a different drug than ours, and therefore, it competes directly with Increlex for the treatment of patients with severe Primary IGFD. Similarly, there may be additional drugs for treating acromegaly that could compete with Somatuline® Autogel® despite its seven-year orphan drug marketing exclusivity, even if granted by the FDA.

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

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

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

Although we have obtained regulatory approval for Increlex in the United States for the treatment of severe Primary IGFD, this product and our manufacturing processes are subject to continued review and ongoing regulation by the FDA post approval, including, for example, changes to manufacturing process standards or good manufacturing practices, changes to product labeling, revisions to existing requirements or new requirements for manufacturing practices, or changing



## **Table of Contents**

interpretations regarding regulatory guidance. Such changes in the regulatory environment and requirements could occur at any time during the commercialization of Increlex. We face similar risks with respect to the commercialization of Somatuline® Autogel® in Canada and, if we receive FDA approval, in the United States. Changes in the regulatory environment or requirements could adversely affect our ability to maintain our approval or require us to expend significant resources to maintain our approvals, which could result in the possible withdrawal of our products from the marketplace, which would harm our business and negatively impact our financial performance.

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

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

### ***Competitors could challenge our patents and file an Abbreviated New Drug Application (ANDA) or a 505(b)(2) new drug application for an IGF-1 or Somatuline® Autogel® 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® Autogel® product or a modified version of IGF-1 or Somatuline® Autogel® 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® Autogel® NDA is invalid or not infringed by the manufacture, use, or sale of the product described in that ANDA or 505(b)(2) application under the Hatch-Waxman Act. If successful, a competitor could come to market at an earlier time than expected. We can provide no assurances that we can prevail in a challenge or litigation related to our patents or exclusivity.

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

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

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

If we are not able to protect our proprietary technology, trade secrets and know-how, our competitors may use our inventions to develop competing products. We have licensed intellectual property rights, including patent rights, relating to rhIGF-1 and Somatuline® Autogel® 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 patent composition coverage on the rhIGF-1 protein alone. Although we have licensed from Genentech its rights to its methods of use and manufacturing patents, it may be more difficult to establish infringement of such patents as compared to a patent directed to the rhIGF-1 protein composition alone. Our licensed patents may not be sufficient to prevent





## Table of Contents

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

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

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. For example, we initiated patent infringement proceedings against Avecia Limited and Insmed Incorporated in the United Kingdom and against Insmed Incorporated in the United States to enforce patent rights we licensed from Genentech. The United States action, among other things, alleges infringement of United States Patent No. 6,311,414 B1 identified above. If the court finds any of the patents at issue in those litigations, including United States Patent No. 6,311,414 B1, to be invalid or unenforceable, we would be prevented from enforcing such patents against third parties in the future, thus preventing us from using the affected patents to exclude others from competing with us. Likewise, if we assert the patents we licensed from Ipsen in an infringement proceeding against a competitor, and if the court were to find in favor of any defense of invalidity or unenforceability raised by the competitor against the asserted patents, we would be unable to use the affected patents to exclude others from competing with Somatuline® Autogel®. In addition, the type and extent of patent claims that will be issued to us in the future are uncertain. Any patents that are issued may not contain claims that will permit us to stop competitors from using technology similar to our Increlex® or Somatuline® Autogel® technologies.

In addition to the patented technology licensed from Genentech and Ipsen, we also rely on unpatented technology, trade secrets and confidential information, such as the proprietary information we use to manufacture Increlex®. We may not be able to effectively protect our rights to this technology or information. Other parties may independently develop substantially equivalent information and techniques or otherwise gain access to or disclose this technology. We generally require each of our employees, consultants, collaborators, and certain contractors to execute a confidentiality agreement at the commencement of an employment, consulting or collaborative relationship with us. However, these agreements may not provide effective protection of this technology or information or, in the event of unauthorized use or disclosure, they may not provide adequate remedies.

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

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

In addition, a third party may claim that we are using its inventions covered by its patents and may initiate litigation to stop us from engaging in our operations and activities. Although no third party has claimed that we are infringing on their patents, patent lawsuits are costly and could affect our results of operations and divert the attention of managerial and technical personnel. There is a risk that a court would decide that we are infringing the third party's patents and would order us to stop the activities covered by the patents. In addition, there is a risk that a court will order us to pay the other party damages for having infringed the other party's patents. The biotechnology industry has produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of

---

**Table of Contents**

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

We are aware of a U.S. patent of Chiron Corporation related to processes of manufacturing rhIGF-1 in yeast host cells, to fusion proteins, DNA, and yeast host cells useful in such processes of manufacturing rhIGF-1 in yeast host cells, and to rhIGF-1 made as a product of such processes. While we use bacterial expression, not yeast expression, in our process for manufacturing Increlex<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 Chiron's patent in the event Chiron brings patent infringement proceedings against us. We may not be able to obtain a license to Chiron's patent under commercially reasonable terms, if at all. If we are unable to obtain a license to Chiron's patent, and if in any patent infringement proceeding Chiron brings against us the court decides that our activities relating to the development and commercialization of Increlex<sup>®</sup> in the United States infringe Chiron's patent, the court may award damages and/or injunctive relief to Chiron. Any such damages, injunctive relief and/or other remedies the court may award could render any further development and commercialization of Increlex<sup>®</sup> commercially infeasible for us or otherwise curtail or cease any further development and commercialization of Increlex<sup>®</sup>.

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

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

patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, and

publications in the scientific literature often lag behind actual discoveries and the filing of patents relating to those discoveries. Patent applications may have been filed and may be filed in the future covering technology similar to ours. Any such patent application may have priority over our patent applications and could further require us to obtain rights to issued patents covering such technologies. In the event that another party has filed a U.S. patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the U.S. Patent and Trademark Office to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful, resulting in a loss of our United States patent position with respect to such inventions.

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

***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 and ability to influence our business through certain protective provisions, Ipsen has significant control over the outcome of most actions by our Board of Directors and those requiring the approval of our stockholders. Accordingly, our other stockholders may be unable to prevent actions by Ipsen. Together with the 12,527,245 shares of our common stock that we issued in connection with the initial closing of our collaboration with Ipsen, the conversion of the convertible notes we issued or that we may issue to Ipsen and the exercise of the warrant that we issued to Ipsen would enable Ipsen to acquire an ownership interest in us of approximately 40% on a fully diluted basis, with the opportunity to increase its ownership position to 60% or greater through market purchases upon the expiration of a one-year standstill period. Ipsen was also granted a preemptive right to purchase its *pro rata* portion of new securities that we may offer in the future to maintain its percentage ownership interest. In addition, under the terms of our affiliation agreement with Ipsen, so long as Ipsen holds at least 15% of the outstanding shares of our common stock, Ipsen would be entitled to nominate two out of the nine directors on our Board of Directors. In the event that Ipsen holds at least 10% of the outstanding shares of our common stock, but less than 15%, it would be entitled to nominate one director to our Board of Directors. Our affiliation agreement with Ipsen also provides that in the event Ipsen holds at least 60% of the outstanding shares of our common stock, Ipsen is entitled to nominate an unlimited number of directors to our Board of Directors. For so long as Ipsen holds at least 15% of the outstanding shares of our common stock, Ipsen is also entitled to nominate additional independent director nominees, who must be independent of Ipsen, starting in 2008. Our certificate of incorporation was also amended in connection with our

collaboration with Ipsen to waive the corporate opportunity provisions under Delaware law and the

**Table of Contents**

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

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

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

***We are subject to Genentech's option rights with respect to the commercialization of Increlex for all diabetes and non-orphan indications in the United States. We are also subject to Ipsen's right of first negotiation to develop and commercialize other products subsequently acquired or owned by us.\****

Under our U.S. license and collaboration agreement with Genentech, Genentech has the option to elect to jointly commercialize rhIGF-1 for all diabetes and non-orphan indications in the United States. Orphan indications are designated by the FDA under the Orphan Drug Act, and are generally rare diseases or conditions that affect fewer than 200,000 individuals in the United States. With respect to those non-orphan and diabetes indications in the United States, once Genentech has exercised its option to jointly develop and commercialize, Genentech has the final decision on disputes relating to development and commercialization of such indications. Our ability to sublicense the development and commercialization of such products requires the consent of Genentech. In addition, 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.

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

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

the FDA or other regulatory authorities either do not approve a clinical trial protocol or place a clinical trial on clinical hold;

patients do not enroll in clinical trials at the rate we expect (for example, in our current Phase III clinical trials of rhIGF-1 in Primary IGF1D, patients have not enrolled at the rate we expected);

patients experience adverse side effects;

patients develop medical problems that are not related to our products or product candidates;

third-party clinical investigators do not perform our clinical trials on our anticipated schedule or consistent with the clinical trial protocol and good clinical practices, or other third-party organizations do not perform data collection and analysis in a timely or

accurate manner;

contract laboratories fail to follow good laboratory practices;

interim results of the clinical trial are inconclusive or negative;

sufficient quantities of the trial drug may not be available, or available drug may become unusable;

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

re-evaluation of our corporate strategies and priorities; and

limited financial resources.

**Table of Contents**

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

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

To gain approval to market a product for treatment of a specific disease, we must provide the FDA and foreign regulatory authorities with clinical data that demonstrate the safety and statistically significant efficacy of that product for the treatment of the disease. Clinical development is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our clinical trials. For example, we may seek to develop Somatuline<sup>®</sup> Autogel<sup>®</sup> for indications other than acromegaly, such as neuroendocrine tumors, 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 preclinical testing and early clinical trials does not ensure that later clinical trials will be successful. If a clinical trial failed to demonstrate safety and statistically significant efficacy, we would likely abandon the development of that product, which could harm our business and may result in a precipitous decline in our stock price.

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

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

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

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

***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.

In addition, we may need additional intellectual property from other third parties to market and sell our products for indications other than severe Primary IGFD, Primary IGFD or acromegaly. 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.

---

## Table of Contents

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

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

a minimum price for our common stock;

the accuracy of representations and warranties made to Kingsbridge;

compliance with laws;

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

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

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

The terms of the CEFF require us to pay certain liquidated damages in the event that the registration statement filed by us with the SEC is not available for the resale of securities purchased by Kingsbridge under the CEFF or upon exercise of the warrant we issued to Kingsbridge. Except for certain periods of ineffectiveness permitted under the CEFF, we are obligated to pay to Kingsbridge an amount equal to the number of shares purchased under the CEFF and held by Kingsbridge at the date the registration statement becomes unavailable, multiplied by any positive difference in price between the volume weighted average price on the trading day prior to such period of unavailability and the volume weighted average price on the first trading day after the period of unavailability. In addition, we are entitled in certain circumstances to deliver a blackout notice to Kingsbridge to suspend the use of the registration statement and prohibit Kingsbridge from selling shares under the registration statement. If we deliver a blackout notice in the 15 trading days following a settlement of a draw down, then we must make a blackout payment to Kingsbridge as liquidated damages, or issue Kingsbridge additional shares in lieu of this payment, calculated by means of a varying percentage of an amount based on the number of shares purchased and held by Kingsbridge and the change in the market price of our common stock during the period in which the use of the registration statement is suspended. If the trading price of our common stock declines during a suspension of the registration statement, the blackout payment could be significant and could adversely affect our liquidity and our ability to raise capital. In addition, under the terms of an affiliation agreement we entered into pursuant to our collaboration with Ipsen, we have only a limited ability to raise capital through the sale of our equity without first obtaining Ipsen's approval.

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

Under the terms of our collaboration with Ipsen, we issued Ipsen a convertible note in the principal amount of \$25.0 million, and may issue up to two additional convertible notes to Ipsen in the principal amounts of \$30.0 million and \$15.0 million, respectively. All of these notes mature on October 13, 2011 and carry a 2.5% coupon per annum from the date of issuance, compounded quarterly. If Ipsen chooses not to convert these notes, we would be required to pay to Ipsen the principal amount of the notes plus accrued interest at maturity. We will also be subject to currency risk on the \$30.0 million convertible note that we may issue to Ipsen, which, if the note is not converted, may result in the need to raise a greater amount of U.S. dollars to repay this note at maturity than would be required based on a conversion of this note to U.S. dollars at the time we entered into the stock purchase and master transaction agreement with Ipsen in July 2006 or issuance of the note. If we are required to pay the notes in cash, we will likely need to raise such amounts from the capital markets or through a strategic transaction. There is no assurance that

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

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.



**Table of Contents**

*If we fail to obtain the capital necessary to fund our operations, we will be unable to execute our business plan.\**

We believe that our cash, cash equivalents and short-term investments as of September 30, 2006, together with the funds that we have received and would potentially receive from our collaboration with Ipsen, would be sufficient to meet our projected operating and capital expenditure requirements through at least the end of 2007. However, our future capital needs and the adequacy of our available funds will depend on many factors, including:

changes in our business plan;

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

the commercial status of the Increlex bulk drug manufacturing operations at Cambrex Baltimore, including the success of our cGMP production activities;

the success of Increlex final drug product manufacturing;

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

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

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

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

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

the status of competing products;

the rate of progress and cost of our future clinical trials and other research and development activities; 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, and the CEFF. However, there can be no assurance that additional financing will be available when needed, or, if available, that the terms will be favorable. In addition, under the terms of an affiliation agreement we entered into pursuant to our collaboration with Ipsen, we have only a limited ability to raise capital through the sale of our equity without first obtaining Ipsen's approval. If additional funds are not available, we may be forced to curtail or cease operations.

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

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

Our ability to implement our business plan requires an effective planning and management process. As of September 30, 2006, we had 103 full-time employees, and we expect to hire additional employees in the near term. Our offices are located in the San Francisco Bay area where competition for personnel with biopharmaceutical skills is intense. If we fail to identify, attract, retain and motivate these highly skilled personnel, we may be unable to continue our development and commercialization activities.

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

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

One potential risk of using growth factors like rhIGF-1 is that it may increase the likelihood of developing cancer or, if patients already have cancer, that the cancer may develop more rapidly. Increlex may also increase the risk that diabetic patients may develop or worsen an existing retinopathy, which could lead to the need for additional therapy such as laser treatment of the eyes or result in blindness. We have Phase III study results from the treatment of more than 76 children with severe Primary IGFD with Increlex for an average of more than 4.4 years, with some patients being treated for over 12 years. None of the children withdrew from the study due to adverse events. However, some patients experienced hypoglycemia, or low blood glucose levels. Other side effects noted in some patients include hearing deficits, enlargement of the tonsils and intracranial hypertension.

## **Table of Contents**

Somatuline® Autogel® 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 or Somatuline® Autogel®, which may result in product liability suits being brought against us. While we have licensed the rights to develop, market and sell Increlex and Somatuline® Autogel® in certain indications, we are not indemnified by any third party, including our contract manufacturers, for any liabilities arising out of our development or use of rhIGF-1 or Somatuline® Autogel®.

Whether or not we are ultimately successful in defending product liability litigation, such litigation would consume substantial amounts of our financial and managerial resources, and might result in adverse publicity or reduced acceptance of Increlex or Somatuline® Autogel® in the market, all of which would impair our business. We have obtained clinical trial insurance and product liability insurance; however, we may not be able to maintain our clinical trial insurance or product liability insurance at an acceptable cost, if at all, and this insurance may not provide adequate coverage against potential claims or losses.

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

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

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

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

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

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

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

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

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

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

---

**Table of Contents**

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 October 13, 2006, our directors, executive officers and principal stockholders and their affiliates beneficially owned approximately 32.0% of our common stock. Our greater than five percent beneficial owners include Ipsen and its affiliates, which beneficially owned 35.8% (not including shares subject to limited voting agreements with certain of our stockholders); entities affiliated with MPM Capital, which beneficially owned 13.8%; entities affiliated with Prospect Management Co. II, LLC, which beneficially owned 6.1%; MedImmune, Inc., which beneficially owned 6.0%; and entities affiliated with Rho Ventures, which beneficially owned 6.0%. Our directors, executive officers and principal stockholders and their affiliates collectively have the ability to determine the election of all of our directors and to determine the outcome of most corporate actions requiring stockholder approval. They may exercise this ability in a manner that advances their best interests and not necessarily those of other stockholders.

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

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

entering into most material transactions or agreements;

merging or consolidating with other entities;

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

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

incurring capital expenditures of more than \$2,000,000 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;

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

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

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

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

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

Provisions of our amended and restated certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us, even if doing so would benefit our stockholders. These provisions:

establish a classified Board of Directors so that not all members of our board may be elected at one time;

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

---

**Table of Contents**

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.

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

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

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

***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, 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;

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

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.



---

**Table of Contents**

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

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

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

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

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

As of October 13, 2006, we had 50,117,193 outstanding shares of common stock. Of these shares, the 18,975,000 shares sold in our public offerings were freely tradable without restriction or further registration unless purchased by our affiliates. Of the remaining 31,142,193 shares outstanding as of October 13, 2006, substantially all of these shares, other than the 12,527,245 shares we issued to an affiliate of Ipsen, were eligible for sale in the public market (subject to certain restrictions on sales by affiliates and vesting in the case of early exercised options). The 12,527,245 shares we issued to an affiliate of Ipsen will become eligible for sale in the public market under Rule 144 in October 2007, subject to compliance with the volume, manner of sale and other limitations under Rule 144. As of October 13, 2006, we had 4,059,150 shares subject to outstanding options granted under our equity compensation plans. In addition, as of October 13, 2006, 8,405,524 shares were issuable upon the exercise of the warrant and conversion of convertible note we issued to Ipsen in connection with the initial closing of our collaboration. Further, the terms of the warrant we issued to Ipsen provide that the number of shares of our common stock subject to the warrant may increase in the event of certain issuances of equity securities by us that dilute Ipsen's percentage ownership interest in us. Moreover, the initial exercise price of the warrant, and the conversion price of convertible notes we issued or that we may issue to Ipsen, are subject to certain weighted-average price-based antidilution adjustments. These terms of the warrant and convertible notes may entitle Ipsen to acquire a greater number of shares of our common stock than we currently anticipate.

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

**Table of Contents**

**ITEM 5. OTHER INFORMATION.**

On September 6, 2006, our Board of Directors approved non-substantive amendments to our 2002 Stock Plan, 2002 Executive Stock Plan, 2004 Stock Plan and 2004 Employee Stock Purchase Plan. These amendments clarify that antidilution adjustments to equity awards under those plans are required and not discretionary actions of the plan administrator. The purpose of these amendments is to ensure that customary antidilution adjustments to equity awards resulting from certain corporate transactions such as a stock split or a stock dividend do not result in the modification of an equity award for purposes of Statement of Financial Accounting Standards No. 123 (revised 2004), Share-Based Payment. If these antidilution adjustments were characterized as a modification of an equity award, we could be required to record incremental compensation expense. The amendments are designed to remove the potential for these types of corporate transactions to be characterized as modifications of equity awards. Copies of each of the plans, as amended, are filed as exhibits to this Quarterly Report on Form 10-Q.

---

**Table of Contents**

**ITEM 6. EXHIBITS**

- 3.1 Amended and Restated Certificate of Incorporation(1)
- 3.2 Amended and Restated Bylaws(2)
- 3.3 Certificate of Amendment of Amended and Restated Certificate of Incorporation(3)
- 4.1 Form of Specimen Stock Certificate
- 4.2 Reference is made to Exhibits 3.1 and 3.2
- 4.3 Warrant issued to Kingsbridge Capital Limited, dated October 14, 2005(4)
- 4.4 Warrant issued to Ipsen, S.A., dated October 13, 2006
- 4.5 First Senior Convertible Promissory Note issued to Ipsen, S.A., dated October 13, 2006
- 4.6A Rights Agreement, dated as of October 13, 2006, between the Registrant and Computershare Trust Company, N.A., as Rights Agent
- 4.6B Form of Right Certificate
- 10.1A 2002 Stock Plan, as amended
- 10.2A 2002 Executive Stock Plan, as amended
- 10.3A 2004 Stock Plan, as amended
- 10.4A 2004 Employee Stock Purchase Plan, as amended
- 10.14A Stock Purchase and Master Transaction Agreement, dated July 18, 2006, by and between the Registrant and Ipsen, S.A.(5)
- 31.1 Certification of Chief Executive Officer of Tercica, Inc., as required by Rule 13a-14(a) or Rule 15d-14(a).
- 31.2 Certification of Chief Financial Officer of Tercica, Inc., as required by Rule 13a-14(a) or Rule 15d-14(a).
- 32.1 Certification by the Chief Executive Officer, as required by Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350).
- 32.2 Certification by the Chief Financial Officer, as required by Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350).

- 
- (1) Incorporated by reference to the 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 Registrant's registration statement on Form S-1 (File No. 333-108729) and amendments thereto, declared effective on March 16, 2004.
  - (3) Incorporated by reference to the 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 4, 2005.
  - (5) 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 July 24, 2006.

**Table of Contents**

**SIGNATURE**

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

Dated: November 3, 2006

TERCICA, INC.

(Registrant)

/s/ Ajay Bansal

Ajay Bansal

Chief Financial Officer

(Authorized Officer and Principal Financial Officer)