

TERCICA INC
Form 10-K
March 09, 2007
Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2006

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____

Commission File No. 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, CA 94005

(650) 624-4900

26-0042539
(I.R.S. Employer

Identification Number)

Edgar Filing: TERCICA INC - Form 10-K

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

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Name of Each Exchange on Which Registered
Common Stock, \$0.001 par value	Nasdaq Global Market

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No

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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act (Check one):

Large accelerated filer Accelerated filer Non-accelerated filer

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

The aggregate market value of the registrant's common stock, \$0.001 par value, held by non-affiliates of the registrant as of June 30, 2006 was \$92,114,611 (based upon the closing sales price of such stock as reported in the Nasdaq Global Market on such date). Excludes an aggregate of 20,168,764 shares of the registrant's common stock held by officers and directors and by each person known by the registrant to own 5% or more of the registrant's outstanding common stock as of June 30, 2006. Exclusion of shares held by any person should not be construed to indicate that such person possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the registrant, or that such person is controlled by or under common control with the registrant.

As of February 28, 2007, there were 50,162,610 shares of the registrant's common stock, \$0.001 par value, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement for the 2007 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission pursuant to Regulation 14A not later than 120 days after the end of the fiscal year covered by this Form 10-K are incorporated by reference in Part III, Items 10-14 of this Form 10-K.

Table of Contents

TERCICA, INC.

FORM 10-K ANNUAL REPORT

FOR THE YEAR ENDED DECEMBER 31, 2006

TABLE OF CONTENTS

	Page
<u>PART I</u>	
Item 1. <u>Business</u>	1
Item 1A. <u>Risk Factors</u>	22
Item 1B. <u>Unresolved Staff Comments</u>	43
Item 2. <u>Properties</u>	43
Item 3. <u>Legal Proceedings</u>	43
Item 4. <u>Submission of Matters to a Vote of Security Holders</u>	44
<u>PART II</u>	
Item 5. <u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	45
Item 6. <u>Selected Financial Data</u>	47
Item 7. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	48
Item 7A. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	59
Item 8. <u>Financial Statements and Supplementary Data</u>	61
Item 9. <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	92
Item 9A. <u>Controls and Procedures</u>	92
Item 9B. <u>Other Information</u>	93
<u>PART III</u>	
Item 10. <u>Directors, Executive Officers and Corporate Governance</u>	94
Item 11. <u>Executive Compensation</u>	94
Item 12. <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	94
Item 13. <u>Certain Relationships and Related Transactions, and Director Independence</u>	95
Item 14. <u>Principal Accountant Fees and Services</u>	95
<u>PART IV</u>	
Item 15. <u>Exhibits and Financial Statement Schedules</u>	96
<u>Signatures</u>	100

Table of Contents

PART I

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 Item 1A, 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.

Item 1. Business.

Tercica, Inc. is a biopharmaceutical company developing and marketing a portfolio of endocrinology products. We currently have the following products in our commercialization and development portfolio:

Increlex, which we began commercializing in the United States in January 2006; and

Somatuline® Autogel®, for which a New Drug Application, or NDA, was submitted in October 2006 to the U.S. Food and Drug Administration, or FDA, by Ipsen S.A., or Ipsen, our collaborator; and was approved for marketing in July 2006 by Health Canada for the treatment of acromegaly.

Increlex. We market Increlex as a long-term 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. We obtained approval for the long-term treatment of severe Primary IGFD from the FDA in August 2005. We are currently conducting a Phase IIIb clinical trial for the use of Increlex for the treatment of children with Primary IGFD. In January 2006, we launched Increlex in the United States. Increlex generated net revenues of \$1.3 million in 2006.

In December 2005, we submitted a Marketing Authorization Application, or 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. We expect to receive an opinion from the Committee for Medicinal Products for Human Use on the Increlex MAA in the second quarter of 2007. Pursuant to our worldwide strategic collaboration with Ipsen that was finalized in October 2006, we granted to Ipsen and its affiliates the exclusive right under our patents and know-how to develop and commercialize Increlex in all countries of the world except the United States, Japan, Canada, and for a certain period of time, Taiwan and certain countries of the Middle East and North Africa, for all indications, other than treatment of central nervous system and diabetes indications.

Somatuline® Autogel®. Pursuant to our worldwide strategic collaboration with Ipsen, we have the exclusive right under Ipsen's patents and know-how to develop and commercialize Somatuline® 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 and is currently in the reimbursement review process. Acromegaly is a hormonal disorder that results when a tumor in the pituitary gland produces excess growth hormone, resulting in overproduction of insulin-like growth factor-1 (IGF-1) and

Table of Contents

excessive growth. In October 2006, Ipsen submitted an NDA to the FDA for the use of Somatuline® Autogel® for the treatment of acromegaly. The FDA accepted the NDA on December 30, 2006, and the Prescription Drug User Fee Act, or PDUFA, date for Somatuline® Autogel® for the treatment of acromegaly is August 30, 2007.

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

Scientific Background Short Stature

We believe that approximately one million children in each of the United States and Western Europe have short stature. Short stature is caused by a deficiency of IGF-1 or growth hormone, or other abnormalities such as genetic defects not associated with a deficiency of either hormone. Physicians use a height standard deviation score, or height SDS, to indicate how many standard deviations a person's height is from the average height of the normal population of a similar age and gender. The American Academy of Pediatrics and the American Academy of Clinical Endocrinology define short stature as a height that is more than two standard deviations below the average population height. Children with short stature are shorter than approximately 97.7% of children of a similar age and gender, and if their deficit in growth continues unchanged, they will attain a final height of no more than approximately 5'4" for boys and 4'11" for girls. Similarly, in evaluating IGF-1 deficiency, physicians can use an IGF-1 standard deviation score, or IGF-1 SDS, to indicate how many standard deviations a person's IGF-1 level is from the average level of the population of a similar age and gender.

We define the indication severe Primary IGFD to mean a child who has both a height SDS and an IGF-1 SDS of minus three or less; and the indication Primary IGFD to mean a child who has both a height SDS and an IGF-1 SDS of less than minus two, in each case in the presence of normal or elevated levels of growth hormone. Children with a height SDS of less than minus three are shorter than 99.9% of children of the same age and sex, while children with a height SDS of less than minus two are shorter than 97.7% of children of the same age and sex. Children with an IGF-1 SDS of less than minus three have IGF-1 levels lower than 99.9% of children of the same age, and children with an IGF-1 SDS of less than minus two have lower IGF-1 values than 97.7% of children of the same age. We are currently conducting a Phase IIIb clinical trial for the use of rhIGF-1 in Primary IGFD.

We believe that approximately 30,000 children in each of the United States and Western Europe suffer from Primary IGFD.

Role of IGF-1 in short stature. The endocrine system regulates metabolism through the use of hormones, including IGF-1, which is a naturally occurring 70 amino acid protein that is necessary for normal human growth and metabolism. A deficiency of IGF-1 can result in short stature and can lead, in children and adults, to a range of other metabolic disorders. These metabolic disorders can include lipid abnormalities, decreased bone density, obesity and insulin resistance. IGF-1 is normally produced as a result of a hormonal cascade beginning with the secretion of growth hormone by the pituitary gland. Growth hormone binds to a growth hormone receptor on a cell which initiates an intracellular process, known as intracellular signaling. This intracellular signaling produces IGF-1 which is released into the blood, which then stimulates cartilage and bone growth.

The cellular production of IGF-1 is regulated by growth hormone. Growth hormone deficiency leads to inadequate IGF-1 production, which results in short stature in children. Growth hormone replacement therapy,

Table of Contents

which increases IGF-1 levels, can often be used to successfully treat growth hormone deficiency. However, we believe many individuals with short stature, despite normal growth hormone secretion, are IGF-1 deficient, because their cells do not respond normally to growth hormone. These children are IGF-1 deficient usually because of abnormalities in either their growth hormone receptors or in their growth hormone signaling pathways. These individuals have Primary IGFD, which is characterized clinically by short stature, IGF-1 deficiency, and growth hormone sufficiency. Individuals with Primary IGFD are candidates for rhIGF-1 replacement therapy.

The following diagram illustrates IGF-1 deficiency and the role of IGF-1 in growth.

Table of Contents

Increlex and Severe Primary IGFD. Our product, Increlex, is identical to naturally occurring human IGF-1, and we believe it performs the same functions in the body. Increlex product label defines severe Primary IGFD to mean a child who has a height SDS and IGF-1 SDS of minus three or less and normal growth hormone levels. These children do not respond to or respond poorly to growth hormone therapy. If their deficit in growth continues unchanged, children with severe Primary IGFD who are untreated will typically attain a final height of no more than approximately 5'1" for boys and 4'2.9" for girls. Increlex therapy supplies these children with the IGF-1 that their bodies are not producing enough of. We estimate that a total of 6,000 children in each of the United States and Western Europe have severe Primary IGFD.

In our Phase III clinical trials of severe Primary IGFD, the data of which we submitted to the FDA in our NDA, some patients experienced hypoglycemia, or low blood glucose levels. Other side effects noted in some patients include hearing deficits, enlargement of the tonsils and intracranial hypertension. Of the children who have completed at least one year of rhIGF-1 replacement therapy, which is the generally accepted length of time required to adequately measure growth responses to drug therapy, a statistically significant increase in average growth rate from 2.8 cm per year prior to treatment to 8.0 cm per year after the first year of rhIGF-1 treatment was demonstrated ($p < 0.0001$). A p-value of less than 0.0001 means that the probability that this result occurred by chance was less than 1 in 10,000. A probability of 5 in 100 or less, or $p < 0.05$, is considered to be statistically significant. Compared to pre-treatment growth rates, statistically significant increases were also observed during each of the next five years of rhIGF-1 treatment ($p < 0.005$). We believe these increases in growth rates were clinically meaningful and comparable to those observed in clinical trials of other approved growth hormone treatments. Statistically significant increases in height SDS compared to baseline were also observed for each of the first eight years of rhIGF-1 treatment ($p < 0.001$).

Increlex and Primary IGFD. Although our first indication is for severe Primary IGFD, we are evaluating the use of Increlex for the treatment of children with Primary IGFD. Children with Primary IGFD suffer from the same hormonal deficiency as those with severe Primary IGFD. If their deficit in growth continues unchanged, children with Primary IGFD who are untreated will typically attain a final height of no more than approximately 5'4" for boys and 4'11" for girls. Excluding children with severe Primary IGFD, we believe that approximately 24,000 children in each of the United States and Western Europe suffer from Primary IGFD.

We are enrolling a Phase IIIb clinical trial in Primary IGFD, which is intended to serve as the basis for a supplemental NDA filing for this indication. We are conducting this study in the United States and Europe. The principal purpose of this clinical trial is to ensure safety in the broader population and to evaluate the safety and efficacy of various doses of Increlex for patients with Primary IGFD. In mid-2005, we initiated another study in Primary IGFD to investigate once-daily dosing of Increlex.

Scientific Background Acromegaly

The term acromegaly is derived from the Greek words *acro* (extremities) and *megaly* (enlargement). Acromegaly is an orphan disease where the pituitary gland secretes too much growth hormone resulting in overproduction of IGF-1 and excessive growth. The most common cause of acromegaly is a benign tumor of the pituitary gland. The condition can be caused by tumors in other parts of the body, such as the adrenal glands, lungs, or pancreas. Sometimes, these type of tumors can secrete growth hormone, or they might produce another hormone (growth hormone-releasing hormone), which stimulates the pituitary gland to make more growth hormone. If the condition develops before bone growth is completed in adolescence, it is called gigantism.

Acromegaly is a condition characterized by enlarged facial features, hands and feet, that results from excessive production of growth hormone by a tumor affecting the pituitary gland in the brain. Lanreotide decreases the production of the growth hormone and treats the symptoms of acromegaly without curing the tumor. It can be used as first line medical treatment when the levels of growth hormone and IGF-1 remain elevated following surgery or radiotherapy to treat the pituitary tumor.

Table of Contents

The excessive growth associated with acromegaly occurs in the extremities where bones and soft tissues increase in size. Because it is an uncommon disorder with symptoms that develop gradually over time, acromegaly can be difficult to diagnose. We believe that a total of approximately 15,000 people in the United States and Canada are estimated to have acromegaly. It is most commonly found in middle-aged adults.

Without treatment, acromegaly can lead to cardiovascular disease, hypertension, diabetes and a possible increased risk of colon cancer. If untreated, the mortality rate of people with acromegaly is at least two times higher, and the life expectancy is five to ten years less than that of the general population. Treatments that control the excess production of growth hormone and IGF-1 have been shown to return the mortality rate in these patients to normal.

Treatment options for acromegaly include surgical removal of the tumor, drug therapy and radiation therapy of the pituitary gland. Depending on each individual case, a combination of these treatment options may be needed to manage the effects of acromegaly. For example, although surgery can be an effective treatment approach, in many cases, hormone levels may improve yet still not return to normal; these patients would then need additional treatment, most commonly with drug therapy.

Drug therapies include somatostatin analogues, dopamine agonists and growth hormone receptor agonists:

Somatostatin analogues operate like a naturally occurring hormone called somatostatin, which decreases the production and secretion of growth hormone.

Dopamine agonists promote the activity of dopamine, a chemical in the brain, to stop growth hormone release by some pituitary tumors. These drugs generally do not work as well as the growth hormone receptor antagonists or the somatostatin analogues.

Growth hormone receptor antagonists, the most recent class of drugs developed to treat acromegaly, prevent growth hormone from stimulating IGF-1 production by blocking the places on cells where growth hormone binds, or connects, with the growth hormone receptor.

Radiation treatment is usually reserved for patients who cannot undergo surgery, or whose tumor is not completely removed during surgery, or who have not responded adequately to medication.

Somatuline® Autogel® and acromegaly. Somatuline® Autogel® injection contains the active ingredient lanreotide. Lanreotide belongs to a class of products called somatostatin analogues that operate similarly to a naturally occurring hormone in the body called somatostatin. Somatostatin is produced in various parts of the body, including the brain, gut and pancreas. It prevents the release of several hormones found in the body, such as growth hormone, serotonin, insulin and vasoactive intestinal peptide (VIP).

Somatuline® Autogel® has marketing authorizations in over 50 countries for the treatment of acromegaly and neuroendocrine tumors. In 2006, Somatuline® and Somatuline® Autogel® generated worldwide sales of 92.2 million (approximately \$120 million), up 12.8% versus 2005. In its main markets in Europe, Somatuline® Autogel® has achieved a 30% to 50% market share of the acromegaly market varying from country-to-country.

Strategy

Our goal is to capitalize on the opportunities presented by Increlex and Somatuline® Autogel® and to develop and commercialize additional new products for the treatment of metabolic disorders. Key elements of our strategy for achieving our goal include:

Grow Increlex usage in severe Primary IGFD. We believe that for the approximately 6,000 children in the United States who suffer from severe Primary IGFD, Increlex provides a favorable efficacy and safety profile. Through our sales and marketing efforts, we make pediatric endocrinologists aware of the risks and benefits of Increlex therapy, including conducting medical education programs, medical symposia, and regional

Table of Contents

speaker programs aimed at increasing physician awareness of Increlex and severe Primary IGFD. We have also established a patient registry to provide additional data on the safety and efficacy of Increlex. In addition, we seek to increase formulary acceptance of Increlex so it can be reimbursed in a timely manner following the writing of a prescription.

Expand Increlex indication from severe Primary IGFD to Primary IGFD. To maximize the opportunities presented by Increlex for the treatment of short stature, we initiated a Phase IIIb clinical trial of Increlex in children with Primary IGFD in late 2004. If the data from this trial are positive, we intend to submit a supplemental NDA to expand the use of Increlex to encompass children with Primary IGFD. If approved for Primary IGFD in the United States and European Union, the market for Increlex would expand from the approximately 6,000 children with severe Primary IGFD to encompass the approximately 30,000 children with Primary IGFD, including severe Primary IGFD, in each of the United States and Western Europe.

Successfully Launch Somatuline® Autogel® in Canada and the United States. There are approximately 500 adult endocrinologists in the United States that prescribe approximately 90% of the prescriptions for acromegaly. Subject to FDA approval, we believe that with the addition of approximately six additional sales representatives to our existing sales force we will be able to effectively market Somatuline® Autogel® to these physicians. In addition, we plan to conduct medical education programs, medical symposia, and regional speaker programs aimed at establishing awareness of Somatuline® Autogel® and its role in treating patients with acromegaly in the physician community. Somatuline® Autogel® has received a marketing approval in Canada and is currently in the reimbursement review process.

Broaden our endocrinology development portfolio. We intend to pursue the development and commercialization of additional products for the treatment of short stature, acromegaly and other metabolic disorders. We are seeking to in-license products that may benefit from our expertise in the field of endocrinology. In addition, as part of our strategic collaboration with Ipsen, we 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. Ipsen has several endocrinology compounds in pre-clinical development, including two products, BIM 23A760 (Dopastatin) and BIM 28131, that could enter clinical development in late 2007. BIM 23A760 (Dopastatin), a chimeric molecule directed towards somatostatin and dopamine receptors, is targeted at the possible treatment of pituitary adenomas, including those causing acromegaly, Cushing's disease and hyperprolactinemia as well as non-functional pituitary adenomas. BIM 28131, a ghrelin agonist, is targeted at restoring normal body composition in wasting diseases associated with chronic illness.

Key Relationships Genentech

rhIGF-1. We entered into a U.S. License and Collaboration Agreement with Genentech in April 2002, which was amended in July and November 2003. In addition, we entered into an International License and Collaboration Agreement with Genentech in July 2003, which expands certain of the rights granted to us under the U.S. License and Collaboration Agreement to the remaining territories of the world outside of the United States. Under these agreements, we have certain rights and licenses to Genentech's intellectual property to research, develop, use, manufacture and market rhIGF-1, alone or in combination with IGF binding protein-3, which we refer to in this document as IGFBP-3, for a broad range of indications. The rights are exclusive with respect to our development and sale of rhIGF-1 and non-exclusive with respect to our manufacture of rhIGF-1. Indications not covered by our licenses from Genentech include diseases and conditions of the central nervous system. In addition, we need to enter into a written agreement with another company if we desire to commercialize rhIGF-1 for diabetes outside of the United States.

Under both the U.S. License and Collaboration Agreement and the International License and Collaboration Agreement, Genentech agreed to transfer to us its pre-clinical and clinical data related to rhIGF-1. This includes data resulting from extensive animal testing as well as Phase I, Phase II and Phase III clinical trials with respect

Table of Contents

to rhIGF-1. In addition, under these agreements Genentech agreed to transfer its manufacturing technology and know-how to us. In consideration of this transfer, we paid Genentech \$1.0 million in cash and approximately \$4.1 million in Series A preferred stock upon execution of the U.S. License and Collaboration Agreement. We paid Genentech \$1.7 million upon execution of the International License and Collaboration Agreement and \$1.4 million related to the license to Genentech's rights to IGF-1 combined with IGFBP-3. In connection with the approval of our NDA in August 2005, we paid Genentech a \$1.0 million milestone payment related to the U.S. License and Collaboration Agreement. We also agreed to pay to Genentech royalties on the sales of rhIGF-1 products and certain one-time payments upon the occurrence of specified milestone events, such as attaining rhIGF-1 indication approvals and aggregate sales levels with respect to rhIGF-1. We are subject to the following milestone payments to Genentech as of December 31, 2006:

In addition to the amounts already paid to Genentech, if we achieve all of the additional milestones for rhIGF-1 under the U.S. License and Collaboration Agreement and the International License and Collaboration Agreement, we will owe Genentech up to an aggregate of approximately \$33.0 million.

If we develop rhIGF-1 in combination with IGFBP-3, we would be subject to these same milestone events and, upon achievement of all of the milestones, would owe Genentech up to an additional aggregate of approximately \$32.5 million. Accordingly, we would owe Genentech up to an aggregate of approximately \$65.5 million in milestone payments if we achieved all of these milestone events for both rhIGF-1 and for rhIGF-1 in combination with IGFBP-3. Both agreements require us to fulfill certain obligations to maintain our licenses.

Under the U.S. License and Collaboration Agreement, Genentech has exclusively licensed to us its right to develop and commercialize rhIGF-1 products in the United States for all indications other than diseases and conditions of the central nervous system. Genentech has a right, the Opt-In Right, to elect, within a limited period of time following an NDA-enabling clinical trial, to participate jointly with us in the development and commercialization of rhIGF-1 products we develop for diabetes indications and for all non-orphan indications. Orphan indications are generally diseases or conditions that affect fewer than 200,000 individuals in the United States. If Genentech elects to exercise its Opt-In Right for a particular indication, Genentech will pay us more than 50% of the past development costs associated with that indication. In addition, after Genentech exercises its Opt-In Right for a particular indication, we would share with Genentech the ongoing net operating losses and profits resulting from the joint development and commercialization effort for that indication. Pursuant to this arrangement, we would fund less than 50% of such operating losses and we would receive less than 50% of any profits associated with any joint indication. In addition, if we elect to discontinue the development of rhIGF-1 products for diabetes or a substitute indication selected by us, subject to Genentech's consent, Genentech has the right to assume development of such indication. Any substitute indication agreed to by Genentech, under the terms of the current agreement, must have a potential market greater than \$250.0 million and not be an indication for the central nervous system. In such event, our rights under the agreement for such indication would terminate and Genentech would be granted a non-exclusive license under our rhIGF-1 intellectual property and technology to manufacture, use and sell rhIGF-1 products for diabetes, or if applicable the substitute indication, subject to an obligation to pay us milestone payments and/or royalties to be negotiated by Genentech and us in good faith on sales of these products.

With respect to those indications in the United States for which Genentech does not have an Opt-In-Right or for which Genentech has not exercised its Opt-In-Right to jointly develop and commercialize rhIGF-1, we have the final decision on disputes relating to development and commercialization of rhIGF-1. With respect to those indications in the United States for which Genentech has exercised its Opt-In-Right, or for which its Opt-In-Right has not expired or been waived by Genentech, Genentech has the final decision on disputes relating to development and commercialization of rhIGF-1.

Under the International License and Collaboration Agreement, Genentech has exclusively licensed to us its right to develop and commercialize rhIGF-1 products outside of the United States for all indications other than

Table of Contents

diseases and conditions of the central nervous system. In addition, we need to enter into a written agreement with another company if we desire to commercialize rhIGF-1 for diabetes outside of the United States. Unlike the U.S. License and Collaboration Agreement, Genentech does not have the right to participate in any of our development or commercialization efforts for rhIGF-1 products outside of the United States.

Upon an uncured material breach of either the U.S. License and Collaboration or the International License and Collaboration Agreement, the non-breaching party may terminate the agreement. We also have the right to terminate either agreement at our sole discretion upon 60 days prior written notice to Genentech. If Genentech terminates either agreement because of our material breach, or if we terminate either agreement for any reason other than a material breach by Genentech, the rights and licenses granted to us under the respective agreement would terminate. In such event, Genentech would be granted a non-exclusive license under our rhIGF-1 intellectual property and technology to manufacture, use and sell rhIGF-1 products, subject to an obligation to pay us royalties on sales of these products to be negotiated by Genentech and us in good faith.

Key Relationships Ipsen

On October 13, 2006, we completed the first 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, a 30.0% premium to the Company's volume-weighted average closing stock price over the preceding 15 trading days ending on July 17, 2006, 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 an amendment to our amended and restated certificate 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 (or \$39.6 million at December 31, 2006) 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 in October 2011 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). The number of shares that Ipsen can purchase by exercising the warrant can increase over time. As of December 31, 2006, Ipsen could purchase up to approximately 5,000,000 shares of our common stock by exercising the warrant.

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 \$10.0 million or \$12.4 million and has agreed to pay us a milestone of \$15.0 million (or \$19.8 million as of December 31, 2006)

Table of Contents

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 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 stock purchase and master transaction agreement is consummated), we would make a milestone payment of \$30.0 million (or \$39.6 million as of December 31, 2006) 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 7 of the Notes to Financial Statements.

Manufacturing

Increlex. We have a Manufacturing Services Agreement with Cambrex Bio Science Baltimore, Inc., or Cambrex Baltimore, for the manufacture and supply of bulk rhIGF-1. We have extended the Manufacturing Service Agreement for four additional years and the agreement now terminates in December 2012. Under this agreement, Cambrex Baltimore is obligated to provide us with up to 24 kilograms of rhIGF-1 per year. We believe this quantity will be sufficient to supply our expected requirements through at least 2011. We also have a quality agreement with Cambrex Baltimore to ensure that product quality, compliance with cGMP and oversight over all critical aspects of rhIGF-1 production, testing and release is maintained.

In October 2006, Cambrex Corporation announced plans to sell its BioPharma subsidiary, which includes its Baltimore manufacturing operations, to Lonza Group AG, or Lonza Baltimore Inc. The sale to Lonza Baltimore was completed in February 2007, and we expect our contractual relationship with Cambrex to continue with Lonza Baltimore.

In November 2006, we executed a Development and Supply Agreement and a Quality Agreement for drug product filling, packaging, and labeling, with a commercial contract manufacturer. These agreements have an initial term of five years from the time of first commercial sale, and thus are anticipated to last through 2012. We expect to complete the technology transfer and manufacturing validation at this manufacturer by the end of 2007.

Our U.S. License and Collaboration Agreement with Genentech provides us with rights and access to Genentech's manufacturing technology and documentation associated with Genentech's manufacture and testing of rhIGF-1, including Genentech's proprietary large-scale manufacturing process for producing bulk rhIGF-1. This includes production cell banks, production batch records, development reports, analytical methods and regulatory documents describing improvements and changes to the production process.

Somatuline® Autogel®. Ipsen is our sole provider of Somatuline® Autogel®. We have no alternative manufacturing facilities or plans for any alternative facilities at this time. We do not have direct control over Ipsen's compliance with regulations and standards. 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 in the United States.

Sales and Marketing

Increlex. Our Increlex sales and marketing efforts target approximately 500 pediatric endocrinologists practicing in the United States. Pediatric endocrinologists are the physicians who customarily treat children with severe Primary IGFD. Because these pediatric endocrinologists are primarily hospital-based and concentrated in major metropolitan areas, we believe that our focused marketing organization and specialized sales force

Table of Contents

effectively serves them. We are conducting a variety of programs aimed at establishing physician awareness of Increlex as a treatment for severe Primary IGFD, including medical education, symposiums and regional speaker programs. We have also established a patient registry in order to provide further data on the safety and efficacy of Increlex.

Somatuline® Autogel®. Patients with acromegaly are typically treated by a subset of adult endocrinologists who sub-specialize in pituitary disorders. We believe there are approximately 500 physicians in the United States who write approximately 90% of the prescriptions for this disease. Subject to approval, we believe that with the addition of approximately six sales representatives to our existing sales force we will be able to effectively market *Somatuline® Autogel®* to these physicians. Like pediatric endocrinologists, adult endocrinologists are primarily hospital-based and concentrated in major metropolitan areas. We plan to conduct medical education programs, medical symposia and regional speaker programs aimed at establishing awareness of *Somatuline® Autogel®* and its role in treating patients with acromegaly.

Somatuline® Autogel® has received marketing approval in Canada and is currently in the reimbursement review process. At present, we have contracted sales and marketing operations in Canada to a third party.

Research and Development

Our principal experience has been developing late-stage product candidates and commercializing them. We do not conduct any of our own pre-clinical laboratory research. However, we consult with academic research institutions and other companies regarding both IGF-1 and non-IGF-1 related projects in endocrinology. Research and development activities consist primarily of severe Primary IGFD, Primary IGFD, and clinical and regulatory activities. Manufacturing development activities include pre-MAA approval preparation activities for current good manufacturing practices (cGMP), regulatory inspection preparation, technology transfer, process development and validation, quality control and assurance activities, and analytical services. Clinical and regulatory activities include the preparation, implementation, management of our clinical trials as well as regulatory compliance, data management and biostatistics. Our research and development expenses were \$42.0 million for the year ended December 31, 2006, \$21.6 million for the year ended December 31, 2005 and \$27.9 million for the year ended December 31, 2004.

Patents and Proprietary Rights

Our policy is to enforce our licensed patents to the extent our licensors have granted us such rights, and to protect our proprietary technology. We intend to continue to file U.S. and foreign patent applications to protect technology, inventions and improvements that are considered important to the development of our business. There can be no assurance that any of these patent applications will result in the grant of a patent either in the United States or elsewhere, or that any patents granted will be valid and enforceable, or will provide a competitive advantage or will afford protection against competitors with similar technologies. Our success could depend, in part, on our ability to obtain additional patents, protect our proprietary rights and operate without infringing third party patents. We will be able to protect our licensed patents or proprietary technologies from unauthorized use by third parties only to the extent that such patents or proprietary rights are covered by valid and enforceable patents or are effectively maintained as trade secrets and such third party does not have any valid defense.

We have licensed from Genentech certain intellectual property rights, including patent rights and pre-clinical and clinical data, and manufacturing know-how, to develop and commercialize rhIGF-1 worldwide for a broad range of indications. Such U.S. patents expire between 2010 and 2020. Our U.S. patent No. 6,331,414 B1 licensed from Genentech is directed to methods for bacterial expression of rhIGF-1 and expires in 2018. We have no equivalent European patent. The European Patent Office has determined that the claims of Genentech's corresponding European patent application are not patentable under European patent law in view of public disclosures made before the application was filed.

Table of Contents

We have licensed from Ipsen their intellectual property rights, including patent rights and pre-clinical and clinical data, to develop and commercialize Somatuline® Autogel® in the United States and Canada for a broad range of indications. Such rights include U.S. patents for the formulation and for methods of using Somatuline® Autogel® that expire between 2015 and 2019. We do not have patent composition coverage on the lanreotide molecule (the active pharmaceutical ingredient of Somatuline® Autogel®) alone.

There has been increasing litigation in the biopharmaceutical industry with respect to the manufacture and sale of new therapeutic products. The validity and breadth of claims in biotechnology patents may involve complex factual and legal issues for which no consistent policy exists. In particular, the patent protection available for protein-based products, such as rhIGF-1, is highly uncertain and involves issues relating to the scope of protection of claims to gene sequences and the production of their corresponding proteins.

There can be no assurance that our licensed patents will not be successfully circumvented by competitors. In particular, we do not have patent composition coverage on the rhIGF-1 protein alone, and we are aware that Chiron Corporation has developed a process to manufacture rhIGF-1 using yeast expression, rather than bacterial expression. In addition, the patent laws of foreign countries differ from those in the United States and the degree of protection afforded by foreign patents may be different from the protection offered by U.S. patents. Our competitors may obtain patents in the United States and Europe directed to methods for the manufacture or use of rhIGF-1 that may be necessary for us to conduct our business free from claims of patent infringement. We may not be able to license such patents on reasonable terms, if at all.

We may need additional intellectual property from other third parties to commercialize rhIGF-1 for diabetes. We cannot be sure that we will be able to obtain a license to any third party technology we may require to conduct our business.

In some cases, litigation or other proceedings may be necessary to defend against claims of infringement, to enforce patents licensed to us, to protect our know-how or other intellectual property rights or to determine the scope and validity of the proprietary rights of third parties. Any potential litigation could result in substantial cost to us and diversion of our resources. We cannot be sure that any of our licensed patents will ultimately be held valid. An adverse outcome in any litigation or proceeding could subject us to significant liability.

Declaratory judgments of invalidity against the patents asserted in any such actions could prevent us from using the affected patents to exclude others from competing with us.

We generally enter into confidentiality agreements with our employees and consultants. Our confidentiality agreements generally require our employees and consultants to hold in confidence and not disclose any of our proprietary information. Despite our efforts to protect our proprietary information, unauthorized parties may attempt to obtain and use our proprietary information. Policing unauthorized use of our proprietary information is difficult, and the steps we have taken might not prevent misappropriation, particularly in foreign countries where the laws may not protect our proprietary rights as fully as do the laws of the United States.

We have applied for registration of the trademarks Increlex, Tercica and the Tercica logo in the United States.

Competition

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® Autogel®. However, we expect that the following factors, among others, will determine our ability to compete effectively:

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

reimbursement adoption;

product price;

manufacturing costs;

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

storage requirements and ease of administration;

dosing regimen;

safety and efficacy;

prevalence and severity of side effects; and

competitive products.

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

Growth hormone products compete with Increlex for the treatment of severe Primary IGFD. If Increlex receives regulatory approval for the treatment of patients with Primary IGFD, growth hormone products will also compete with Increlex for the treatment of patients in that indication. The major suppliers of commercially available growth hormone products in the United States are Genentech, 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 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 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.

Edgar Filing: TERCICA INC - Form 10-K

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. It is possible that there are other products currently in development or that exist on the market that may compete directly with Increlex.

Table of Contents

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

We are aware that Ambrilia Biopharma, QLT Inc., Valera Pharmaceuticals 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 (SOM 230) 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 Somatuline® Autogel®.

Government Regulation and Product Approval

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the clinical development, manufacture and marketing of pharmaceutical products. These agencies and other federal, state and local entities regulate the testing, manufacture, quality control, safety, effectiveness, labeling, storage, record keeping, advertising and promotion of our products. Failure to comply with regulatory requirements may result in criminal prosecution, civil penalties, recall or seizure of products, total or partial suspension of production or injunction, as well as other actions that could affect our potential products or us. Any failure by us to comply with regulatory requirements, to obtain and maintain regulatory approvals, or any delay in obtaining regulatory approvals could materially adversely affect our business.

The process required by the FDA before drugs may be marketed in the United States generally involves the following:

pre-clinical laboratory and animal tests;

submission of an IND application, which must become effective before human clinical trials may begin;

adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug for its intended use; and

FDA approval of an NDA.

The testing and approval process requires substantial time, effort, and financial resources, and we cannot be certain that any approvals for rhIGF-1 or Somatuline® Autogel® will be granted on a timely basis, if at all.

Once a pharmaceutical candidate is identified for development it enters the pre-clinical testing stage. During pre-clinical studies, laboratory and animal studies are conducted to show biological activity of the drug candidate in animals, both healthy and with the targeted disease. Also, pre-clinical tests evaluate the safety of drug candidates. Pre-clinical tests must be conducted in compliance with good laboratory practice regulations. In some cases, long-term pre-clinical studies are conducted while clinical studies are ongoing.

Prior to commencing a clinical trial, we must submit an IND application to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises

Table of Contents

concerns or questions. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Our submission of an IND may not result in FDA authorization to commence a clinical trial. All clinical trials must be conducted under the supervision of a qualified investigator in accordance with good clinical practice regulations. These regulations include the requirement that all subjects provide informed consent. Further, an independent institutional review board at the medical center proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences. Reports detailing the results of the clinical trials must be submitted at least annually to the FDA, and more frequently, if adverse events occur.

Human clinical trials are typically conducted in three sequential phases that may overlap:

Phase I: The drug is initially introduced into healthy human subjects or patients and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion.

Phase II: Involves studies in a limited patient population to identify possible adverse effects and safety risks, to determine the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.

Phase III: Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical study sites. These studies are intended to establish the overall risk-benefit ratio of the product and provide, if appropriate, an adequate basis for product labeling.

In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients. Because these patients already have the target disease, these studies may provide initial evidence of efficacy traditionally obtained in Phase II trials, and thus these trials are frequently referred to as Phase I/II trials.

The FDA or an institutional review board or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

Concurrent with clinical trials and pre-clinical studies, companies also must develop information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product and the manufacturer must develop methods for testing the quality, purity, and potency of the final drugs. Additionally, appropriate packaging must be selected and tested and chemistry stability studies must be conducted to demonstrate that the product does not undergo unacceptable deterioration over its shelf-life.

The results of product development, pre-clinical studies and clinical studies, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, and results of chemical studies are submitted to the FDA as part of an NDA requesting approval to market the product. The FDA reviews all NDAs submitted before it accepts them for filing. It may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. The submission of an NDA is subject to user fees, but a waiver of such fees may be obtained. The FDA may deny an NDA if the applicable regulatory criteria are not satisfied or may require additional clinical or other data. Even if such data is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Once issued, the FDA may withdraw product approval if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. In addition, the FDA may require testing and surveillance programs to monitor the effect of approved products, which have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs.

Table of Contents

The FDA has established priority and standard review classifications for original NDAs and efficacy supplements. Priority review applies to the time frame for FDA review of completed marketing applications and is separate from and independent of orphan drug status and the FDA's fast track and accelerated approval mechanisms. The classification system, which does not preclude the FDA from doing work on other projects, provides a way of prioritizing NDAs upon receipt and throughout the FDA application review process.

The classification system sets the target date for the completion of FDA review and for taking action to approve or not approve an NDA after its acceptance for filing. If the priority review designation criteria are not met, standard review procedures apply. Under the Prescription Drug User Fee Amendments of 2002, the FDA's performance goals for fiscal years 2003-2007 involve reviewing 90% of priority applications within six months of filing and 90% of standard applications within ten months of submission of the NDA.

Priority designation applies to new drugs that have the potential for providing significant improvement compared to marketed products in the treatment, diagnosis or prevention of a disease. Hence, even if an NDA is initially classified as a priority application, this status can change during the FDA review process, such as in the situation where another product is approved for the same disease for which previously there was no available therapy.

We cannot guarantee that the FDA will grant a request for priority review designation or will permit expedited development, accelerated approval, or treatment use of any product. We also cannot guarantee that if such statutory or regulatory provisions apply to our products, that they will necessarily affect the time period for FDA review or the requirements for approval. Additionally, the FDA's approval of drugs can include restrictions on the product's use or distribution, such as permitting use only for specified medical procedures, limiting distribution to physicians or facilities with special training or experience, or requiring pre-submission of advertising and promotional materials.

Satisfaction of FDA requirements or similar requirements of state, local and foreign regulatory agencies typically takes several years and the actual time required may vary substantially, based upon the type, complexity and novelty of the product or disease. Government regulation may delay or prevent marketing of potential products or new diseases for a considerable period of time and impose costly procedures upon our activities. Success in early stage clinical trials does not assure success in later stage clinical trials. Data obtained from clinical activities are not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. Even if a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages. Further, even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. Delays in obtaining, or failures to obtain regulatory approvals for rhIGF-1 could harm our business. In addition, we cannot predict what adverse governmental regulations may arise from future U.S. or foreign governmental action.

Any drug products manufactured or distributed by us pursuant to FDA approvals are subject to continuing regulation by the FDA, including record-keeping requirements, reporting of adverse experiences with the drug, drug sampling and distribution requirements, notifying the FDA and gaining its approval of certain manufacturing or labeling changes, complying with certain electronic records and signature requirements, and complying with FDA promotion and advertising requirements. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, which impose certain procedural and documentation requirements upon us and our third party manufacturers. We cannot be certain that we or our present or future suppliers will be able to comply with the pharmaceutical cGMP regulations and other FDA regulatory requirements.

The FDA's policies may change and additional government regulations may be enacted which could prevent or delay regulatory approval of Increlex for other indications, including Primary IGFD, and Somatuline®

Table of Contents

Autogel® for acromegaly. We cannot predict the likelihood, nature or extent of adverse governmental regulation, which might arise from future legislative or administrative action, either in the United States or abroad.

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat rare diseases or conditions, which are generally diseases or conditions that affect fewer than 200,000 individuals in the U.S. Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process. If a product that has orphan drug designation subsequently receives FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication, except in limited circumstances, for seven years. The FDA may, however, approve applications to market the same drug for different indications, and applications to market different drugs for the same indication as the drug that has orphan exclusivity.

The FDA granted Increlex seven years of orphan exclusivity for the long-term treatment of growth failure in children with severe Primary IGF1 or with growth hormone gene deletion who have developed neutralizing antibodies to growth hormone. In addition, we intend to file for orphan drug designation for other rhIGF-1 diseases that meet the criteria for orphan exclusivity.

Under the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, Congress created an abbreviated FDA review process for generic versions of pioneer (brand name) drug products like Increlex. The law also provides incentives by awarding, in certain circumstances, non-patent marketing exclusivities to pioneer drug manufacturers. For example, the Hatch-Waxman Act provides five years of new chemical entity exclusivity to the first applicant to gain approval of an NDA for a product that does not contain an active ingredient found in any other approved product. The FDA granted Increlex new chemical entity exclusivity, which expires on August 30, 2010.

During this period, the FDA is prohibited from accepting any abbreviated NDA, or an ANDA, for a generic version of Increlex. An ANDA is a type of application in which approval is based on a showing of sameness to an already approved drug product. An ANDA does not contain full reports of safety and effectiveness, as do NDAs, but rather demonstrates that the proposed product is the same as a reference product in terms of conditions of use, active ingredient, route of administration, dosage form, strength, and labeling. ANDA applicants are also required to demonstrate the bioequivalence of their products to reference products. Bioequivalence generally means that there is no significant difference in the rate and extent to which the active ingredient in the products becomes available at the site of drug action. ANDAs also must contain data relating to formulation, raw materials, stability, manufacturing, packaging, labeling, and quality control, among other information.

During this exclusivity period, the FDA is also prohibited from accepting any NDA for a modified version of Increlex where the applicant does not own or have a legal right of reference to all of the data required for approval, otherwise known as a 505(b)(2) application. The FDA has determined that 505(b)(2) applications may be submitted for products that represent changes to approved products like Increlex. Such changes may be to the approved product's conditions of use, active ingredient, route of administration, dosage form, strength, labeling, or bioavailability. A 505(b)(2) applicant also may reference more than one approved product. It is the FDA's position that such an applicant must only submit the pre-clinical and clinical data necessary to demonstrate the safety and effectiveness of the changes made to the approved product.

This new chemical entity exclusivity protects the entire new chemical entity franchise, including all products containing Increlex's active ingredient for any use and in any strength or dosage form. This exclusivity will not, however, prevent the submission or approval of a full NDA, as opposed to an ANDA or 505(b)(2) application, for any drug, including a drug with the same conditions of use, active ingredient, route of

Table of Contents

administration, dosage form, and strength as Increlex. In addition, an ANDA or a 505(b)(2) application may be submitted after four years, rather than five years, if that ANDA or 505(b)(2) application contains a certification (known as a Paragraph IV certification) that one of the patents listed with the Increlex NDA is invalid or will not be infringed by the manufacture, use, or sale of the product described in that ANDA or 505(b)(2) application.

The Hatch-Waxman Act also provides three years of new use exclusivity for the approval of NDAs, 505(b)(2) applications, and NDA supplements, where those applications contain the results of new clinical investigations (other than bioavailability studies) essential to the FDA's approval of the applications. Such applications may be submitted for new indications, new dosage forms, new strengths, or new conditions of use of already approved products like Increlex. So long as the new clinical investigations are essential to the FDA's approval of the change, this new use exclusivity prohibits the approval of ANDAs or 505(b)(2) applications for products with the specific changes associated with those clinical investigations. Should Increlex receive this exclusivity, however, it will not prevent the submission or approval of a full NDA for any drug, including a drug with the same changes as are protected by the exclusivity. It also would not prohibit the FDA from accepting or approving ANDAs or 505(b)(2) applications for other products containing the same active ingredient. It would only protect against the approval of ANDAs and 505(b)(2) applications for products with the specific changes to Increlex that were approved based on the new clinical investigations.

The Hatch-Waxman Act also requires an ANDA or 505(b)(2) applicant that has submitted an ANDA or a 505(b)(2) application with a Paragraph IV certification to notify the owner of the patent that is the subject of the Paragraph IV certification and the holder of the approved NDA of the factual and legal basis for the applicant's opinion that that patent is invalid or will not be infringed by the manufacture, use, or sale of the product described in that ANDA or 505(b)(2) application. The NDA holder or patent owner may then sue such an ANDA or 505(b)(2) applicant for infringement. If the

NDA holder or patent owner files suit within 45 days of receiving notice of the Paragraph IV certification, a one-time 30-month stay of the FDA's ability to approve the ANDA or 505(b)(2) application is triggered. However, the FDA may approve the ANDA or 505(b)(2) application before the expiration of the 30-month stay if a court finds the patent invalid or not infringed, or if the court shortens the 30-month period because a party failed to cooperate in expediting the litigation. In addition, if the NDA holder or patent owner chooses not to sue such an ANDA or 505(b)(2) applicant after receiving notification of the Paragraph IV certification, or sues outside of the 45-day window, the FDA may approve the ANDA or 505(b)(2) application whenever all of the other requirements for approval are met.

The FDA Modernization Act of 1997 included a pediatric exclusivity provision that was extended by the Best Pharmaceuticals for Children Act of 2002. Pediatric exclusivity is designed to provide an incentive to manufacturers to conduct research about the safety and effectiveness of their products in children. Pediatric exclusivity, if granted, provides an additional six months of market exclusivity in the United States for new or currently marketed drugs. Under Section 505a of the Federal Food, Drug, and Cosmetic Act, the extra six months of market exclusivity may be granted in exchange for the voluntary completion of pediatric studies in accordance with an FDA-issued Written Request. The FDA may issue a Written Request for studies on unapproved or approved indications, where it determines that information relating to the use of a drug in a pediatric population, or part of a pediatric population, may produce health benefits in that population. We have not requested or received a Written Request for such pediatric studies, although we may ask the FDA to issue a Written Request for such studies in the future. To receive the six-month pediatric exclusivity, we would have to receive a Written Request from the FDA, conduct the requested studies, and submit reports of the studies in accordance with a written agreement or commonly accepted scientific principles. There is no guarantee that the FDA will issue a Written Request for such studies or accept the reports of the studies. We believe that Increlex may become eligible for pediatric exclusivity, although there can be no assurances that FDA will grant such exclusivity. The current pediatric exclusivity provision is scheduled to expire on October 1, 2007, and there can be no assurances that it will be reauthorized.

Table of Contents

Reimbursement

Sales of biopharmaceutical products depend in significant part on the availability of third-party reimbursement. Third-party payors provide reimbursement for Increlex and, if approved by the FDA, we expect they would pay for Somatuline[®] Autogel[®]. It is time consuming and expensive for us to seek reimbursement from third-party payors. Reimbursement may not be available or sufficient to allow us to sell our products on a competitive and profitable basis.

The passage of the Medicare Prescription Drug and Modernization Act of 2003, or the MMA, imposed new requirements for the distribution and pricing of prescription drugs for Medicare beneficiaries, which may affect the marketing of our products. The MMA also introduced a new reimbursement methodology, part of which went into effect in 2004. At this point, it is not clear what effect the MMA will have on the prices paid for currently approved drugs and the pricing options for new drugs approved after January 1, 2006. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payors.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the medicinal product.

We expect that there will continue to be a number of federal and state proposals to implement governmental pricing controls. While we cannot predict whether such legislative or regulatory proposals will be adopted, the adoption of such proposals could have a material adverse effect on our business, financial condition and profitability.

Employees

As of December 31, 2006, we had 106 full-time employees. Of the full-time employees, 34 were engaged in research and product development and 72 were engaged in selling, general and administrative positions. We believe that our employee base will need to grow in order to execute our development and commercialization plans for rhIGF-1. We believe our relations with our employees are good.

Table of Contents**Executive Officers of the Registrant**

Our executive officers, their ages and their positions as of March 7, 2007, are as follows:

Name	Age	Position(s)
John A. Scarlett, M.D.	56	President, Chief Executive Officer and Director
Ross G. Clark, Ph.D.	56	Chief Technical Officer and Director
Ajay Bansal	45	Chief Financial Officer and Senior Vice President of Finance
Richard A. King	42	Chief Operating Officer
Stephen N. Rosenfield	57	Executive Vice President of Legal Affairs, General Counsel and Secretary
Andrew J. Grethlein, Ph.D.	42	Senior Vice President, Pharmaceutical Operations
Thorsten von Stein, M.D., Ph.D.	45	Chief Medical Officer and Senior Vice President of Clinical and Regulatory Affairs
Susan Wong	44	Vice President, Finance and Chief Accounting Officer

John A. Scarlett, M.D., has served as our President and Chief Executive Officer and as a member of our board of directors since February 2002. From March 1993 to May 2001, Dr. Scarlett served as President and Chief Executive Officer of Sensus Drug Development Corporation, a development stage pharmaceutical company. In 1995, he co-founded Covance Biotechnology Services, Inc., a biotechnology contract manufacturing company, and served as a member of its board of directors from inception to 2000. From 1991 to 1993, Dr. Scarlett headed the North American Clinical Development Center and served as Senior Vice President of Medical and Scientific Affairs at Novo Nordisk Pharmaceuticals, Inc., a wholly owned subsidiary of Novo Nordisk A/S, a pharmaceutical company. From 1985 to 1990, Dr. Scarlett served as Vice President, Clinical Affairs and headed the clinical development group at Greenwich Pharmaceuticals, Inc., a pharmaceutical company. From 1982 to 1985, Dr. Scarlett served as Associate Director and, subsequently, as Director, of Medical Research and Services at Ortho-McNeil Pharmaceuticals, a wholly owned subsidiary of Johnson & Johnson. Dr. Scarlett received his B.A. degree in chemistry from Earlham College and his M.D. from the University of Chicago, Pritzker School of Medicine.

Ross G. Clark, Ph.D., has served as our Chief Technical Officer since May 2002 and as a member of our board of directors since December 2001. From December 2001 to August 2003, Dr. Clark served as Chairman of our board of directors. From December 2001 to February 2002, Dr. Clark served as our Chief Executive Officer and President. Dr. Clark founded Tercica Limited, our predecessor company in New Zealand, in September 2000. Since September 1997, Dr. Clark has served as Professor of Endocrinology at the University of Auckland. From October 1997 to January 2000, Dr. Clark served as Chief Scientist for NeuronZ Limited, a New Zealand biotechnology company. In July 1999, Dr. Clark served as a board member of ViaLactia Biosciences (NZ) Ltd, a biotechnology subsidiary of the New Zealand Dairy Board. From 1990 to 1997, Dr. Clark served as a senior scientist for Genentech, Inc., a biotechnology company. Dr. Clark received his B.Sc., Dip.Sci. and Ph.D. degrees in veterinary physiology from Massey University, New Zealand.

Ajay Bansal has served as our Chief Financial Officer and Senior Vice President of Finance since March 2006. From February 2003 to January 2006, Mr. Bansal served as Vice Present of Finance and Administration and Chief Financial Officer of Nektar Therapeutics. From July 2002 until February 2003, Mr. Bansal served as Director of Operations Analysis at Capital One Financial. From August 1998 to June 2002, Mr. Bansal was at Mehta Partners LLC, a financial advisory firm where he was named partner in January 2000. Prior to joining Mehta Partners, Mr. Bansal spent more than 10 years in management roles at Novartis and in consulting at Arthur D. Little, Inc., McKinsey & Company, Inc. and ZS Associates. Mr. Bansal holds a Bachelor of Technology degree from the Indian Institute of Technology (Delhi), an M.S. in Operations Management from Northwestern University and an M.B.A. from Northwestern University.

Richard A. King, has served as our Chief Operating Officer since February 2007. From January 2002 to September 2006, Mr. King served as Executive Vice President, Commercial Operations of Kos Pharmaceuticals, Inc.,

Table of Contents

where he was responsible for sales, marketing, managed care, sales operations and customer service functions. From January 2000 to January 2002, Mr. King served as Senior Vice President of Commercial Operations at Solvay Pharmaceuticals. From January 1992 to January 2000, Mr. King held various marketing positions at SmithKline Beecham Pharmaceuticals. Mr. King began his career in the pharmaceutical industry at Lederle Laboratories, Ltd. Mr. King received his B.S. degree in chemical engineering from the University of Surrey and his M.B.A. from Manchester Business School.

Stephen N. Rosenfield has served as our Executive Vice President of Legal Affairs, General Counsel and Secretary since March 2006. From July 2004 through February 2006, Mr. Rosenfield acted as our Senior Vice President of Legal Affairs, General Counsel and Secretary. From February 2003 to May 2004, Mr. Rosenfield served as Executive Vice President of Legal Affairs, General Counsel and Secretary of InterMune, Inc., a biopharmaceutical company. From February 2000 to February 2003, Mr. Rosenfield served as Senior Vice President of Legal Affairs, General Counsel and Secretary of InterMune, Inc. From February 1996 to March 2000, Mr. Rosenfield was as an attorney at Cooley Godward LLP and served as outside counsel for biotechnology and technology clients. Mr. Rosenfield received his B.S. degree from Hofstra University and his J.D. degree from Northeastern University School of Law.

Andrew Grethlein, Ph.D., has served as our Senior Vice President, Pharmaceutical Operations since August 2005 and served as our Vice President, Manufacturing from April 2003 to August 2005. From December 2000 to April 2003, Dr. Grethlein served as Senior Director, South San Francisco Operations for Elan Corporation, plc, a pharmaceutical company. From November 1998 to December 2000, he served as Director, Biopharmaceutical Operations for Elan Corporation, plc. From 1997 to November 1998, Dr. Grethlein served as Associate Director, Neurotoxin Production for Elan Corporation, plc. From 1995 to 1997, Dr. Grethlein served as Manager, Biologics Development and Manufacturing for Athena Neurosciences, Inc., a biotechnology company. From 1991 to 1995, Dr. Grethlein served in various engineering positions for Michigan Biotechnology Institute, a non-profit technology research and business development corporation, and its wholly-owned subsidiary, Grand River Technologies, Inc. Dr. Grethlein received his B.S. degree in biology from Bates College and his Ph.D. in chemical engineering from Michigan State University.

Thorsten von Stein, M.D., Ph.D., has served as our Chief Medical Officer and Senior Vice President of Clinical and Regulatory Affairs since January 2005. From August 2003 to January 2005, Dr. von Stein served as Chief Medical Officer at NeurogesX, Inc., a pharmaceutical company. From December 2001 to July 2003, Dr. von Stein served as Vice President, Clinical Development at Neurogesx. From 1994 to 2001, Dr. von Stein held positions of increasing responsibility in medical research, global clinical development and project management for Roche Palo Alto and F. Hoffman-La Roche AG in Basel, Switzerland. Dr. von Stein served as Director of Medical Research at Roche Palo Alto from 1998 to December 2001. Dr. von Stein received his M.D. degree from Munich University, Germany, and his Ph.D. degree in computer science from the University of Hamburg, Germany.

Susan Wong has served as our Vice President of Finance and Chief Accounting Officer since March 2006 and Acting Chief Financial Officer from June 2005 to March 2006; and Vice President, Finance and Controller from January 2004 to March 2006. From November 2001 to December 2003, Ms. Wong was an independent financial services consultant. From August 2000 to October 2001, she served as Senior Vice President and Corporate Controller at innoVentry Corp., a privately-held provider of fee-based financial services. From September 1993 to July 2000, Ms. Wong served as Vice President and Corporate Controller at Ocular Sciences, Inc., a publicly-held manufacturer and distributor of soft contact lenses. From September 1989 to 1993, Ms. Wong served as Director of Corporate Accounting and Financial Reporting, Planning & Analysis at Vanstar, Inc., a computer reseller. Ms. Wong held various positions in the audit group at Coopers & Lybrand from August 1985 to August 1989. Ms. Wong is a Certified Public Accountant, and received her B.S. degree in finance and accounting from University of California, Berkeley.

Table of Contents

Corporate Information

Tercica, Inc. was formed in December 2001 as a Delaware corporation. In early 2002, Tercica, Inc. acquired all the intellectual property rights and assumed specified liabilities of Tercica Limited, which was formed in October 2000 as a New Zealand company. Tercica Limited was subsequently liquidated.

Available Information

We file electronically with the U.S. Securities and Exchange Commission, or SEC, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934. We make available on our website at <http://www.tercica.com>, free of charge, copies of these reports as soon as reasonably practicable after filing these reports with, or furnishing them to, the SEC.

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.

Risks Related to Our Business

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

We are primarily focused on the development and commercialization of products for the treatment of short stature and other endocrine disorders. We had an accumulated deficit of \$248.7 million at December 31, 2006. We had net revenues of \$1.5 million and incurred a net loss of \$83.0 million during the year ended December 31, 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 in the United States and Canada. There is no assurance that we will be able to obtain or maintain governmental regulatory approvals to market our products in the United States or rest of the world for these or any other indications. If we are unable to generate significant revenue from Increlex or Somatuline® 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.

Table of Contents

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.

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 at 100% compliance is approximately \$27,200 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

Edgar Filing: TERCICA INC - Form 10-K

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

Table of Contents

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

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

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

Table of Contents

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.

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

acceptance of Increlex and Somatuline® Autogel® 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;

Table of Contents

prevalence and severity of side effects; and

competitive products.

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

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

We are aware that Ambrilia Biopharma, QLT Inc., Valera Pharmaceuticals, 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[®].

Table of Contents

If we do not receive additional regulatory marketing approvals for the target labels, our business will be harmed.

We are currently developing Increlex for the treatment of Primary IGFD. The FDA has substantial discretion in the approval process and may decide that the data from our clinical trial is insufficient to allow approval of Increlex for Primary IGFD for the target label. If we do not receive regulatory marketing approval in the United States for Primary IGFD for the target label, 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 FDA does not approve Somatuline® Autogel® for the treatment of acromegaly, or the approval is significantly delayed, or we do not receive the target label that we anticipate, our ability to generate revenues would be adversely affected, and our business would be harmed. We may also 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 are attempting to move our process to another fill-finish manufacturer. It will take a significant amount of time and expense to complete the transfer to, and validate an alternative manufacturer. For us to change to this commercial fill-finish manufacturer, the manufacturer's facilities and processes, prior to our use, will need to undergo pre-approval and/or cGMP compliance inspections. In addition, we need to transfer and validate the processes and certain analytical methods necessary for the production and testing of rhIGF-1 to this new manufacturer. A delay in this 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 IGFD. 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, Lonza Baltimore 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 Lonza 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, Lonza 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.

Table of Contents

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. 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®.

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

Table of Contents

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

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

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 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 which product containing rhIGF-1 to prescribe to their patients. As a result, we would have limited ability to prevent off-label use of a competitor's product containing rhIGF-1 to treat any diseases for which we have received FDA approval, even if it violates our method of use patents and/or we have orphan drug exclusivity for the use of rhIGF-1 to treat such diseases.

Competitors could challenge our patents and file an Abbreviated New Drug Application or 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.

Table of Contents

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

We do not have 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. 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

Table of Contents

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

A third party may claim that we are using its inventions covered by its patents and may initiate litigation to stop us from engaging in our operations and activities. Although no third party has claimed that we are infringing on their patents, patent lawsuits are costly and could affect our results of operations and divert the attention of managerial and technical personnel. There is a risk that a court would decide that we are infringing the third party's patents and would order us to stop the activities covered by the patents. In addition, there is a risk that a court will order us to pay the other party damages for having infringed the other party's patents. The biotechnology industry has produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our products or methods of use do not infringe the patent claims of the relevant patent and/or that the patent claims are invalid, and we may not be able to do so. Proving invalidity, in particular, is difficult since it requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents.

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

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

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

Table of Contents

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

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

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

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

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

Table of Contents

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;

Edgar Filing: TERCICA INC - Form 10-K

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® Autogel® 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 pre-clinical 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.

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.

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

Table of Contents

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 Global Market, or Nasdaq.

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

Table of Contents

required to pay the notes in cash, we will likely need to raise such amounts from the capital markets or through a strategic transaction. There is no assurance that we would be able to do so in a timely manner or on reasonable terms. If we are unable to do so, we may be required to delay or curtail our development and commercialization efforts, which would harm our business.

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

increasing our vulnerability to general adverse economic and industry conditions;

limiting our ability to obtain additional financing;

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

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

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

We believe that our cash, cash equivalents and short-term investments as of December 31, 2006, together with the funds that we would potentially receive from our collaboration with Ipsen, will be sufficient to meet our projected operating and capital expenditure requirements through at least the middle of 2008 based on our current business plan. However, our future capital needs and the adequacy of our available funds will depend on many factors, including:

changes in our business plan;

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

the commercial status of the Increlex bulk drug manufacturing operations at Lonza 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®;

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

Edgar Filing: TERCICA INC - Form 10-K

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.

Table of Contents

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

Our ability to implement our business plan requires an effective planning and management process. As of December 31, 2006, we had 106 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. In our Phase III clinical trials for severe Primary IGF1, the data of which we submitted to the FDA in our NDA, some patients experienced hypoglycemia, or low blood glucose levels. Other side effects noted in some patients include hearing deficits, enlargement of the tonsils and intracranial hypertension.

Somatuline® 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.

Table of Contents

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, or Section 404, 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 our independent registered public accounting firm is unable to provide us with an unqualified report as to the effectiveness of our internal control over financial reporting, investors could lose confidence in the reliability of our internal control over financial reporting, which could adversely affect our stock price.

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

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

Risks Related to Our Common Stock

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

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

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

As of December 31, 2006, our directors, executive officers and principal stockholders and their affiliates beneficially owned approximately 73.16% of our common stock. Our greater than five percent beneficial owners include Ipsen and its affiliates, which beneficially owned 35.7% (not including shares subject to limited voting agreements with certain of our stockholders); entities affiliated with MPM Capital, L.P. which beneficially owned 13.8%; entities affiliated with Prospect Management Co. II, LLC, which beneficially owned 6.1%; MedImmune, Inc., which beneficially owned 6.0%; and entities affiliated with Rho Capital Partners, which beneficially owned 6.0%; and AIMS Fund Management, Inc., which beneficially owned 5.7%. 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.

Table of Contents

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 \$2.0 million in any given year;

making any investment, other than certain permitted investments;

entering into any transaction that results in competition with Ipsen;

declaring or paying any cash dividends;

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

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

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

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

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

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

Edgar Filing: TERCICA INC - Form 10-K

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

limit who may call a special meeting of stockholders;

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

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

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

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

Table of Contents

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;

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;

Edgar Filing: TERCICA INC - Form 10-K

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 December 31, 2006, we had 50,162,610 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 31,187,610 shares outstanding as of December 31, 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 December 31, 2006, we had 3,873,806 shares subject to outstanding options granted under our equity compensation plans. In addition, as of December 31, 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 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Our facilities consist of approximately 32,000 square feet of office space located in Brisbane, California that is leased to us until October 2011. We have no laboratory or research facilities. We believe that our Brisbane facilities will be adequate for our near-term needs and that suitable additional space will be available on commercially reasonable terms to accommodate expansion of our operations, if any.

Item 3. Legal Proceedings.

On December 20, 2004, we initiated patent infringement proceedings against Avecia Limited and Insmmed 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 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. There were no material developments in our patent infringement litigation against Avecia and Insmmed in the United Kingdom during the 12 months ended December 31, 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. On October 13, 2006, Genentech and we filed an opposition to Insmmed's motion for partial reconsideration of the court's summary judgment order. On October 31, 2006, the court issued a written ruling denying Insmmed's motion for partial reconsideration of the court's summary judgment order.

On November 6, 2006, the court initiated jury trial proceedings relating to Genentech's and our claims that Insmmed had infringed U.S. Pat. No. 5,258,287 and 5,187,151 and relating to Insmmed's defense of invalidity against the asserted claims of U.S. Pat. No. 6,331,414. On December 6, 2006, the jury returned a verdict finding that Insmmed had infringed U.S. Pat. No. 5,258,287 and U.S. Pat. No. 5,187,151 and that the asserted claims of U.S. Pat. No. 6,331,414 were not invalid. In addition, the jury found that Insmmed's infringement of U.S. Pat. No. 5,187,151 was willful. For Insmmed's past acts of infringement, the jury awarded Genentech and us damages of an upfront payment of \$7.5 million and a 15 percent royalty on past net sales of Iplex. This award has not been reflected in our financial statements in 2006 in accordance with U.S. GAAP as we have not realized the value of the award which will occur upon payment to us.

On November 29, 2006, the court held an evidentiary hearing on Insmmed's defense of inequitable conduct against U.S. Pat. No. 5,187,151, instructed Insmmed to submit a brief in support of Insmmed's inequitable conduct defense, granted Genentech and us leave to submit Genentech's and our closing arguments regarding Insmmed's inequitable conduct defense in the form of a brief in opposition to such defense, and granted Insmmed leave to submit a brief in reply to any opposition brief that Genentech and we may submit. On December 6, 2006, Insmmed submitted a brief in support of Insmmed's inequitable conduct defense against U.S. Pat. No. 5,187,151. On

Table of Contents

December 11, 2006, Genentech and we submitted closing arguments regarding Insmed's defense of inequitable conduct in the form of a brief in opposition to such defense. On December 13, 2006, Insmed submitted a brief in reply to Genentech's and our opposition brief.

On December 22, 2006, Genentech and we filed a motion requesting that the court award Genentech and us a permanent injunction prohibiting Insmed from making or selling Iplex for commercial use as a treatment for Severe Primary Insulin-Like Growth Factor Deficiency, award Genentech and us a trebling of the damages awarded by the jury, and award Genentech and us our attorneys' fees, costs and expenses.

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 alleged 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.

On March 6, 2007, Insmed, Avecia, Tercica and Genentech publicly announced agreements that settled all the ongoing litigation among the companies.

Item 4. Submission of Matters to a Vote of Security Holders.

A special meeting of our stockholders was held on October 12, 2006 for the purposes of:

1. To approve the issuance of the following securities to Ipsen or its designated affiliate in connection with the transactions contemplated by the Stock Purchase and Master Transaction Agreement dated July 18, 2006:

12,527,245 shares of our common stock for an aggregate purchase price of \$77.0 million;

a warrant to purchase a minimum of 4,948,795 shares of our common stock at an initial exercise price of \$7.41 per share and the shares of our common stock issuable upon exercise of the warrant;

a convertible promissory note in the principal amount of \$25.0 million, which would be convertible into shares of our common stock at an initial conversion price of \$7.41 per share, and the shares of our common stock issuable upon conversion of the note; a convertible promissory note in the principal amount of \$30.0 million, which would be convertible into shares of our common stock at an initial conversion price of \$5.92 per share, and the shares of our common stock issuable upon conversion of the note; and

a convertible promissory note in the principal amount of \$15.0 million, which would be convertible into shares of our common stock at an initial conversion price of \$7.41 per share, and the shares of our common stock issuable upon conversion of the note.

2. To approve amendments to our amended and restated certificate of incorporation and amended and restated bylaws to eliminate our classified board of directors and certain other anti-takeover protections.

3. To approve amendments to our amended and restated certificate of incorporation to waive the corporate opportunity provisions under Delaware law and corporate opportunity doctrine with respect to opportunities of which Ipsen and the Ipsen designees to our Board of Directors may become aware as a result of Ipsen's affiliation with us.

Edgar Filing: TERCICA INC - Form 10-K

4. To approve a stockholders rights plan, commonly referred to as a poison pill, to be entered into between us and Computershare Trust Company, N.A. as rights agent.

Table of Contents

Proxies for the special meeting were solicited pursuant to Section 14(a) of the Securities Exchange Act of 1934, as amended, and there was no solicitation in opposition of management's solicitations. The final vote on the proposals were recorded as follows:

1. Proposal No. 1

For	29,928,554
Against	40,900
Abstain	3,475
Broker Non-Votes	

2. Proposal No. 2

For	22,428,495
Against	7,518,959
Abstain	5,475
Broker Non-Votes	

3. Proposal No. 3

For	29,928,254
Against	39,200
Abstain	5,475
Broker Non-Votes	

4. Proposal No. 4

For	21,700,295
Against	8,267,159
Abstain	5,475
Broker Non-Votes	

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Our common stock has been traded on the Nasdaq Global Market under the symbol "TRCA" since March 17, 2004. The following table sets forth for the periods indicated the high and low closing sale prices of our common stock, as reported by the Nasdaq Global Market.

	Prices	
	High	Low
Fiscal 2006:		
First Fiscal Quarter	\$ 7.90	\$ 6.29
Second Fiscal Quarter	6.88	3.07
Third Fiscal Quarter	6.70	4.21
Fourth Fiscal Quarter	6.24	4.90
Fiscal 2005:		
First Fiscal Quarter	\$ 10.55	\$ 7.63
Second Fiscal Quarter	9.21	7.14
Third Fiscal Quarter	12.65	8.41

Edgar Filing: TERCICA INC - Form 10-K

Fourth Fiscal Quarter

11.94 6.74

There were approximately 37 holders of record of our common stock as of February 28, 2007. In addition, we believe that a significant number of beneficial owners of our common stock hold their shares in street name.

Table of Contents

Dividend Policy

We have never declared or paid any cash dividends on our common stock. We currently expect to retain any future earnings for use in the operation and expansion of our business and do not anticipate paying any cash dividends on our common stock in the foreseeable future.

Stockholder Return Comparison

The following graph shows the total stockholder return of an investment of \$100 cash on March 17, 2004, the date Tercica became a public company, for our common stock, or on February 28, 2004 in the NASDAQ Global Market US Index and the NASDAQ Biotechnology Index. The stock price performance shown on the graph is not necessarily indicative of future price performance.

The information required by this item regarding equity compensation plans is incorporated by reference to the information set forth in Item 12 of this Annual Report on Form 10-K.

Table of Contents**Item 6. Selected Financial Data.**

The following selected financial data has been derived from the audited consolidated financial statements. The information below is not necessarily indicative of results of future operations, and should be read in conjunction with Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations of this Form 10-K and the financial statements and related notes thereto, included in Item 8 of this Form 10-K to fully understand factors that may affect the comparability of the information presented below.

	Year Ended December 31,				
	2006	2005	2004	2003	2002
Statements of Operations Data (in thousands, except per share data):					
Net revenues:					
Net product sales	\$ 1,315	\$	\$	\$	\$
License revenue	194				
Total net revenues:	1,509				
Costs and expenses:					
Cost of sales	1,667				
Research and development	42,034	21,587	29,335	20,916	7,045
Selling, general and administrative	44,248	25,913	12,552	4,834	1,978
Total costs and expenses	87,949	47,500	41,887	25,750	9,023
Loss from operations	(86,440)	(47,500)	(41,887)	(25,750)	(9,023)
Interest expense	(162)	(1,080)			(106)
Interest and other income, net	4,226	2,347	885	327	177
Loss before income taxes	(82,376)	(46,233)	(41,002)	(24,423)	(8,952)
Provision for income taxes	(621)				
Net loss	(82,997)	(46,233)	(41,002)	(25,423)	(8,952)
Deemed dividend related to beneficial conversion features of convertible preferred stock(3)				(44,153)	
Net loss allocable to common stockholders	\$ (82,997)	\$ (46,233)	\$ (41,002)	\$ (69,576)	\$ (8,952)
Basic and diluted net loss per share allocable to common stockholders(1)	\$ (2.09)	\$ (1.51)	\$ (2.12)	\$ (38.59)	\$ (5.76)
Shares used in computing basic and diluted net loss per share allocable to common stockholders(1)	39,789	30,590	19,302	1,803	1,555
	December 31,				
	2006	2005	2004	2003	2002
Balance Sheet Data (in thousands):					
Cash, cash equivalents and short-term investments	\$ 125,575	\$ 58,626	\$ 52,001	\$ 37,313	\$ 15,870
Working capital	123,181	53,752	45,542	33,346	15,707
Total assets	137,687	66,316	55,022	42,484	16,348
Long-term convertible debt(2)	25,172				
Convertible preferred stock				68,637	24,693
Accumulated deficit	(248,738)	(165,741)	(119,508)	(78,506)	(8,930)
Total stockholders' equity (deficit)	89,931	56,798	47,677	(33,198)	(8,913)

Edgar Filing: TERCICA INC - Form 10-K

- (1) See Note 3 of the Notes to Financial Statements for information regarding the computation of per share amounts.
- (2) See Note 7 of the Notes to Financial Statements for information regarding the collaboration agreement with Ipsen.
- (3) We recorded a deemed dividend of \$44,153,000 associated with this issuance of preferred shares to reflect the value of the beneficial conversion feature embedded in the Series B convertible preferred stock. The deemed dividend increases the net loss allocable to common stockholders in the calculation of basic and diluted net loss per common share for the year ended December 31, 2003.

Table of Contents**Item 7. 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 Item 1A above, 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.

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

Increlex, which we began commercializing in the United States in January 2006;

Somatuline® Autogel®, for which a New Drug Application, or NDA, was submitted in 2006 to the U.S. Food and Drug Administration, or FDA, by Ipsen S.A., or Ipsen, our collaborator; and was approved for marketing in July 2006 by Health Canada for the treatment of acromegaly.

Increlex. We market Increlex as a long-term 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, or growth hormone. We obtained approval for the long-term treatment of severe Primary IGFD, from the U.S. Food and Drug Administration, or FDA, in August 2005. We are currently conducting a Phase IIIb clinical trial for the use of Increlex for the treatment of children with Primary IGFD. In January 2006, we launched Increlex in the United States. Increlex generated net revenues of \$1.3 million in 2006.

In December 2005, we submitted a Marketing Authorization Application, or 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. We expect to receive an opinion from the Committee for Medicinal Products for Human Use on the Increlex MAA in the second quarter of 2007. Pursuant to our worldwide strategic collaboration with Ipsen that was finalized in October 2006, we granted to Ipsen and its affiliates the exclusive right under our patents and know-how to develop and commercialize Increlex in all countries of the world except the United States, Japan, Canada, and for a certain period of time, Taiwan and certain countries of the Middle East and North Africa, for all indications, other than treatment of central nervous system and diabetes indications.

Somatuline® Autogel®. Pursuant to our worldwide strategic collaboration with Ipsen, we have the exclusive right under Ipsen's patents and know-how to develop and commercialize Somatuline® 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 and is currently in the reimbursement review process. Acromegaly is a hormonal disorder that results when a tumor in the pituitary gland produces excess growth hormone, resulting in overproduction of insulin-like growth factor-1 (IGF-1) and excessive

Table of Contents

growth. In October 2006, Ipsen submitted an NDA to the FDA for the use of Somatuline® Autogel® for the treatment of acromegaly. The FDA accepted the NDA on December 30, 2006, and the Prescription Drug User Fee Act, or PDUFA, date for Somatuline® Autogel® for the treatment of acromegaly is August 30, 2007.

Somatuline® Autogel® is an injectable sustained-release formulation containing lanreotide, a somatostatin analogue. The Somatuline® Autogel® formulation requires no excipient other than water and is generally injected monthly. In some patients, the time between injections can be lengthened to up to 56 days. The product is contained in a pre-filled syringe, and can be administered as a deep subcutaneous injection. In contrast, Sandostatin LAR, the only currently available, long-acting somatostatin analogue, which is marketed by Novartis, must be reconstituted from a powdered form and drawn up into a syringe, and must be then be given as a deep intramuscular injection. Like Sandostatin LAR, Somatuline® Autogel® is used primarily when circulating levels of growth hormone remain high despite surgery or radiotherapy in patients with acromegaly. Through its inhibitory effects, Somatuline® Autogel® lowers growth hormone and IGF-1 levels, thus controlling disease progression and relieving the symptoms associated with active disease.

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, a maximum of approximately 6,000,000 newly issued shares of our common stock over a three-year period for cash up to an aggregate of \$75.0 million, subject to certain conditions and restrictions. See the discussion below under **Committed Equity Financing Facility** for further details on the CEFF. As of December 31, 2006, we had not issued any shares under this facility. 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.

As of December 31, 2006, we had approximately \$125.6 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.

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 U.S., or GAAP. 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

We recognize revenue from the sale of our products and contract arrangements. Our revenue arrangements with multiple elements are divided into separate units of accounting if certain criteria are met, including whether the delivered element has stand-alone value to the customer and whether there is objective and reliable evidence of the fair value of the undelivered items. The consideration we receive is allocated among the separate units based on their respective fair values, and the applicable revenue recognition criteria are applied to each of the separate units. Advance payments in excess of amounts earned are classified as deferred revenue until earned.

We recognize revenue from product sales when there is persuasive evidence that an arrangement exists, title passes, the price is fixed and determinable and collectibility is reasonably assured. We record provisions for discounts to customers, rebates to government agencies, product returns and other adjustments which are based on our historical experience.

Table of Contents

License revenue includes upfront and continuing licensing fees. Nonrefundable upfront fees that require our continuing involvement in the manufacturing or other commercialization efforts by us are recognized as revenue ratably over the contractual term. We believe the contractual term is our best estimate for recognition of license revenue which could change in the future if we decide another methodology is appropriate.

Stock-based Compensation

Prior to 2006, we accounted for 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*. 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. 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.

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 December 31, 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.

As a result of adopting SFAS No. 123R, we recognized stock-based compensation expense of \$5.7 million during the year ended December 31, 2006, which primarily affected our reported research and development and selling, general, and administrative expenses. Approximately \$2.0 and \$3.7 million are included in research and development expenses, and selling, general and administrative expenses, respectively, for the year ended December 31, 2006. 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 December 31, 2006, total unrecognized compensation expense related to unvested share-based compensation arrangements previously granted under our various plans was \$10.4 million, which we expect to recognize over a weighted-average period of 2.6 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.

During the period from February 1, 2003 through January 31, 2004, we granted certain stock options 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

Table of Contents

\$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.

For more information on stock-based compensation expense recorded for the year ended December 31, 2006, please refer to Note 10 Stock Based Compensation in the Notes to 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 these third-party clinical research organizations. 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. Such adjustments to date have not been material to our results of operations or financial position.

Valuation of Warrants

In order to estimate the value of warrants, we use the Black-Scholes-Merton valuation model, which requires the use of certain subjective assumptions. The most significant assumption is the estimate of the expected volatility. The value of a warrant is derived from its potential for appreciation in value. The more volatile the stock, the more valuable the option becomes because of the greater possibility of significant changes in the stock price. We record the value of a warrant to additional paid-in capital based on the estimated value, using certain assumptions, at the closing of a warrant transaction. However, it is difficult to predict the valuation of warrants issued in future periods as that value can be affected by changes in the volatility assumptions of our common stock.

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.

Table of Contents**Results of Operations*****Year Ended December 31, 2006 Compared to Year Ended December 31, 2005***

Revenues. We began shipment of Increlex to specialty pharmacy distributors in January 2006. Product sales less product returns and cash discounts were \$1.3 million for the year ended December 31, 2006. There were minimal government rebates to state Medicaid agencies for the year ended December 31, 2006. As Increlex is generally ordered by our distributors to fill specific prescriptions, we believe that our distributors carry minimal levels of inventory. We also recorded \$194,000 of amortized license revenue in connection with our Increlex License and Collaboration Agreement with Ipsen, or the Increlex License. We are amortizing the upfront payment, received in October 2006 of 10.0 million or \$12.4 million over a period of approximately 16 years (See Note 7 in the Notes to Financial Statements for further details on our collaboration with Ipsen). There were no revenues in 2005.

The Prescription Drug User Fee Act, or PDUFA date for Somatuline® Autogel® for the treatment of acromegaly is August 30, 2007. Somatuline® Autogel® has already received marketing approval in Canada and is currently in the reimbursement review process.

Cost of Product Sales. Our cost of product sales represents the supply cost and cost of production, shipping, distribution and handling costs, royalties owed to our licensor, inventory write-downs/write-offs based on our review of obsolete, excess, expired and failed inventory lots, and other costs related to production activities, including technology transfer and validation cost associated with manufacturing site changes.

Cost of product sales was \$1.7 million for the year ended December 31, 2006 which included write-offs of inventory totaling \$0.7 million due to manufacturing lot failures as well as costs related to transfer of manufacturing processes to an alternative manufacturer of \$0.1 million. 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 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, as we execute other production activities, and the percentage of manufacturing lots that are successfully completed. There was no cost of product sales in 2005.

Research and Development Expenses. Research and development expenses have consisted primarily of costs associated with clinical, regulatory, manufacturing development activities and acquired rights to technology or products in development. 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. Manufacturing development activities include pre-regulatory approval activities associated with technology transfer, process development and validation, quality control and assurance, analytical services, as well as preparations for current good manufacturing practices (cGMP) and regulatory inspections. In addition to these manufacturing development and clinical activities, license payments for patents and know-how to develop and commercialize products, are also recorded as research and development expense.

Research and development expenses increased to \$42.0 million for the year ended December 31, 2006 from \$21.6 million for the same period in 2005. The \$20.4 million increase was due primarily to:

A license fee of \$25.0 million paid in October 2006 to Ipsen related to our Somatuline® License and Collaboration Agreement. (See Note 7 in the Notes to Financial Statements for further details on our collaboration with Ipsen),

partially offset by \$3.8 million in lower external project costs, primarily due to lower manufacturing development activities in 2006 as compared to 2005 and \$1.0 million paid in 2005 to Genentech related to Increlex. Manufacturing development in 2005 was focused on production and validation of our rhIGF-1 manufacturing process and pre-NDA activities.

Table of Contents

The \$42.0 million in expense for the year ended December 31, 2006 was comprised primarily of \$25.0 million license fees paid to Ipsen, personnel and related costs of \$10.7 million, external project costs related to our clinical activities for Primary IGFD and severe Primary IGFD of \$4.7 million, and costs associated with our MAA filing activities of \$1.3 million.

Excluding the \$25.0 million license fee charged in 2006, we expect our research and development expenses to increase in 2007 as we continue our clinical activities in Primary IGFD and severe Primary IGFD, Increlex activities in support of our MAA, Somatuline® Autogel® activities in acromegaly and other clinical development activities. 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 activities, medical education, facility costs, insurance, information technology and accounting services. We expanded our corporate staffing, infrastructure, and commercial activities in 2005 as we prepared for our January 2006 launch of Increlex, as well as our 2005 implementation of Section 404 of the Sarbanes-Oxley Act of 2002. Activities associated with litigation and with marketing Increlex for severe Primary IGFD, medical education and other infrastructure support increased in 2006.

Selling, general and administrative expenses increased to \$44.2 million for the year ended December 31, 2006, from \$25.9 million for the same period in 2005. The \$18.3 million increase was attributable to:

additional expenditures associated with sales and marketing activities of \$7.9 million;

increased general and administrative personnel and other costs of \$3.2 million;

increased legal expenses primarily associated with litigation with Insmed of \$2.8 million;

increased expenses of \$2.3 million associated with medical education and

free goods expense of \$1.5 million, of which \$0.8 million was related to inventory write-offs due to manufacturing lot failures and \$0.1 million for inventory write-downs.

We expect total selling, general and administrative expenses in 2007 to be similar to expenses in 2006. We expect that increases in our expenses due to commercial activities associated with Somatuline® Autogel® in the United States and Canada, will be largely offset by decreased legal costs associated with our litigation with Insmed and Avecia.

Interest expense. Interest expense for the year ended December 31, 2006 was \$0.2 million. Interest expense was \$1.1 million for the year ended December 31, 2005 due to the issuance of our common stock to VLL. Interest expense in 2005 represented the value of 112,500 shares of common stock we issued in 2005 in connection with our loan agreement with VLL of \$1.0 million and \$0.1 million of commitment fees related to our loan agreement with VLL.

Interest and Other Income, net. Interest and other income, net, increased to \$4.2 million for the year ended December 31, 2006, from \$2.3 million for the same period in 2005. The increase was primarily due to interest income on higher average cash, cash equivalents and short-term investment balances as a result the cash received from Ipsen transaction in October 2006 and the impact of higher interest rates in 2006 compared to 2005.

Provision for income taxes. The provision for income taxes for the year ended December 31, 2006 represents \$0.6 million of French foreign income taxes withheld on an upfront license fee received from Ipsen under the Increlex License. There is no domestic provision for income taxes for the years ended December 31, 2006 and 2005 because we have incurred operating losses to date.

Table of Contents

Year Ended December 31, 2005 Compared to Year Ended December 31, 2004

Research and Development Expenses. Upon FDA approval for Increlex in August 2005, costs associated with manufacturing activities associated with the Increlex commercial production were charged to inventory or cost of sales. Manufacturing development activities included in research and development expenses starting in September 2005 were primarily in support of our MAA as well as clinical supply production. Prior to receiving regulatory approval, we charged all drug supply production costs to research and development.

Research and development expenses decreased to \$21.6 million for the year ended December 31, 2005, from \$29.3 million for the same period in 2004. The decrease of \$7.7 million was primarily due to lower costs related to manufacturing activities, which decreased by \$8.8 million from the same period in 2004. Manufacturing development expenses in 2004 included establishment and validation of our rhIGF-1 manufacturing process at our contract manufacturers and cGMP preparations for the anticipated NDA filing in severe Primary IGFD, neither of which were required in 2005, and \$1.4 million of acquired in-process research and development primarily related to a license payment to Genentech. Costs in 2005 associated with our development projects for Primary IGFD and severe Primary IGFD decreased by \$1.3 million due primarily to the timing of certain start up clinical trial expenses incurred in 2004. These decreases were partially offset by higher personnel costs of \$2.3 million and a milestone payment to Genentech of \$1.0 million in 2005.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased to \$25.9 million for the year ended December 31, 2005, from \$12.6 million for the same period in 2004. The \$13.3 million increase was attributable to increased legal fees of \$7.0 million primarily associated with our litigation with Insmed and Avecia, increased personnel costs of \$2.8 million and increased corporate administration expenses including consulting, professional fees, insurance, facilities and other expenses of \$3.5 million.

Interest Expense. Interest expense was \$1.1 million for the year ended December 31, 2005. We did not incur any interest expense in the comparable period in 2004. Interest expense in 2005 represented the value of 112,500 shares of common stock we issued in 2005 in connection with our loan agreement with VLL of \$1.0 million and \$0.1 million of commitment fees related to our loan agreement with VLL.

Interest and Other Income, net. Interest and other income, net, increased to \$2.3 million for the year ended December 31, 2005, from \$0.9 million for the same period in 2004. The increase was primarily due to interest income on higher average cash, cash equivalents and short-term investment balances as a result of the cash proceeds received from our initial public offering in March 2004 and our follow-on public offering in February 2005 and the impact of higher interest rates in 2005 compared to 2004.

Liquidity and Capital Resources

Sources of Liquidity

As of December 31, 2006, we had an accumulated deficit of \$248.7 million, which was primarily comprised of \$205.7 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 December 31, 2006 with net cash proceeds of \$66.0 in private equity financings and \$135.3 million from our public offerings of common stock and \$100.0 million, net of issuance costs, from the issuance of common stock and a convertible note to Ipsen.

Committed Equity Financing Facility

Under the terms of the CEFF, Kingsbridge committed to purchase a maximum of approximately 6,000,000 newly issued shares of our common stock over a three-year period beginning in October 2005, for cash up to an aggregate of \$75.0 million, subject to certain conditions. We may draw down under the CEFF in tranches of up to the lesser of \$7.0 million or 2% of our market capitalization at the time of the draw down of such tranche.

Table of Contents

subject to certain conditions. The common stock to be issued for each draw down will be issued and priced over an eight-day pricing period at discounts ranging from 6% to 10% from the volume weighted average price of our common stock during the pricing period. During the term of the CEFF, Kingsbridge may not short our stock, nor may it enter into any derivative transaction directly related to our stock. The minimum acceptable purchase price, prior to the application of the appropriate discount for any shares to be sold to Kingsbridge during the eight-day pricing period, is determined by the greater of \$3.00 or 90% of our closing share price on the trading day immediately prior to the commencement of each draw down. In connection with the CEFF, we issued a warrant to Kingsbridge to purchase up to 260,000 shares of our common stock at an exercise price of \$13.12 per share. We intend to exercise our right to draw down amounts under the CEFF, if and to the extent available, at such times as we have a need for additional capital and when we believe that sales of our common stock under the CEFF provide an appropriate means of raising capital. However, we are not obligated to sell any of the \$75.0 million of common stock available under the CEFF, and there are no minimum commitments or minimum use penalties. Under the terms of the affiliation agreement with Ipsen, we have 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.

Convertible Note

On July 18, 2006, we entered into a Stock Purchase and Master Transaction Agreement, or the Purchase Agreement, with Ipsen (see Note 7 in the Notes to Financial Statements – Ipsen Collaboration). Under the terms of the Purchase Agreement, we agreed to issue to Ipsen a convertible note in the principal amount of \$25.0 million, or the First Convertible Note. In accordance with the Purchase Agreement, at the first closing, we issued the First Convertible Note in the principal amount of \$25.0 million to Ipsen on October 13, 2006, the First Closing. The First Convertible Note accrues interest at a rate of 2.5% per year, compounded quarterly, and is convertible into our common stock at an initial conversion price of \$7.41 per share, subject to adjustment, which represents 3,397,031 shares at December 31, 2006. The number of conversion shares could increase depending on the market value of our common stock. 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 us that it will not convert the First Convertible Note in full. As of December 31, 2006, approximately \$0.1 million of interest expense on the First Convertible Note was accrued.

Cash Flow

Cash, cash equivalents and short-term investments totaled \$125.6 million at December 31, 2006, compared to \$58.6 million at December 31, 2005 and \$52.0 million at December 31, 2004. The increase in 2006 was primarily due to net proceeds of \$34.2 million from the issuance of common stock under a shelf registration and net proceeds of \$100.0 million, net of issuance costs, from the issuance of common stock and the First Convertible Note to Ipsen, partially offset by cash used in operating activities of \$67.4 million. The increase in 2005 was primarily due to net proceeds of \$51.1 million from the issuance of common stock in a follow-on public offering, partially offset by cash used in operating activities of \$43.4 million.

Net cash used in operating activities totaled \$67.4 million in the year ended December 31, 2006, compared to \$43.4 million in the year ended December 31, 2005 and \$34.7 million in the year ended December 31, 2004. The increase in net cash used in 2006 operating activities from 2005 was primarily due to the increase in our net loss in 2006 adjusted for the non-cash compensation charge of \$5.7 million related to our adoption of FAS 123R compared to 2005, which is discussed above in the results of operations, and the increase in our inventory balance; partially offset by the \$12.4 million received from Ipsen for the upfront Increlex license fee. Cash used in operating activities in 2005 includes the receipt of a \$1.0 million reimbursement from our landlord for facility improvements which was recorded as deferred rent. The increase in net cash used in 2005 operating activities from 2004 was primarily due to the increase of our net loss in 2005 compared to 2004, which is discussed above in the results of operations, and the capitalization of inventory after we obtained FDA approval of Increlex, partially offset by the recognition of the leasehold improvement allowance received from our landlord.

Table of Contents

Net cash used in investing activities totaled \$41.8 million in the year ended December 31, 2006, compared to \$7.7 million in the year ended December 31, 2005 and \$3.4 million in the year ended December 31, 2004. Net cash used in investing activities represent purchases, sales and maturities of investments and purchases of property and equipment net against proceeds received from the sale of equipment. Net purchases of short-term investments were \$40.7 million in 2006, an increase of \$35.5 million from 2005. Due to the relatively short-term maturities of our investment portfolio during 2004, 2005 and 2006, the increases and decreases in net purchases of short-term investments were primarily due to timing of maturities, sales and purchases of short-term investments. Net purchases of short-term investments were \$5.2 million in 2005, an increase of \$2.2 million from 2004. Purchases of property and equipment were \$1.1 million in 2006, a decrease \$1.7 million from 2005. Purchases of property and equipment were lower in 2006 because leasehold improvements for the new office building recorded in 2005 did not continue in 2006. Purchases of property and equipment were \$2.8 million in 2005, an increase of \$2.4 million from 2004. The increase in purchases of property and equipment in 2005 primarily relate to the purchase of leasehold improvements and office furniture for our new offices located in Brisbane, California, and the purchase of computer equipment and software for new employees hired in 2005. Proceeds received from the sale of equipment were \$0.3 million in 2005, compared to \$0 in 2004.

Net cash provided by financing activities for the year ended December 31, 2006 was \$134.7 million, compared to \$51.8 million for the year ended December 31, 2005 and \$50.3 million for the year ended December 31, 2004. Net cash provided by financing activities primarily relate to net proceeds received from our public offerings of common stock, proceeds from the issuance of the First Convertible Note to Ipsen, interest on our cash investments and proceeds received from the issuance of common stock under our stock plans. Net proceeds received from our public offerings of common stock were \$34.2 million, \$51.1 million and \$50.0 million in 2006, 2005 and 2004, respectively. Net proceeds from the issuance of common stock and a convertible note to Ipsen were \$100.0 million in 2006. Proceeds from the issuance of common stock under our equity compensation plans were \$0.5 million, \$0.8 million and \$0.3 million for 2006, 2005 and 2004, respectively.

We expect capital outlays and operating expenditures to increase over the next several years as we expand our operations. We believe that our cash, cash equivalents and short-term investments as of December 31, 2006, together with the funds that we would potentially receive from our collaboration with Ipsen, will be sufficient to meet our projected operating and capital expenditure requirements through at least the middle of 2008 based on our current business plan. However, our future capital needs and the adequacy of our available funds will depend on many factors, including:

changes to our business plan;

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

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

the success of Increlex final drug product manufacturing;

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

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

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

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

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

the status of competing products;

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

the pace of expansion of administrative and legal expenses.

Table of Contents

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.

As a result, 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.

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 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. There were no material developments in our patent infringement litigation against Avecia and Insmmed in the United Kingdom during the 12 months ended December 31, 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. On October 13, 2006, Genentech and we filed an opposition to Insmmed's motion for partial reconsideration of the court's summary judgment order. On October 31, 2006, the court issued a written ruling denying Insmmed's motion for partial reconsideration of the court's summary judgment order.

On November 6, 2006, the court initiated jury trial proceedings relating to Genentech's and our claims that Insmmed had infringed U.S. Pat. No. 5,258,287 and 5,187,151 and relating to Insmmed's defense of invalidity against the asserted claims of U.S. Pat. No. 6,331,414. On December 6, 2006, the jury returned a verdict finding that Insmmed had infringed U.S. Pat. No. 5,258,287 and U.S. Pat. No. 5,187,151 and that the asserted claims of U.S. Pat. No. 6,331,414 were not invalid. In addition, the jury found that Insmmed's infringement of U.S. Pat. No. 5,187,151 was willful. For Insmmed's past acts of infringement, the jury awarded Genentech and us damages of an upfront payment of \$7.5 million and a 15 percent royalty on past net sales of Iplex. This award has not been reflected in our financial statements in 2006 in accordance with U.S. GAAP as we have not realized the value of the award which will occur upon payment to us. This award has not been reflected in our financial statements in 2006 in accordance with U.S. GAAP as we have not realized the value of the award which will occur upon payment to us.

Table of Contents

On November 29, 2006, the court held an evidentiary hearing on Insmed's defense of inequitable conduct against U.S. Pat. No. 5,187,151, instructed Insmed to submit a brief in support of Insmed's inequitable conduct defense, granted Genentech and us leave to submit Genentech's and our closing arguments regarding Insmed's inequitable conduct defense in the form of a brief in opposition to such defense, and granted Insmed leave to submit a brief in reply to any opposition brief that Genentech and we may submit. On December 6, 2006, Insmed submitted a brief in support of Insmed's inequitable conduct defense against U.S. Pat. No. 5,187,151. On December 11, 2006, Genentech and we submitted closing arguments regarding Insmed's defense of inequitable conduct in the form of a brief in opposition to such defense. On December 13, 2006, Insmed submitted a brief in reply to Genentech's and our opposition brief.

On December 22, 2006, Genentech and we filed a motion requesting that the court award Genentech and us a permanent injunction prohibiting Insmed from making or selling Iplex for commercial use as a treatment for Severe Primary Insulin-Like Growth Factor Deficiency, award Genentech and us a trebling of the damages awarded by the jury, and award Genentech and us our attorneys' fees, costs and expenses.

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 alleged 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.

On March 6, 2007, Insmed, Avecia, Tercica and Genentech publicly announced agreements that settled all the ongoing litigation among the companies.

Contractual Obligations and Commercial Commitments

Our contractual obligations as of December 31, 2006 were as follows (in thousands):

	Total	Payment due by Period			More than 5 Years
		Less than 1 Year	1-3 Years	3-5 Years	
Contractual Obligations					
Operating lease obligations(1)	\$ 4,270	\$ 811	\$ 1,800	\$ 1,659	\$
Other long-term liabilities reflected on the Registrant's Balance Sheet under GAAP(2)	28,362			28,362	
Total contractual obligations	\$ 32,632	\$ 811	\$ 1,800	\$ 30,021	\$

- (1) Our obligations for operating leases include leases for our present office facility and office equipment. In 2005, we obtained a \$340,000 irrevocable letter of credit in conjunction with the lease agreement covering our present facility. This irrevocable letter of credit is collateralized for the same amount by cash, cash equivalents and short-term investments held in a Company bank account and has been recorded as restricted cash.
- (2) Other long-term liabilities reflected on our Balance Sheet under GAAP refers to the long-term convertible note issued in connection with the Purchase Agreement with Ipsen, which accrues interest at a rate of 2.5% per year, compounded quarterly, and is convertible into our common stock at an initial conversion

Table of Contents

price of \$7.41 per share, subject to adjustment. 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 us that it will not convert the First Convertible Note in full. The balance as of December 31, 2006 included accrued interest of \$0.1 million.

We also have contractual payment obligations, the timing of which is contingent on future events. Under our license agreements with Genentech, aggregate payments of up to \$0.5 million would be due if milestones relating to the initial product approval of rhIGF-1 for severe Primary IGF1D in Europe are achieved. Additional milestone payments would be due for subsequent indication approvals, including for approvals of products consisting of rhIGF-1 or IGF binding protein 3, in the United States or Europe.

Our Purchase Agreement with Ipsen provides that, at the Second Closing of the transaction contemplated by the Purchase Agreement (see Note 7 to the financial statements), subject to the satisfaction or waiver of the conditions thereto, the Company would issue a convertible note to Ipsen for the sum of 30.0 million (\$39.6 million). Conditions to the Second Closing include the occurrence of the milestone event provided for in the Somatuline[®] License related to marketing approval of Somatuline[®] Autogel[®] by the FDA for the targeted product label.

Pursuant to the Increlex License we 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. Further to the Increlex License, we granted to Ipsen product development rights and agreed to share the costs for improvements to, or new indications for Increlex, and also agreed to rights of first negotiation for the endocrine pipelines. Under the Increlex License Agreement, we are required to provide Ipsen with 100% of their Increlex supply to meet their demand and development activities through the term of the Increlex License which extends 15 years from the first commercial sale by Ipsen. Additionally in connection with the Increlex License, we have granted an exclusive option for Ipsen to make or have made the drug product known and marketed in the United States as Increlex if we fail to provide drug product in accordance with the terms of the Increlex License.

Under our agreement with Lonza Baltimore Inc., we have a non-cancelable obligation to reimburse Lonza Baltimore Inc. 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 Lonza Baltimore Inc. is approximately \$8.5 million through December 31, 2007. Further, as we reach certain milestones, we will be committed to make certain future purchases.

Under our agreement with a third-party fill and finish agent, we have a non-cancelable obligation to reimburse such agent on a milestone basis in connection with the preparation for commercial production of Increlex. We estimate that our total purchase commitment to this agent, as we validate the fill and finish processes which must then be approved by the FDA, is approximately \$1.0 million through December 31, 2007. If we reach certain milestone, we will be committed to make certain future purchases.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

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

Table of Contents

As of December 31, 2006, we held \$40.3 million in cash and cash equivalents consisting of highly liquid investments having original maturity dates of less than 90 days. Declines of interest rates over time would reduce our interest income from our highly liquid short-term investments. Based upon our balance of cash and cash equivalents, a decrease in interest rates of 100 basis points would cause a corresponding decrease in our annual interest income of approximately \$0.4 million for these investments. Due to the nature of our highly liquid cash equivalents, a change in interest rates would not materially change the fair market value of our cash and cash equivalents.

As of December 31, 2006, we held \$85.2 million in short-term investments, which consisted primarily of money market funds held by large institutions in the United States, federal agency bonds, commercial paper, auction market preferred securities, corporate bonds, repurchase agreements and asset-backed securities maturing in less than twelve months. The weighted average interest rate of our portfolio was approximately 5.50% at December 31, 2006. A decline in interest rates over time would reduce our interest income from our short-term investments. A decrease in interest rates of 100 basis points would cause a corresponding decrease in our annual interest income of approximately \$0.9 million for these investments. Due to the nature of our highly liquid cash equivalents, a change in interest rates would not materially change the fair market value of our short-term investments.

Table of Contents

Item 8. Financial Statements and Supplementary Data.

TERCICA, INC.

INDEX TO FINANCIAL STATEMENTS

	Page
<u>Reports of Independent Registered Public Accounting Firm</u>	62
<u>Balance Sheets</u>	64
<u>Statements of Operations</u>	65
<u>Statements of Stockholders' Equity (Deficit)</u>	66
<u>Statements of Cash Flows</u>	68
<u>Notes to Financial Statements</u>	69

Table of Contents

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of

Tercica, Inc.

We have audited the accompanying balance sheets of Tercica, Inc. as of December 31, 2006 and 2005, and the related statements of operations, stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2006. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Tercica, Inc. at December 31, 2006 and 2005, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2006, in conformity with U.S. generally accepted accounting principles.

As discussed in Note 2 to the financial statements, in 2006, Tercica, Inc., changed its method of accounting for stock-based compensation in accordance with guidance provided in Statement of Financial Accounting Standards No. 123R, "Share-Based Payment".

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Tercica, Inc.'s internal control over financial reporting as of December 31, 2006, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 5, 2007 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

Palo Alto, California

March 5, 2007

Table of Contents

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of

Tercica, Inc.

We have audited management's assessment, included in the accompanying Management's Annual Report on Internal Control over Financial Reporting at Item 9A, that Tercica, Inc. maintained effective internal control over financial reporting as of December 31, 2006, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Tercica, Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management's assessment that Tercica, Inc. maintained effective internal control over financial reporting as of December 31, 2006, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, Tercica, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2006, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheets as of December 31, 2006 and 2005, and the related statements of operations, stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2006 of Tercica, Inc. and our report dated March 5, 2007 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

Palo Alto, California

March 5, 2007

Table of Contents**TE RCICA, INC.****BALANCE SHEETS****(In thousands, except share and per share data)**

	December 31,	
	2006	2005
Assets		
Current assets:		
Cash and cash equivalents	\$ 40,339	\$ 14,817
Short-term investments	85,236	43,809
Accounts receivable, less allowance of \$8 at December 31, 2006	335	
Inventories	5,092	1,636
Prepaid expenses and other current assets	1,948	1,555
Total current assets	132,950	61,817
Property and equipment, net	3,861	4,021
Restricted cash	340	340
Other assets	536	138
Total assets	\$ 137,687	\$ 66,316
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 2,457	\$ 2,245
Accrued expenses	6,214	5,750
Liability for early exercise of stock options, less long-term portion	32	70
Other current liabilities	290	
Deferred revenue, less long-term portion	776	
Total current liabilities	9,769	8,065
Liability for early exercise of stock options, long-term portion		24
Long-term convertible note	25,172	
Deferred rent	1,363	1,429
Deferred revenue - long-term portion	11,452	
Total liabilities	47,756	9,518
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value: 5,000,000 shares authorized, no shares issued and outstanding at December 31, 2006 and 2005		
Common stock, \$0.001 par value: 100,000,000 shares authorized; 50,141,776 and 31,578,859 shares issued and outstanding at December 31, 2006 and 2005, respectively	50	32
Additional paid-in capital	338,608	225,100
Deferred stock compensation		(2,591)
Accumulated other comprehensive income (loss)	11	(2)
Accumulated deficit	(248,738)	(165,741)
Total stockholders' equity	89,931	56,798
Total liabilities and stockholders' equity	\$ 137,687	\$ 66,316

See accompanying notes.

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

	Year Ended December 31,		
	2006	2005	2004
Net revenues:			
Net product sales	\$ 1,315	\$	\$
License revenue	194		
Total net revenues	1,509		
Costs and expenses:			
Cost of sales	1,667		
Research and development*	42,034	21,587	29,335
Selling, general and administrative*	44,248	25,913	12,552
Total costs and expenses	87,949	47,500	41,887
Loss from operations	(86,440)	(47,500)	(41,887)
Interest expense	(162)	(1,080)	
Interest and other income, net	4,226	2,347	885
Loss before income taxes	(82,376)	(46,233)	(41,002)
Provision for income taxes	(621)		
Net loss	\$ (82,997)	\$ (46,233)	\$ (41,002)
Basic and diluted net loss per share	\$ (2.09)	\$ (1.51)	\$ (2.12)
Shares used to compute basic and diluted net loss per share	39,789	30,590	19,302
* Includes stock-based compensation expense as follows:			
Research and development	\$ 2,043	\$ 1,188	\$ 1,386
Selling, general and administrative	3,680	1,006	1,455
Total	\$ 5,723	\$ 2,194	\$ 2,841

See accompanying notes.

Table of Contents

TERCICA, INC.

STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT)

(In thousands, except share and per share data)

	Common Stock		Additional Paid-in Capital	Deferred Stock Compensation	Accumulated Other Comprehensive Income (Loss)	Deficit Accumulated	Total Stockholders Equity (Deficit)
	Shares	Amount					
Balances at December 31, 2003	2,083,741	\$ 2	\$ 51,308	\$ (5,984)	\$ (18)	\$ (78,506)	\$ (33,198)
Issuance of common stock upon net exercise of warrants	139,750						
Conversion of Series A convertible preferred stock to common stock	6,466,662	7	24,846				24,853
Conversion of Series B convertible preferred stock to common stock	8,830,646	9	43,775				43,784
Issuance of common stock upon initial public offering at \$9.00 per share in March and April 2004, net of underwriting discount and offering expenses of \$6,905	6,325,000	6	50,014				50,020
Vesting of common stock from early exercises of stock options	258,913		173				173
Issuance of common stock	67,450		260				260
Deferred stock compensation, net of forfeitures			3,138	(3,138)			
Amortization of deferred stock compensation				2,734			2,734
Issuance of stock options to consultants in exchange for services			107				107
Comprehensive loss:							
Unrealized loss on marketable securities					(54)		(54)
Net loss						(41,002)	(41,002)
Comprehensive loss							(41,056)
Balances at December 31, 2004	24,172,162	\$ 24	\$ 173,621	\$ (6,388)	\$ (72)	\$ (119,508)	\$ 47,677
Issuance of common stock upon initial public offering at \$8.00 per share in February 2005, net of underwriting discount and offering expenses of \$4,058	6,900,000	7	51,135				51,142
Vesting of common stock from early exercises of stock options	201,373	1	140				141
Issuance of common stock	192,824		806				806
Reversal of deferred stock compensation due to forfeitures			(1,695)	1,695			
Amortization of deferred stock compensation				2,102			2,102
Issuance of stock options to consultants in exchange for services			72				72
Stock-based compensation recognized due to stock option modifications			20				20
Issuance of common stock in connection with senior credit facility, net of issuance costs of \$1	112,500		1,001				1,001
Financing cost of warrant issued in connection with committed equity financing facility			(1,196)				(1,196)
Issuance of warrant in connection with committed equity financing facility			1,196				1,196
Comprehensive loss:							
Unrealized gain on marketable securities					70		70
Net loss						(46,233)	(46,233)

Edgar Filing: TERCICA INC - Form 10-K

Comprehensive loss (46,163)

Balances at December 31, 2005 (carried forward) 31,578,859 \$ 32 \$ 225,100 \$ (2,591) \$ (2) \$ (165,741) \$ 56,798
See accompanying notes.

Table of Contents**TERCICA, INC.****STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT) (Continued)**

(In thousands, except share and per share data)

	Common Stock		Additional Paid-in Capital	Deferred Stock Compensation	Accumulated Other Comprehensive Income (Loss)	Deficit Accumulated	Total Stockholders Equity (Deficit)
	Shares	Amount					
Balances at December 31, 2005 (brought forward)	31,578,859	\$ 32	\$ 225,100	\$ (2,591)	\$ (2)	\$ (165,741)	\$ 56,798
Vesting of common stock from early exercises of stock options	88,513		84				84
Reversal of deferred stock compensation pursuant to SFAS 123(R) adoption			(2,591)	2,591			
Issuance of common stock in connection with Ipsen, net of issuance costs of \$15,457	12,527,245	12	61,850				61,862
Issuance of warrant in connection with Ipsen collaboration			13,623				13,623
Issuance of common stock sold pursuant to public offering, net of issuance costs of \$278	5,750,000	6	34,216				34,222
Issuance of common stock	197,159		519				519
Stock-based compensation			5,807				5,807
Comprehensive loss:							
Unrealized gain on marketable securities					13		13
Net loss						(82,997)	(82,997)
Comprehensive loss							(82,984)
Balances at December 31, 2006	50,141,776	\$ 50	\$ 338,608	\$	\$ 11	\$ (248,738)	\$ 89,931

See accompanying notes.

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

	Year Ended December 31,		
	2006	2005	2004
Cash flows from operating activities:			
Net loss	\$ (82,997)	\$ (46,233)	\$ (41,002)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,162	707	446
Loss on disposal of property and equipment	121	76	9
(Accretion) / Amortization of (discounts) /premiums relating to available-for-sale securities	(756)	(701)	454
Stock based compensation	5,723	2,102	2,734
Amortization of debt issuance costs	28	1,002	
Commitment fee written-off due to termination of senior credit facility		75	
Stock compensation to consultants in exchange for services		72	107
Other		23	
Changes in operating assets and liabilities:			
Prepaid expenses and other assets	(300)	(938)	2,101
Accounts receivable, net	(335)		
Inventories	(3,372)	(1,636)	
Restricted cash		(340)	
Accounts payable	212	(1,722)	(1,384)
Accrued expenses	464	2,718	1,818
Deferred rent	224	1,429	
Deferred revenue	12,226		
Interest payable (long-term)	136		
Net cash used in operating activities	(67,464)	(43,366)	(34,717)
Cash flows from investing activities:			
Purchases of property and equipment	(1,123)	(2,838)	(407)
Proceeds received from sale of equipment		300	
Purchases of available-for-sale securities	(92,294)	(110,641)	(113,184)
Proceeds from maturities and sales of available-for-sale securities	51,636	105,475	110,165
Net cash used in investing activities	(41,781)	(7,704)	(3,426)
Cash flows from financing activities:			
Proceeds from issuance of convertible note, net of issuance costs	24,555		
Proceeds from issuance of common stock, excluding early exercised options	519	806	260
Proceeds from early exercised options	23		40
Repurchases of unvested early exercised options		(111)	
Payment of commitment fees for senior credit facility		(76)	
Net proceeds from public offerings of common stock	34,186	51,142	50,020
Net proceeds from the sale of common stock to Ipsen, S.A.	75,484		
Net cash provided by financing activities	134,767	51,761	50,320
Net increase in cash and cash equivalents	25,522	691	12,177
Cash and cash equivalents, beginning of year	14,817	14,126	1,949
Cash and cash equivalents, end of year	\$ 40,339	\$ 14,817	\$ 14,126

Supplemental schedule of noncash activities:**Cash paid during the year for:**

Edgar Filing: TERCICA INC - Form 10-K

Taxes paid	\$ 632	\$	\$
Cash paid for interest			75
Non-cash investing and financing activities:			
Reversal of deferred stock upon adoption of SFAS 123R	\$ (2,591)	\$	\$
Increase in common stock from vesting of early exercises of stock options	84	140	173
Issuance of common stock for senior credit facility		1,001	
Issuance of warrant in connection with committed equity financing facility		1,196	
Issuance of warrant in connection with Ipsen transaction	13,622		
Deferred stock compensation, net of forfeitures		(1,695)	3,138
Conversion of Series A and B convertible preferred stock into common stock			68,637

See accompanying notes.

Table of Contents

TERCICA, INC.

NOTES TO FINANCIAL STATEMENTS

1. Company and Basis of Presentation

Company

Tercica, Inc. (the Company), is a biopharmaceutical company developing and marketing a portfolio of endocrinology products. The Company currently has the following products in our commercialization and development portfolio:

Increlex, which the Company began commercializing in the United States in January 2006;

Somatuline® Autogel®, for which a New Drug Application, or NDA, was submitted in 2006 to the U.S. Food and Drug Administration, or FDA, by Ipsen S.A., or Ipsen, the Company's collaborator; and was approved for marketing in July 2006 by Health Canada for the treatment of acromegaly.

Increlex. The Company markets Increlex as a long-term 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. The Company obtained approval for the long-term treatment of severe Primary IGFD, from the U.S. Food and Drug Administration, or FDA, in August 2005. We are currently conducting a Phase IIIb clinical trial for the use of Increlex for the treatment of children with Primary IGFD. In January 2006, the Company launched Increlex in the United States. Increlex generated net revenues of \$1.3 million in 2006.

In December 2005, the Company submitted a Marketing Authorization Application, or 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 expects to receive an opinion from the Committee for Medicinal Products for Human Use on the Increlex MAA in the second quarter of 2007. Pursuant to the Company's worldwide strategic collaboration with Ipsen that was finalized in October 2006, 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 and diabetes indications.

Somatuline® Autogel®. Pursuant to the worldwide strategic collaboration with Ipsen, the Company has 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 and is currently in the reimbursement review process. Acromegaly is a hormonal disorder that results when a tumor in the pituitary gland produces excess growth hormone, resulting in overproduction of insulin-like growth factor-1 (IGF-1) and excessive growth. In October 2006, Ipsen submitted an NDA to the FDA for the use of Somatuline® Autogel® for the treatment of acromegaly. The FDA accepted the NDA on December 30, 2006, and the Prescription Drug User Fee Act, or PDUFA, date for Somatuline® Autogel® for the treatment of acromegaly is August 30, 2007.

Basis of Presentation

Prior to 2006, the Company had been considered to be a development stage company as it has not yet generated significant revenue from product sales. The Company had 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. The Company began commercializing Increlex in 2006 and generated net revenues of \$1.3 million from sales of Increlex. Based on these factors, the Company is no longer considered to be in the development stage.

Table of Contents

TERCICA, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

Use of Estimates and Reclassifications

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

Certain reclassifications of prior period amounts have been made to our financial statements to conform to current period presentation.

2. Summary of Significant Accounting Policies

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 and investment maturity.

The Company sources all of its bulk manufacturing and fill-finish manufacturing 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 of Increlex, which could delay or prevent the supply of commercial and clinical product, or delay or otherwise adversely affect revenues and our license and collaboration agreement with Ipsen whereby we are required to supply to them Increlex. The Company believes that it has established guidelines to maintain an adequate level of inventory to mitigate this potential negative impact.

We promote our products to medical professionals, but we sell our products primarily to distributors and our product revenues and accounts receivable are concentrated with a few customers. Customer concentrations in gross product sales that are greater than 10% of the relative total are 24%, 23%, 22% and 14% for the year ended December 31, 2006. Customer concentrations in trade accounts receivable that are greater than 10% of the relative total are 21%, 17%, 16%, 15% and 11% at December 31, 2006. Commercialization of our product Increlex began in 2006 and, therefore, we had no sales or accounts receivable in prior years. Sales of the Company's product in the US represent approximately 92% of total product sales.

Cash, and Cash Equivalents, Short-Term Investments and Restricted Cash

The Company considers all highly liquid investments with a remaining maturity of 90 days or less at the date of purchase to be cash equivalents. Cash equivalents are carried at cost, which approximates fair value. The Company's cash equivalents include interest-bearing money market funds. The Company's short-term investments primarily consist of readily marketable debt securities with remaining maturities of more than 90 days at the time of purchase but not exceeding one year.

The Company has classified its entire investment portfolio as available-for-sale. These securities are recorded as either cash equivalents or short-term investments and are carried at fair value with unrealized gains or losses included in accumulated other comprehensive income (loss) in the stockholders' equity (deficit). The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion are included in interest and other income, net. Realized gains and losses are also included in interest and other income, net. The cost of all securities sold is based on the specific identification method.

Table of Contents**TERCICA, INC.****NOTES TO FINANCIAL STATEMENTS (Continued)**

The Company obtained a \$340,000 irrevocable letter of credit in conjunction with a lease agreement for its facility. The letter of credit is collateralized for the same amount by cash, cash equivalents and short-term investments held in a Company bank account and has been recorded as restricted cash (see Note 6) in the accompanying balance sheet.

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

	December 31, 2006			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Available-for-sale debt securities maturing within 1 year:				
Auction market preferred	\$ 30,700	\$	\$	\$ 30,700
Corporate bonds	4,289			4,289
Commercial paper	58,942	8		58,950
Government sponsored entity bonds	10,866	2		10,868
Repurchase agreements	9,325			9,325
Asset-backed securities	7,410	1		7,411
Total available-for-sale debt securities	\$ 121,532	\$ 11	\$	\$ 121,543

	December 31, 2005			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Available-for-sale debt securities maturing within 1 year:				
Corporate bonds	\$ 36,150	\$	\$	\$ 36,150
Commercial paper	13,468	3		13,471
Government sponsored entity bonds	5,477		(5)	5,472
Municipal bonds	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):

	December 31,	
	2006	2005
Cash	\$ 4,372	\$ 873
Cash equivalents	35,967	13,944
Cash and cash equivalents	40,339	14,817
Short-term investments	85,236	43,809
Long-term restricted cash	340	340
Total	\$ 125,915	\$ 58,966

Edgar Filing: TERCICA INC - Form 10-K

Realized losses on the sale of available-for-sale securities for the years ended December 31, 2006, 2005 and 2004 were immaterial.

Table of Contents

TERCICA, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

Fair Value of Financial Instruments

The fair value of our cash equivalents and marketable securities is based on quoted market prices. The carrying amount of cash equivalents and marketable securities is equal to their respective fair values at December 31, 2006 and 2005.

Other financial instruments, including accounts receivable, accounts payable and accrued expenses, are carried at cost, which we believe approximates fair value because of the short-term maturity of these instruments. The fair value of our convertible debt was \$25.2 million at December 31, 2006. We determined this value using available market information and a valuation of the instrument by an independent third-party valuation expert. Other long-term obligations at December 31, 2005 approximate their fair values due to the relatively short maturities.

Trade Accounts Receivable

Trade accounts receivable are recorded at the invoiced amount. We perform evaluations of our customers' financial condition and generally do not require collateral. We make judgments as to our ability to collect outstanding receivables and provide allowances for the portion of receivables when collection becomes doubtful. We have not recorded reserves related to the collectibility of our trade accounts receivable for the year ended December 31, 2006. All allowances recorded are based on net payment terms afforded to our customers.

Inventories

Inventories are stated at the lower of cost or market. Cost is determined using the first-in, first-out basis. The valuation of inventory requires the Company to estimate obsolete or excess inventory based on analysis of future demand for our products. If inventory costs exceed expected market value due to obsolescence or lack of demand, inventory write-downs may be recorded as deemed necessary by management for the difference between the cost and the market value. These inventory write-downs are determined based on significant estimates by management and will be recorded as a write-down to net realizable value in the period that impairment is first recognized.

Products released from inventory which have been 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 free goods expense as appropriate.

The Company recorded inventory write-downs of approximately \$1,566,000, during the year ended December 31, 2006. Inventory write-downs for the year ended December 31, 2006 primarily related to Increlex manufacturing lot failures in the second and third quarters of 2006. Cost of inventory write-downs allocated to cost of goods sold and free goods expenses was \$690,000 and \$876,000, respectively, for the year ended December 31, 2006.

Revenue Recognition

We recognize revenue from the sale of our products, royalties earned and contract arrangements. Our revenue arrangements with multiple elements are divided into separate units of accounting if certain criteria are met, including whether the delivered element has stand-alone value to the customer and whether there is objective and reliable evidence of the fair value of the undelivered items. The consideration we receive is allocated among the separate units based on their respective fair values, and the applicable revenue recognition

Table of Contents

TERCICA, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

criteria are applied to each of the separate units. Advance payments in excess of amounts earned are classified as deferred revenue until earned.

We recognize revenue from product sales when there is persuasive evidence that an arrangement exists, title passes, the price is fixed and determinable, and collectibility is reasonably assured. We record provisions for discounts to customers, rebates to government agencies, product returns and other adjustments.

License revenue includes upfront and continuing licensing fees. Nonrefundable upfront fees that require our continuing involvement in the manufacturing or other commercialization efforts by us are recognized as revenue ratably over the contractual term.

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 clinical and regulatory activities, payroll and related costs, non-cash stock-based compensation, laboratory supplies, certain allocated costs, manufacturing development activities and in 2006 an upfront licensing fee associated with our license of Somatuline® Autogel®. 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-regulatory 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.

Acquired in-process research and development relates to in-licensed, in-process technology, intellectual property and know-how. The nature of the remaining efforts for completion of research and development activities generally include completion of clinical trials, completion of manufacturing validation, interpretation of clinical and pre-clinical 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 research and development expense.

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 and efforts expended. 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 each clinical study or trial contract. The Company monitors each of these factors to the extent possible and adjusts estimates accordingly.

Table of Contents**TERCICA, INC.****NOTES TO FINANCIAL STATEMENTS (Continued)****Promotional and Advertising Expenses**

The Company expenses the costs of promotional and advertising expenses, as incurred. Promotional and advertising expenses consist primarily of promotional materials and activities, design and layout costs of promotional materials, and direct mail advertising. Promotional and advertising expenses were \$1,396,000, \$1,069,000 and \$75,000 in the years ended December 31, 2006, 2005 and 2004, respectively.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, but not more than:

Description	Estimated Useful Lives
Computer equipment and software	3 years
Office equipment	5 years
Furniture and fixtures	7 years
Manufacturing equipment	10 years
Leasehold improvements	Shorter of useful life or life of lease

Impairment of Long-Lived Assets

The Company reviews its long-lived assets, including property and equipment, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. An impairment loss is recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount. Impairment, if any, is assessed using discounted cash flows.

Income Taxes

The Company utilizes the liability method of accounting for income taxes as required by SFAS No. 109, *Accounting for Income Taxes*. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and tax reporting bases of assets and liabilities and are measured using enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. The provision for income taxes for the year ended December 31, 2006 represents \$621,000 of French foreign income taxes withheld on an upfront license fee received from Ipsen under the Increlex License. There is no domestic provision for income taxes for the years ended December 31, 2006, 2005 and 2004 because the Company has incurred operating losses to date.

Valuation of Warrants

In order to estimate the value of warrants, the Company uses the Black-Scholes-Merton valuation model, which requires the use of certain subjective assumptions. The most significant assumption is estimate of the expected volatility. The value of a warrant is derived from its potential for appreciation in value. The more volatile the stock, the more valuable the option becomes because of the greater possibility of significant changes in the stock price. The Company records the value of a warrant to additional paid-in capital based on the estimated value, using certain assumptions, at closing of a warrant transaction. However, it is difficult to predict the valuation of warrants issued in future periods as that value can be affected by changes in the volatility of the Company's common stock.

Table of Contents**TERCICA, INC.****NOTES TO FINANCIAL STATEMENTS (Continued)****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 10 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):

	Year Ended December 31,		
	2006	2005	2004
Net loss, as reported	\$ (82,997)	\$ (46,233)	\$ (41,002)
Change in unrealized gains/(losses) on marketable securities, net of taxes	13	70	(54)
Comprehensive loss	\$ (82,984)	\$ (46,163)	\$ (41,056)

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 position or results of operations.

Table of Contents**TERCICA, INC.****NOTES TO FINANCIAL STATEMENTS (Continued)****3. Net Loss Per Share**

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

	Year Ended December 31,		
	2006	2005	2004
	(In thousands, except per share data)		
Numerator:			
Net loss	\$ (82,997)	\$ (46,233)	\$ (41,002)
Denominator:			
Weighted-average common shares outstanding	39,789	30,619	19,377
Less: Weighted-average unvested common shares subject to repurchase		(29)	(75)
Denominator for basic and diluted net loss per share	39,789	30,590	19,302
Basic and diluted net loss per share	\$ (2.09)	\$ (1.51)	\$ (2.12)

	Year Ended December 31,		
	2006	2005	2004
	(In thousands)		
Outstanding dilutive securities not included in diluted net loss per share			
Options to purchase common stock	3,895	2,851	2,077
Convertible note	3,397		
Warrants	5,268	260	
	12,560	3,111	2,077

4. Balance Sheet Details

Inventories consisted of the following (in thousands):

	December 31,	
	2006	2005
Raw materials	\$ 1,477	\$ 319
Work-in-process	3,280	1,229
Finished goods	335	88
Total	\$ 5,092	\$ 1,636

Edgar Filing: TERCICA INC - Form 10-K

The Company's finished goods included obsolescence write downs of approximately \$246,000 and \$45,000 for the years ended December 31, 2006 and 2005, respectively.

Table of Contents**TERCICA, INC.****NOTES TO FINANCIAL STATEMENTS (Continued)**

Property and equipment, net, consists of the following (in thousands):

	December 31,	
	2006	2005
Office equipment	\$ 316	\$ 292
Furniture and fixtures	635	628
Computer equipment and software	2,291	1,683
Manufacturing equipment	1,240	1,004
Leasehold improvements	1,302	1,450
Construction in progress	216	175
	6,000	5,232
Less accumulated depreciation and amortization	(2,139)	(1,211)
Property and equipment, net	\$ 3,861	\$ 4,021

Depreciation expense was \$1,240,000, \$707,000 and \$446,000 for the years ended December 31, 2006, 2005 and 2004, respectively.

Accrued liabilities consist of the following (in thousands):

	December 31,	
	2006	2005
Accrued compensation and related liabilities	\$ 2,938	\$ 2,626
Accrued professional fees	1,691	1,577
Accrued contract manufacturing expenses	629	543
Clinical trial costs	335	276
Other accrued liabilities	621	728
	\$ 6,214	\$ 5,750

5. Long-Term Debt**Convertible Note**

On October 13, 2006, the Company issued to Ipsen a convertible note in the principal amount of \$25,037,000 (the "First Convertible Note"). The First Convertible Note accrues interest at a rate of 2.5% per year, compounded quarterly, and is convertible into the Company's common stock at an initial conversion price of \$7.41 per share, subject to adjustment, which represents 3,397,031 shares at December 31, 2006. See "Ipsen Collaboration" in Note 7 in the Notes to Financial Statements for further discussion regarding the First Convertible Note.

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 on the dates of issuance of \$1,002,000. As of

Edgar Filing: TERCICA INC - Form 10-K

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.

Table of Contents**TERCICA, INC.****NOTES TO FINANCIAL STATEMENTS (Continued)****6. Commitments and Contingencies**

The Company leases approximately 32,000 square feet of office space in Brisbane, California. The lease expires in October 2011 with an option to renew for five years. This lease agreement includes scheduled rent increases over the lease term and rent abatement for the first 15 months. The Company recognizes rent expense on a straight-line basis over the term that the facility is physically utilized, taking into account the scheduled rent increases, rent abatement, rent holidays and the leasehold improvement reimbursement. In September 2005, the Company received a \$1,046,000 reimbursement from the landlord for facility improvements, which was recorded as deferred rent and is being amortized to offset rent expense over the remaining life of the lease. Under the lease agreement, the Company originally provided the landlord with irrevocable letters of credit amounting to \$790,000, which were subsequently reduced to \$340,000 in September 2005 after the FDA approved Increlex for marketing in late August 2005. The remaining irrevocable letter of credit is collateralized for the same amount by cash, cash equivalents and short-term investments held in a Company bank account. The Company has recorded the collateralized bank account balance as restricted cash.

At December 31, 2006, future minimum lease commitments under operating leases were as follows (in thousands):

Year ending December 31,	
2007	\$ 811
2008	889
2009	911
2010	944
2011	715
Thereafter	
	\$ 4,270

Rent expense, including the impact of the allowance for leasehold improvements of \$172,000 in 2006, was \$389,000, \$641,000 and \$453,000 for the years ended December 31, 2006, 2005 and 2004, respectively.

Manufacturing Services Agreement

In December 2002, the Company entered into a development and commercial supply agreement (the *Manufacturing Agreement*) with Cambrex Bio Science Baltimore, Inc. (*Cambrex Baltimore*). At that time, the Company began to transfer its manufacturing technology to Cambrex Baltimore in order for them to establish the process for rhIGF-1 fermentation and purification. 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. In February 2007, Cambrex Baltimore was purchased by Lonza Group AG, or Lonza Baltimore Inc. The Company's contractual relationship continued with Lonza Baltimore Inc. and has a non-cancelable obligation to reimburse Lonza Baltimore Inc. on a time and materials and per batch basis in connection with the commercial production of Increlex of approximately \$8,500,000 through December 31, 2007. Payments under this agreement were \$3,638,000, \$6,887,000 and \$11,699,000 for the years ended December 31, 2006, 2005 and 2004, respectively.

In November 2006, the Company entered into a development and commercial supply agreement with a third-party fill and finish agent. At that time, the Company began to transfer its manufacturing technology to this agent in order for the agent to establish the process for drug product fill and finish. Further, under the terms of this agreement, the agent is obligated to annually provide the Company with certain minimum quantities of finished rhIGF-1 drug product. The Company has a non-cancelable obligation to reimburse the agent on a

Table of Contents

TERCICA, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

milestone basis in connection with the preparation for commercial production of Increlex. We estimate that our total purchase commitment to this agent as we validate the fill and finish processes which must then be approved by the FDA is approximately \$950,000 through December 31, 2007.

Guarantees and Indemnifications

The Company, as permitted under Delaware law and in accordance with its Bylaws, indemnifies its officers and directors for certain events or occurrences, subject to certain limits, while the officer or director is or was serving at the Company's request in such capacity. The term of the indemnification period is for the officer's or director's lifetime. The Company may terminate the indemnification agreements with its officers and directors upon 90 days written notice, but termination will not affect claims for indemnification relating to events occurring prior to the effective date of termination. The maximum amount of potential future indemnification is unlimited; however, the Company has a director and officer insurance policy that limits its exposure and may enable it to recover a portion of any future amounts paid. The Company believes the fair value of these indemnification agreements is minimal. Accordingly, the Company has not recorded any liabilities for these agreements as of December 31, 2006.

Contingencies

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 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. There were no material developments in our patent infringement litigation against Avecia and Insmmed in the United Kingdom during the 12 months ended December 31, 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 it 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. On October 13, 2006, Genentech and the Company filed an opposition to Insmmed's motion for partial reconsideration of the court's summary judgment order. On October 31, 2006, the court issued a written ruling denying Insmmed's motion for partial reconsideration of the court's summary judgment order.

On November 6, 2006, the court initiated jury trial proceedings relating to Genentech's and the Company's claims that Insmmed had infringed U.S. Pat. No. 5,258,287 and 5,187,151 and relating to Insmmed's defense of invalidity against the asserted claims of U.S. Pat. No. 6,331,414. On December 6, 2006, the jury returned a verdict finding that Insmmed had infringed U.S. Pat. No. 5,258,287 and U.S. Pat. No. 5,187,151 and that the

Table of Contents

TERCICA, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

asserted claims of U.S. Pat. No. 6,331,414 were not invalid. In addition, the jury found that Insmed's infringement of U.S. Pat. No. 5,187,151 was willful. For Insmed's past acts of infringement, the jury awarded Genentech and the Company damages of an upfront payment of \$7.5 million and a 15 percent royalty on past net sales of Iplex. This award has not been reflected in the Company's financial statements for 2006, and will not be until the award has been paid.

On November 29, 2006, the court held an evidentiary hearing on Insmed's defense of inequitable conduct against U.S. Pat. No. 5,187,151, instructed Insmed to submit a brief in support of Insmed's inequitable conduct defense, granted Genentech and the Company leave to submit Genentech's and the Company's closing arguments regarding Insmed's inequitable conduct defense in the form of a brief in opposition to such defense, and granted Insmed leave to submit a brief in reply to any opposition brief that Genentech and the Company may submit. On December 6, 2006, Insmed submitted a brief in support of Insmed's inequitable conduct defense against U.S. Pat. No. 5,187,151. On December 11, 2006, Genentech and the Company submitted closing arguments regarding Insmed's defense of inequitable conduct in the form of a brief in opposition to such defense. On December 13, 2006, Insmed submitted a brief in reply to Genentech's and the Company's opposition brief.

On December 22, 2006, Genentech and the Company filed a motion requesting that the court award Genentech and the Company a permanent injunction prohibiting Insmed from making or selling Iplex for commercial use as a treatment for Severe Primary Insulin-Like Growth Factor Deficiency, award Genentech and the Company a trebling of the damages awarded by the jury, and award Genentech and the Company our attorneys' fees, costs and expenses.

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 alleged 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.

On March 6, 2007, Insmed, Avecia, Tercica and Genentech publicly announced agreements that settled all the ongoing litigation among the companies.

7. License and Collaboration Agreements and Related Party Transactions

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 (\$39,600,000 at December 31, 2006; 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

Table of Contents**TERCICA, INC.****NOTES TO FINANCIAL STATEMENTS (Continued)**

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 Somatuline® Autogel® in the United States and Canada for all indications other than ophthalmic indications. 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. 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 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, 10,000,000 or \$12,422,000 as an upfront license fee under the Increlex License. For 2006, approximately \$194,000 was recognized as License Revenue, and as of December 31, 2006 \$11,452,000 was recorded as Long Term Deferred Revenue and \$776,000 was recorded as Short Term Deferred Revenue. The upfront license fee is amortized over the life of the license agreement which is approximately 16 years. The Company paid an upfront license fee of \$25,037,000 under the Somatuline® License and was recorded to research and development for the year ended December 31, 2006. As indicated above, the First Convertible Note in the principal amount of \$25,037,000 was issued to Ipsen at the First Closing. The First Convertible Note accrues interest at a rate of 2.5% per year, compounded quarterly, and is convertible into the Company's common stock at an initial conversion price of \$7.41 per share, subject to adjustment, which represents 3,397,031 shares at December 31, 2006. The number of conversion shares could increase depending on the market value of the Company common stock. 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. As of December 31, 2006, approximately \$135,000 of interest expense on the First Convertible Note was accrued. The amount payable on October 13, 2011 will be \$28,362,000 which includes interest of \$3,325,000.

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 number of common shares exercisable under the Warrant as of the First Closing was 5,026,712 with a fair value of \$13,622,000, estimated using the Black-Scholes-Merton valuation model, and recorded to Additional Paid in Capital. The number of

Table of Contents

TERCICA, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

common stock shares exercisable under the warrant as of December 31, 2006 was 5,008,429. 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 initial exercise price of \$7.41 per share, subject to adjustment under certain circumstances.

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 will issue the Second Convertible Note and the Third Convertible Note, and Ipsen would deliver the sum of 30,000,000 (\$39,600,000 at December 31, 2006) 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[®] License related to marketing approval of Somatuline[®] Autogel[®] by the FDA for the targeted product label. There can be no assurance that the Second Closing will occur on a timely basis or at all.

Upon closing the Ipsen transaction, the Company incurred \$3,004,000 in issuance costs, and allocated these costs to the license, debt and equity components of the agreement based on the relative fair value of the components. \$687,000 was allocated to the License and Collaboration Agreements for Somatuline[®] Autogel[®] and Increlex and was expensed to SG&A as incurred. \$1,835,000 was allocated to the equity financing and recorded to additional paid in capital. \$482,000 was allocated to the Convertible Note and recorded as a prepaid financing cost. In 2006, \$28,000 of prepaid financing costs was amortized, and as of December 31, 2006, the remaining balance was \$454,000.

Related Party Transactions

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

Genentech Collaboration

On April 15, 2002, the Company entered into a license and collaboration agreement (the U.S. License and Collaboration Agreement) with Genentech under which it obtained licenses to certain technology, know-how, and intellectual property rights to develop and commercialize rhIGF-1 in the U.S.

The Company is required to make cash payments based on the achievement of certain milestones and royalties on sales. Genentech has certain Opt-In rights to participate in the commercialization of certain rhIGF-1 products. If Genentech elects to exercise its Opt-In Right for a particular indication, Genentech will pay the Company more than 50% of the past development costs associated with that indication. In addition, after Genentech exercises its Opt-In Right for a particular indication, the Company would share with Genentech the ongoing net operating losses and profits resulting from the joint development and commercialization effort for that indication. Pursuant to this arrangement, the Company would fund less than 50% of such operating losses and the Company would receive less than 50% of any profits. In 2004 and early 2006, the Company paid Genentech cash of \$1,100,000 and \$100,000, respectively, under this agreement.

On July 25, 2003, the Company entered into an international license and collaboration agreement (the International License and Collaboration Agreement) with Genentech, obtaining certain rights to develop and commercialize rhIGF-1 for a broad range of indications, including short stature, outside of the United States. The Company paid Genentech cash of \$1,670,000 upon the execution of this license in 2003 and \$167,000 in 2004.

Table of Contents**TERCICA, INC.****NOTES TO FINANCIAL STATEMENTS (Continued)**

The Company also agreed to pay to Genentech royalties on the sales of rhIGF-1 products and certain one-time payments upon the occurrence of specified milestone events. As the Company was several years away from having an approved product to market, the amount paid for this license was charged to acquired in-process research and development expense.

In addition to the amounts already paid to Genentech, if the Company achieves all of the additional milestones for rhIGF-1 under the U.S. and International License and Collaboration Agreements, the Company will owe Genentech up to an aggregate of approximately \$33,000,000 in milestone payments. If the Company develops rhIGF-1 in combination with IGF binding protein-3, the Company would be subject to these same milestone events and, upon achievement of all of the milestones, would owe Genentech up to an additional aggregate of approximately \$32,500,000 in milestone payments. In connection with the U.S. License and Collaboration Agreement, the Company paid \$100,000 and \$1,000,000 milestone payments to Genentech in the year ended December 31, 2006 and 2005, respectively. These amounts were recorded as research and development expense when such payments became due. Additionally, the Company paid royalties of \$256,000 in 2006.

8. 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 derivative transaction directly related to the Company's stock. The minimum acceptable purchase price, prior to the application of the appropriate discount for any shares to be sold to Kingsbridge during the eight-day pricing period, is determined by the greater of \$3.00 or 90% of the Company's closing share price on the trading day immediately prior to the commencement of each draw down. In connection with the CEFF, the Company issued a warrant to Kingsbridge to purchase up to 260,000 shares of the Company's common stock at an exercise price of \$13.12 per share. The exercise term of the warrant is five years beginning on April 14, 2006. The warrant was valued on the date of grant using the Black-Scholes 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 warrant agreement noted above. The Company will not sell common stock under this registration statement and will not receive any of the proceeds from the sale of shares by the selling stockholder.

During the year ended December 31, 2006, the Company did not draw down any funds under the CEFF and had not issued any shares pursuant to the CEFF as of December 31, 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.

Table of Contents

TERCICA, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

9. Stockholders Equity

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 approximately \$34,200,000 after deducting underwriter discounts and other offering expenses.

Preferred Stock

As of December 31, 2006, the Company was authorized to issue 5,000,000 shares of preferred stock. The board of directors has the authority, without action by its stockholders with the exception of stockholders who hold board positions, to designate and issue shares of preferred stock in one or more series. The board of directors may also designate the rights, preferences and powers of each series of preferred stock, any or all of which may be greater than the rights of the common stock including restrictions of dividends on the common stock, dilution of the voting power of the common stock, reduction of the liquidation rights of the common stock, and delaying or preventing a change in control of the Company without further action by the stockholders. To date, the board of directors has not designated any rights, preference or powers of any preferred stock and no shares have been issued.

Warrants

On October 13, 2006, the Company issued to Ipsen a warrant to purchase a minimum of 4,948,795 shares of the Company's common stock. The warrant 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 number of common stock shares exercisable under the warrant as of the First Closing was 5,026,712. The fair value of the warrant, based on a measurement date of October 13, 2006, was \$13,622,000, estimated using the Black-Scholes-Merton valuation model. This value was recorded as offsetting entries to additional paid in capital since the warrants are accounted for as common stock issuance costs. The number of common stock shares exercisable under the warrant as of December 31, 2006 was 5,008,429. 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. See Ipsen Collaboration in Note 7 in the Notes to Financial Statements for further discussion regarding the warrant.

In connection with the CEFF (see Note 8), 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. This 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 0.54. 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.

Restricted Stock Purchases and Early Exercise of Options

In February 2002, 328,158 restricted shares of common stock were issued to an employee in exchange for \$2,000 in cash. As of December 31, 2006 there were no shares subject to repurchase by the Company related to this purchase. Shares subject to repurchase by the Company at December 31, 2005 were 3,895.

In December 2002, the Company issued 692,943 shares of its common stock to two employees under restricted stock purchase agreements pursuant to the early exercise of their stock options for \$71,000 in cash in

Table of Contents**TERCICA, INC.****NOTES TO FINANCIAL STATEMENTS (Continued)**

December 2002 and \$206,000 in cash in January 2003. During 2003, the Company issued 237,500 shares of common stock under restricted stock purchase agreements to three employees pursuant to the early exercises of their stock options in exchange for \$305,000 in cash. In January 2004, the Company issued 10,000 shares of common stock under a restricted stock purchase agreement to a director pursuant to the early exercise of stock options in exchange for \$40,000 in cash. In February 2006, the Company issued 15,647 shares of common stock under restricted stock purchase agreements to an employee pursuant to the early exercises of stock options in exchange for \$23,000 in cash. Under the terms of these agreements, these shares generally vest over a four-year period for employees and over a three-year period for the director. Total unvested shares, which amounted to 20,834 and 93,700 at December 31, 2006 and 2005, respectively, are subject to a repurchase option held by the Company at the original issuance price in the event the optionees' employment or director's tenure is terminated either voluntarily or involuntarily. These repurchase terms are considered to be a forfeiture provision and do not result in variable accounting. During the year ended December 31, 2005, the Company repurchased 130,718 shares of its common stock for approximately \$111,350 under restricted stock purchase agreements due to employee forfeitures. In accordance with EITF No. 00-23, *Issues Related to the Accounting for Stock Compensation under APB Opinion No. 25*, and FIN No. 44, the shares purchased by the employees pursuant to the early exercise of stock options are not deemed to be issued until those shares vest. Therefore, amounts received in exchange for these shares have been recorded as liability for early exercise of stock options on the balance sheet, and will be reclassified into common stock and additional paid-in capital as the shares vest. There were no repurchases in the year ended December 31, 2006. There were 88,513 shares at an original purchase price of \$84,000 reclassified into common stock and additional paid-in capital during the year ended December 31, 2006, 201,374 shares at an original purchase price of \$141,000 reclassified into common stock and additional paid-in capital during the year ended December 31, 2005 and 258,913 shares at an original purchase price of \$173,000 reclassified into common stock and additional paid-in capital during the year ended December 31, 2004.

Shares Reserved for Issuance

The Company had reserved shares of common stock for future issuance as follows:

	December 31,	
	2006	2005
2004 Employee Stock Purchase Plan	191,070	152,101
Stock option plans:		
Shares available for grant	1,439,865	1,338,983
Options outstanding	3,894,640	2,945,163
Shares available for issuance under the CEFF	6,036,912	6,036,912
Shares available for issuance under the convertible notes	3,397,095	
Warrants outstanding to purchase common stock	5,268,429	260,000
	20,228,011	10,733,159

10. 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 \$5,723,000 was recorded during the year ended December 31, 2006.

Table of Contents

TERCICA, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

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

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% 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. The Company's Board of Directors approved an increase of 1,250,000 shares to the reserve for the year ended December 31, 2006.

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 December 31, 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

Table of Contents

TERCICA, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

Employee Stock Purchase Plan (the Purchase Plan) became effective on March 16, 2004. As of December 31, 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 Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-Based Payment*, or SFAS No. 123R using the modified prospective transition method, 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. Under that transition method, non-cash compensation expense was recognized in the year ended December 31, 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 statements as of and for the year ended December 31, 2006 reflects 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 was recognized and \$2,542,000 was reversed as a result of employee terminations. Stock-based compensation expense recognized in the years ended December 31, 2005 and 2004 was \$2,102,000 and \$2,734,000, respectively. 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 stock-based compensation expense related to SFAS No. 123R for year ended December 31, 2006 was \$5,723,000. As a result of adopting SFAS No. 123R on January 1, 2006, the Company's net loss and basic and

Table of Contents**TERCICA, INC.****NOTES TO FINANCIAL STATEMENTS (Continued)**

diluted net loss per share for the year ended December 31, 2006 was \$4,069,000 and \$0.10 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 years ended December 31, 2005 and 2004 (in thousands, except per share amounts):

	Year Ended December 31,	
	2005	2004
	(In thousand except per share data)	
Net loss, as reported	\$ (46,233)	\$ (41,002)
Plus: Employee stock compensation expense based on intrinsic value method	2,102	2,734
Less: Employee stock compensation expense determined under the fair value method for all awards	(4,424)	(3,307)
Pro forma net loss	\$ (48,555)	\$ (41,575)
Net loss per share:		
Basic and diluted, as reported	\$ (1.51)	\$ (2.12)
Basic and diluted, pro forma	\$ (1.59)	\$ (2.15)

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 year ended December 31, 2005.

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

	Year Ended	
	December 31,	
	2006	2005
Expected volatility	75.2%	50%
Expected term (years)	6.2	3.6
Risk-free interest rate	5.1%	3.8%
Dividend yield		

The Company's computation of expected volatility for the year ended December 31, 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 year ended December 31, 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 treasury constant maturities rates in effect at the time of grant. The Company recognizes stock-based compensation expense for the fair values of these awards on a straight-line basis over the requisite service period of each of these awards.

Table of Contents

TERCICA, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

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

	Shares	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2003	1,202	\$ 0.71		
Options granted	1,284	7.38		
Options granted outside of Plans	22	4.00		
Options exercised	(298)	0.72		
Options cancelled/forfeited	(133)	3.25		
Outstanding at December 31, 2004	2,077	4.72		
Options granted	1,959	9.13		
Options exercised	(352)	1.76		
Options cancelled/forfeited	(586)	8.18		
Options cancelled/forfeited outside of Plans	(22)	4.00		
Options repurchased	(131)	0.85		
Outstanding at December 31, 2005	2,945	7.49		
Options granted	1,788	6.71		
Options exercised	(199)	1.04		
Options cancelled/forfeited	(639)	9.06		
Outstanding at December 31, 2006	3,895	\$ 7.21	8.5	\$ 1,428
Exercisable at December 31, 2006	3,097	\$ 6.98	8.4	\$ 1,342

The aggregate intrinsic value in the table above represents the total pre-tax intrinsic value, based on the Company's closing stock price of \$5.00 on December 29, 2006, which would have been received by the option holders had all option holders exercised their options on December 31, 2006. This amount changes based on the fair market value of the Company's stock. Total intrinsic value of options exercised for the years ended December 31, 2006, 2005 and 2004 were \$1,084,000, \$2,685,000 and \$2,514,000, respectively. The weighted-average grant date fair value of options granted during the years ended December 31, 2006, 2005 and 2004 were \$4.74, \$3.94 and \$6.13 per share, respectively. Total fair value of options vested for the years ended December 31, 2006, 2005 and 2004 was \$4,359,000, \$4,736,000 and \$2,678,000.

As of December 31, 2006, unrecognized stock-based compensation expense related to stock options of \$10,372,000 was expected to be recognized over a weighted-average period of 2.6 years.

The following table summarizes information concerning total outstanding and vested options as of December 31, 2006 (in thousands, except per share data and contractual term):

Edgar Filing: TERCICA INC - Form 10-K

Range of Exercise Prices	Options Outstanding Weighted-Average			Options Exercisable		
	Number Outstanding	Remaining Contractual Term	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price	
\$0.40 \$1.60	251	6.4	\$ 0.71	239	\$ 0.69	
\$3.46 \$5.81	651	8.5	\$ 4.55	521	\$ 4.50	
\$6.41 \$8.85	2,437	8.7	\$ 7.72	1,992	\$ 7.74	
\$9.04 \$12.65	556	8.4	\$ 10.99	345	\$ 10.69	
	3,895			3,097		

Table of Contents**TERCICA, INC.****NOTES TO FINANCIAL STATEMENTS (Continued)**

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

		Weighted- Average
		Grant Date Fair
	Shares	Value
Nonvested stock options at December 31, 2005	2,259	\$ 8.01
Granted	1,788	6.71
Vested	(973)	7.22
Forfeited	(404)	8.31
Nonvested stock options at December 31, 2006	2,670	\$ 7.38

Employee Stock Purchase Plan

For the year ended December 31, 2006, the Company recorded \$353,000 of compensation expense related to the Purchase Plan. During the years ended December 31, 2006, 2005 and 2004, 86,031, 42,584 and 28,294 shares, respectively, 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 weighted average term of the awards were 1.49, 1.25 and 0.91 years for the years ended December 31, 2006, 2005 and 2004, respectively.

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 years ended December 31, 2006, 2005 and 2004 was \$542,000, \$806,000 and \$300,000, 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 years ended December 31, 2006 and 2005.

11. Income Taxes

The provision for income taxes for the year ended December 31, 2006 represents \$621,000 of French foreign income taxes withheld on an upfront license fee received from Ipsen under the Increlex License (see footnote 7 Ipsen Collaboration). There is no domestic provision for income taxes because the Company has incurred operating losses to date. Deferred income taxes reflect the tax effects of net operating loss and tax credit carryovers and temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets are as follows (in thousands):

	December 31,	
	2006	2005
Net operating loss carryforwards	\$ 45,705	\$ 30,403
Capitalized license fees	13,044	3,168
Orphan drug credits	9,065	5,881
Capitalized research expenses	8,913	1,779
Deferred revenue	5,013	
Research tax credit carryforwards	4,332	3,948
Capitalized inventory costs	2,519	

Edgar Filing: TERCICA INC - Form 10-K

Capitalized start-up costs	304	531
Other	350	250
Total deferred tax assets	89,245	45,960
Valuation allowance	(89,245)	(45,960)
Net deferred tax assets	\$	\$

Table of Contents**TERCICA, INC.****NOTES TO FINANCIAL STATEMENTS (Continued)**

Realization of the deferred tax assets is dependent upon the generation of future taxable income, if any, the amount and timing of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by approximately \$43,285,000, \$11,843,000 and \$19,040,000 for the years ended December 31, 2006, 2005 and 2004, respectively.

As of December 31, 2006, the Company had federal net operating loss carryforwards of approximately \$115,324,000. The Company also had California net operating loss carryforwards of approximately \$92,045,000. The federal net operating loss carryforwards will expire at various dates beginning in 2022, if not utilized. The California net operating loss carryforwards expire beginning in 2012. The Company also has federal research, state research and federal orphan drug credit carryforwards of approximately \$2,212,000, \$3,261,000 and \$9,065,000, respectively. The federal research and orphan drug credits expire beginning in 2022 and the state research credits have no expiration date.

Utilization of the net operating loss carryforwards is subject to a substantial annual limitation due to the ownership change limitations provided by the Internal Revenue Code of 1986, as amended, and similar state provisions. The annual limitation may result in the expiration of net operating losses and credits before utilization.

12. 401(k) Plan

Effective January 2005, the Company began sponsoring a 401(k) plan, which covers all eligible employees. Under this plan, employees may contribute specified percentages of their eligible compensation, subject to certain Internal Revenue Service restrictions. The plan does not currently allow for matching contributions by the Company.

13. Quarterly Financial Data Unaudited

The following table presents unaudited quarterly financial data of the Company. The Company's quarterly results of operations for these periods are not necessarily indicative of future results of operations.

	Fiscal year 2006 Quarter Ended			
	March 31	June 30	September 30	December 31
	(In thousands, except per share data)			
Total net revenues	\$ 85	\$ 166	\$ 316	\$ 942
Net product sales	\$ 85	\$ 166	\$ 316	\$ 748
Cost of product sales	\$ (83)	\$ (557)	\$ (516)	\$ (511)
Research and development	\$ (4,630)	\$ (4,596)	\$ (3,513)	\$ (29,295)
Selling, general and administrative	\$ (10,504)	\$ (10,586)	\$ (10,162)	\$ (12,996)
Net loss	\$ (14,269)	\$ (14,684)	\$ (13,063)	\$ (40,981)
Basic and diluted net loss per share	\$ (0.40)	\$ (0.39)	\$ (0.35)	\$ (0.85)

	Fiscal year 2005 Quarter Ended			
	March 31	June 30	September 30	December 31
	(In thousands, except per share data)			
Research and development	\$ (4,871)	\$ (6,320)	\$ (5,681)	\$ (4,716)
Selling, general and administrative	\$ (4,179)	\$ (6,458)	\$ (6,393)	\$ (8,882)
Net loss	\$ (9,108)	\$ (12,401)	\$ (11,518)	\$ (13,206)
Basic and diluted net loss per share	\$ (0.32)	\$ (0.40)	\$ (0.37)	\$ (0.42)

Table of Contents

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Disclosure Controls and Procedures

Based on their evaluation as of December 31, 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.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Securities and Exchange Act of 1934. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Acting Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2006 using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control - Integrated Framework*. Based on this evaluation, our management concluded that as of December 31, 2006, our internal control over financial reporting was effective.

Attestation Report of the Registered Public Accounting Firm

Ernst & Young LLP, our independent registered public accounting firm that has audited our financial statements included herein, has issued an attestation report on management's assessment of our internal control over financial reporting, which report is included under Item 8 of this Annual Report on Form 10-K.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended December 31, 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

Table of Contents

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.

Item 9B. Other Information.

None

Table of Contents

PART III

Certain information required by Part III is omitted from this Annual Report on Form 10-K because the registrant will file with the U.S. Securities and Exchange Commission a definitive proxy statement pursuant to Regulation 14A in connection with the solicitation of proxies for the Company's Annual Meeting of Stockholders expected to be held in May 2007 (the Proxy Statement) not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, and certain information included therein is incorporated herein by reference.

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item with respect to directors and executive officers may be found under the caption Executive Officers of the Registrant in Part I, Item 1 of this Annual Report on Form 10-K, and in the section entitled Proposal 1 Election of Directors appearing in the Proxy Statement. Such information is incorporated herein by reference.

The information required by this Item with respect to our audit committee and audit committee financial expert may be found in the section entitled Proposal 1 Election of Directors Audit Committee appearing in the Proxy Statement. Such information is incorporated herein by reference.

The information required by this Item with respect to compliance with Section 16(a) of the Securities Exchange Act of 1934 and our code of ethics may be found in the sections entitled Section 16(a) Beneficial Ownership Reporting Compliance and Proposal 1 Election of Directors Code of Business Conduct and Ethics, respectively, appearing in the Proxy Statement. Such information is incorporated herein by reference.

Item 11. Executive Compensation.

The information required by this Item with respect to director and executive officer compensation is incorporated herein by reference to the information from the Proxy Statement under the section entitled Executive Compensation.

The information required by this Item with respect to Compensation Committee interlocks and insider participation is incorporated herein by reference to the information from the Proxy Statement under the section entitled Proposal 1 Election of Directors Compensation Committee Interlocks and Insider Participation.

The information required by this Item with respect to our Compensation Committee's review and discussion of the Compensation Discussion and Analysis included in the Proxy Statement is incorporated herein by reference to the information from the Proxy Statement under the section entitled Proposal 1 Election of Directors Compensation Committee Report.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this Item with respect to security ownership of certain beneficial owners and management is incorporated herein by reference to the information from the Proxy Statement under the section entitled Security Ownership of Certain Beneficial Owners and Management.

The information required by this Item with respect to securities authorized for issuance under our equity compensation plans is incorporated herein by reference to the information from the Proxy Statement under the section entitled Equity Compensation Plan Information.

Table of Contents

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this Item with respect to related party transactions is incorporated herein by reference to the information from the Proxy Statement under the section entitled Certain Relationships and Related Transactions.

The information required by this Item with respect to director independence is incorporated herein by reference to the information from the Proxy Statement under the section entitled Proposal 1 Election of Directors Independence of the Board of Directors.

Item 14. Principal Accountant Fees and Services.

The information required by this Item is incorporated herein by reference to the information from the Proxy Statement under the section entitled Proposal 2 Ratification of Selection of Independent Registered Public Accounting Firm.

Table of Contents**PART IV****Item 15. Exhibits and Financial Statement Schedules****(a) Documents filed as part of this report***1. Financial Statements*

See Index to Financial Statements in Item 8 of this Annual Report on Form 10-K, which is incorporated herein by reference.

2. Financial Statement Schedules

All financial statement schedules are omitted because the information is inapplicable or presented in the Notes to Financial Statements.

3. The following exhibits are included herein or incorporated herein by reference:

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation(1)
3.2	Amended and Restated Bylaws(2)
3.3	Certificate of Designation of Series A Junior Participating Preferred Stock(3)
3.4	Certification of Amendment of Amended and Restated Certificate of Incorporation(3)
4.1	Form of Specimen Stock Certificate(4)
4.2	Reference is made to Exhibits 3.1, 3.2, 3.3, and 3.4
4.3	Warrant issued to Kingsbridge Capital Limited, dated October 14, 2005(5)
4.4	Warrant issued to Ipsen, S.A., dated October 13, 2006(4)
4.5	First Senior Convertible Promissory Note issued to Ipsen, S.A., dated October 13, 2006(4)
4.6A	Rights Agreement, dated as of October 13, 2006, between the Registrant and Computershare Trust Company, N.A., as Rights Agent(4)
4.6B	Form of Right Certificate(4)
10.1A	2002 Stock Plan, as amended(4)*
10.1B	Form of Stock Option Agreement under the 2002 Stock Plan(2)*
10.2A	2002 Executive Stock Plan, as amended(4)*
10.2B	Form of Stock Option Agreement under the 2002 Executive Stock Plan(2)*
10.3A	2004 Stock Plan(4)*
10.3B	Form of Stock Option Agreement under the 2004 Stock Plan(2)*
10.4A	2004 Employee Stock Purchase Plan(4)*
10.4B	Form of Subscription Agreement under the 2004 Employee Stock Purchase Plan(2)*
10.5	Form of Indemnification Agreement(2)*
10.6A	Sublease Agreement dated June 24, 2002 between Elan Pharmaceuticals, Inc. and the Registrant(2)
10.6B	Sublease Agreement dated March 21, 2003 between Elan Pharmaceuticals, Inc. and the Registrant(2)

Edgar Filing: TERCICA INC - Form 10-K

10.6C Lease Agreement dated July 24, 2003 between Gateway Center, LLC and the Registrant(2)

Table of Contents

Exhibit Number	Description
10.6D	First Amendment to Lease Agreement dated September 24, 2003 between Gateway Center, LLC and the Registrant(2)
10.6E	Second Amendment to Lease Agreement dated June 28, 2004 between Gateway Center, LLC and the Registrant(6)
10.6F	Lease Agreement dated March 7, 2005 between 2000 Sierra Point, LLC and the Registrant(7)
10.6G	First Amended to Lease Agreement dated May 1, 2006 between Clarendon Hills Investors, LLC and the Registrant(8)
10.7A	License and Collaboration Agreement, between Genentech, Inc. and the Registrant, dated as of April 15, 2002(2)
10.7B	First Amendment to the License and Collaboration Agreement, between Genentech, Inc. and the Registrant, dated as of July 25, 2003(2)
10.7C	International License and Collaboration Agreement, between Genentech, Inc. and the Registrant, dated as of July 25, 2003(2)
10.7D	Second Amendment to the License and Collaboration Agreement, between Genentech, Inc. and the Registrant, dated as of November 25, 2003(9)
10.8	Manufacturing Services Agreement between the Registrant and Cambrex Bio Science Baltimore, Inc., dated as of December 20, 2002(2)
10.9A	Key Employment Agreement for John A. Scarlett, M.D. dated February 27, 2002(2)*
10.9B	Amendment to Key Employment Agreement for John A. Scarlett, M.D. dated May 15, 2002(2)*
10.9C	Key Employment Agreement for Ross G. Clark dated May 15, 2002(2)*
10.9D	Intentionally omitted
10.9E	Intentionally omitted
10.9F	Intentionally omitted
10.9G	Employment Letter to Andrew Grethlein dated March 5, 2003(2)*
10.9H	Intentionally omitted
10.9I	Intentionally omitted
10.9J	Intentionally omitted
10.9K	Intentionally omitted
10.9L	Employment Letter to Stephen Rosenfield dated June 23, 2004(3)*
10.9M	Employment Letter to Thorsten von Stein dated December 3, 2004(5)*
10.9N	Amendment to Key Employment Agreement for John A. Scarlett, M.D. dated February 22, 2005(4)*
10.9O	Amendment to Key Employment Agreement for Ross G. Clark dated February 22, 2005(4)*
10.9P	Intentionally omitted
10.9Q	Intentionally omitted
10.9R	Amendment to Employment Letter for Stephen N. Rosenfield dated February 22, 2005(7)*
10.9S	Intentionally omitted
10.9T	Non-Employee Director Compensation Arrangements(11)
10.9U	Employment Letter to Christopher E. Rivera, dated March 31, 2005(12)*

Table of Contents

Exhibit Number	Description
10.9V	Intentionally omitted
10.9W	Tercica, Inc. Incentive Compensation Plan(13)
10.9X	Employment letter to AjayBansal, dated February 27, 2006(14)
10.10	Amended and Restated Investors Rights Agreement dated July 9, 2003(2)
10.11A	Amendment to Amended and Restated Investors Rights Agreement dated February 27, 2004(2)
10.11B	Consent, Waiver and Amendment, dated as of October 13, 2006
10.12A	Intentionally omitted
10.12B	Common Stock Purchase Agreement, dated January 21, 2005, between Venture Lending & Leasing IV, LLC and the Registrant(10)
10.13A	Common Stock Purchase Agreement, by and between Kingsbridge Capital Limited and the Registrant, dated October 14, 2005(5)
10.13B	Registration Rights Agreement, by and between Kingsbridge Capital Limited and the Registrant, dated October 14, 2005(5)
10.14A	Stock Purchase and Master Transaction Agreement, by and between the Registrant and Ipsen, S.A., dated July 18, 2006(15)
10.14B	Affiliation Agreement, by and between the Registrant, Suraypharm and Ipsen, S.A., dated October 13, 2006 Registration Rights Agreement, by and between the Registrant, Suraypharm and Ipsen, S.A., dated October 13, 2006
10.14C	Increlex License and Collaboration Agreement, by and between the Registrant and Beaufour Ipsen Pharma, dated October 13, 2006
10.14D	Somatuline [®] License and Collaboration Agreement, by and between the Registrant, SCRAS and Beaufour Ipsen Pharma, dated October 13, 2006
23.1	Consent of Independent Registered Public Accounting Firm
24.1	Power of Attorney (included on the signature pages hereto)
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 Rule 13a-14(b) or Rule 15d-14(b) and 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 Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350).

* Management contract or compensation plan or arrangement.
Confidential treatment has been granted with respect to certain portions of this exhibit. This exhibit omits the information subject to this confidentiality request. Omitted portions have been filed separately with the SEC.
Confidential treatment has been requested with respect to certain portions of this exhibit. This exhibit omits the information subject to this confidentiality request. Omitted portions have been filed separately with the SEC.

Table of Contents

- (1) Incorporated by reference to the similarly described exhibit included with the Registrant's quarterly report on Form 10-Q (File No. 000-50461) filed on May 13, 2004.
- (2) Incorporated by reference to the similarly described exhibit included with the Registrant's 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 3, 2006.
- (5) Incorporated by reference to the similarly described exhibit included with the Registrant's quarterly report on Form 10-Q (File No. 000-50461) filed on November 4, 2005.
- (6) Incorporated by reference to the similarly described exhibit included with the Registrant's quarterly report on Form 10-Q (File No. 000-50461) filed on August 16, 2004.
- (7) Incorporated by reference to the similarly described exhibit included with the Registrant's annual report on Form 10-K (File No. 000-50461) filed on March 24, 2005.
- (8) Incorporated by reference to the similarly described exhibit included with the Registrant's quarterly report on Form 10-Q (File No. 000-50461) filed on August 9, 2006.
- (9) Incorporated by reference to the similarly described exhibit included with the Registrant's quarterly report on Form 10-Q (File No. 000-50461) filed on August 4, 2005.
- (10) Incorporated by reference to the similarly described exhibit included with the Registrant's registration statement on Form S-1 (File No. 333-122224) and amendments thereto, declared effective on February 7, 2005.
- (11) Incorporated by reference to the information under the heading "Executive Compensation - Compensation of Directors" in the Registrant's definitive proxy statement filed pursuant to Regulation 14A (File No. 000-50461) on April 24, 2006.
- (12) 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 16, 2005.
- (13) 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 February 28, 2006.
- (14) 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 10, 2006.
- (15) 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

SIGNATURES

Pursuant to Section 13 or 15(d) of the Securities Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

TERCICA, INC.

By: /s/ JOHN A. SCARLETT, M.D.
John A. Scarlett, M.D.

President, Chief Executive Officer and Director

Dated: March 9, 2007

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints John A. Scarlett, M.D. and Ajay Bansal, and each of them, as his true and lawful attorneys-in-fact and agents, with full power of substitution for him, and in his name in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, and any of them or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1934, this report has been signed by the following persons on behalf of the Registrant in the capacities indicated on March 9, 2007:

Signature	Title
/s/ JOHN A. SCARLETT, M.D. John A. Scarlett, M.D.	President, Chief Executive Officer and Director (Principal Executive Officer)
/s/ AJAY BANSAL Ajay Bansal	Chief Financial Officer (Principal Accounting and Financial Officer)
/s/ ALEXANDER BARKAS, PH.D. Alexander Barkas, Ph.D.	Director
/s/ ROSS G. CLARK, PH.D. Ross G. Clark, Ph.D.	Director
/s/ KARIN EASTHAM Karin Eastham	Director
/s/ DENNIS HENNER, PH.D.	Director

Edgar Filing: TERCICA INC - Form 10-K

Dennis Henner, Ph.D.

/s/ MARK LESCHLY

Director

Mark Leschly

/s/ DAVID L. MAHONEY

Director

David L. Mahoney

/s/ CHRISTOPHE JEAN

Director

Christophe Jean

/s/ JEAN-LUC BÉLINGARD

Director

Jean-Luc Bélingard